IQVIA MEDTECH

White Paper

Enhancing the Assessment of Medical Devices in Malaysia

A comprehensive value-based approach

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Executive summary

Introduction

This white paper explores the critical role of medical devices in advancing Malaysia's healthcare system. Through the integration of advanced technologies, Malaysia can address current health challenges, optimize healthcare delivery, and improve population health outcomes. This paper aims to guide future strategies and policies for medical device value assessment, fostering informed decision-making to ensure their effective adoption and utilization within the healthcare system.

Healthcare system and population health situation in Malaysia

Malaysia aspires to provide comprehensive, accessible, and high-quality healthcare. However, the healthcare system faces considerable challenges, such as an aging population, rising rates of non-communicable diseases (NCDs), health disparities, and issues with healthcare affordability. Addressing these challenges requires strategic efforts to improve infrastructure, promote preventive care, and leverage technological advancements to realize the vision of universal health coverage.

The role and innovation of medical devices

Medical devices play a vital role in managing chronic diseases, supporting an aging population, reducing health disparities, and addressing public health emergencies. Their critical importance necessitates continuous innovation to meet the evolving needs of the healthcare system. Unlike pharmaceuticals, which follow a more standardized development pathway, medical device innovation is heavily driven by advancements in engineering and technology. This dynamic and rapidly evolving nature demands flexible assessment and integration strategies to ensure these devices effectively enhance healthcare delivery.

Importance of understanding the value of medical devices

Understanding the value of medical devices is crucial for optimizing their integration into Malaysia's healthcare system. Comprehensive evaluations shape healthcare quality, affordability, resource allocation, and patient outcomes. These assessments must consider clinical efficacy, cost-effectiveness, and broader societal impacts. Through this approach, they ensure that medical devices contribute effectively to public health goals.

Current assessment practice in Malaysia's health system

In Malaysia, the evaluation of medical devices extends beyond regulatory oversight by the Medical Device Authority (MDA) through the implementation of Health Technology Assessment (HTA), which is applied to prioritized technologies upon request by relevant stakeholders. Health Technology Assessment (HTA) is a vital tool for evaluating medical devices in Malaysia. The Malaysian Health Technology Assessment Section (MaHTAS) conducts these assessments, focusing on clinical effectiveness, cost-effectiveness, and organizational implications. Despite robust HTA practices, challenges remain in fully capturing the multifaceted value of medical devices, particularly in areas such as innovation, patient-centered outcomes, and long-term benefits. This necessitates enhancements in evaluation processes and methodologies.

Challenges and issues in value assessment

The evaluation of medical devices faces several challenges, including limitations in scope of assessments and difficulties in generating sufficient evidence. Additionally, unique characteristics of medical devices such as the learning curve effect, further complicate the evaluation process. Transparent and inclusive assessment processes are crucial to addressing these issues and meeting the diverse healthcare needs of Malaysia's population. Enhancing value assessment practices is essential to improving healthcare quality, ensuring equitable access to innovative medical technologies and advancing the nation's healthcare system.

Case studies

Three case studies illustrate the value and challenges of specific medical technologies:

1. **Pulsed Field Ablation (PFA)** for cardiac arrhythmias improves clinical outcomes, enhances efficiency, and addresses population health challenges.
2. **Water Vapor Thermal Therapy (WVTT)** for benign prostatic hyperplasia (BPH) is a less invasive alternative to traditional procedures. This technology preserves erectile and urinary functions, enhances patient safety, reduces healthcare costs, and can be performed in the outpatient setting, potentially expanding access in rural and underserved areas.
3. **Intravascular Ultrasound (IVUS)** for Percutaneous Coronary Intervention (PCI) enhances clinical precision, improves patient outcomes, and optimizes resource use, with a crucial imaging impact often overlooked in current assessments.

Recommendations for advancing value assessment

To advance the value assessment of medical devices, the following recommendations are proposed:

1. **Establish key value domains:** Customize value assessment criteria to fit the Malaysian context, capturing the full spectrum of medical device value.
2. **Enhance evidence generation and development of research ecosystem:** Encourage the generation of real-world data, develop methodologies tailored to medical devices, improve research infrastructure and foster stakeholder collaboration.
3. **Strengthen stakeholder engagement:** Establish structured engagement processes to incorporate diverse perspectives in assessments. Encourage early stakeholder involvement and provide educational resources.
4. **Implement framework adoption strategies:** Pilot new frameworks and establish metrics for regular performance evaluations.
5. **Address rapid technological advancements:** Develop flexible assessment protocols that can be quickly adapted to new technologies and iterations of existing devices.
6. **Strengthen training and capacity building:** Implement specialized training programs for effective participation from stakeholders and increase capacity within the assessment body.
7. **Align with economic and regulatory policies:** Ensure assessment frameworks align with national policies, streamline funding processes, and leverage private insurance reimbursement mechanisms.

Conclusion

This white paper initiates a critical dialogue on medical device value assessment, aiming to drive future advancements in healthcare technology evaluation. By adopting comprehensive and adaptive assessment frameworks, Malaysia can ensure that its healthcare system remains innovative, efficient, and responsive to the evolving needs of its population. This proactive approach should be complemented by efforts to bridge the gap between assessment outcomes and funding mechanisms. Positive assessments should prompt dedicated funding initiatives to facilitate the integration of innovative medical technologies, ensuring equitable access and sustainable healthcare growth.

Introduction

Health is a fundamental pillar of any nation's progress. A robust healthcare system is crucial for societal well-being. It not only provides essential care during illness but also ensures extensive social protection during health crises, benefiting both individuals and communities. Ensuring a nation's health is instrumental in fostering a civilized, skilled, and inclusive society. This underlines the need for a healthcare system that is both effective and resilient.

In the modern era, integrating advanced medical technologies into healthcare infrastructure is indispensable. Medical technologies such as diagnostics, digital applications, surgical equipment, and interventional devices play a transformative role in significantly improving health outcomes and enhancing the operational efficiency of healthcare services. Their adoption enables a more dynamic response to the evolving health needs of the population. It helps optimize direct health outcomes, reduce risks of adverse events, and provide patient-centered solutions that align with individual preferences and acceptance. However, the impact of these technologies varies. Certain technologies may enhance clinical outcomes, system efficiency or patient satisfaction, but they may not represent an efficient allocation of resources. This demonstrates the need for a comprehensive approach to evaluating their value.

Recognizing healthcare spending as a strategic investment, rather than merely as a cost is paramount. Viewing healthcare expenditure as an investment in human capital and societal resilience helps stakeholders appreciate the long-term returns and value from proactive health measures and adoption of innovative medical technologies. This perspective encourages a shift from short-term cost containment to long-term health optimization, ensuring sustainable progress and prosperity for future generations.

Building on this notion, the concept of 'value' in medical technologies is complex and multifaceted, shaped by diverse stakeholder perspectives within and beyond the healthcare sector. These varying views on value must align with national health objectives and societal goals. Given the lack of a comprehensive platform for discussion among local stakeholders, this paper aims to bridge this gap by initiating a focused dialogue on medical device value assessment. Through detailed exploration and contextual analysis, this paper seeks to provide stakeholders with a deeper understanding of medical device innovation, development, and the broader definition of value across various domains. The goal is to provide actionable recommendations that clarify these complexities and guide the strategic direction of medical device value assessment, supporting the overarching objectives of societal well-being and healthcare efficacy.

This paper aspires to be a pivotal resource in steering future strategies and policies for medical device value assessment, aligned with societal needs and national goals. It strives to spur broader discourse and facilitate informed decision-making among policymakers, healthcare providers, and industry leaders, contributing to the realization of a health-empowered society.

Healthcare system and population health situation in Malaysia

Vision, strategic goals and challenges of Malaysia's healthcare system

Malaysia aspires to provide a comprehensive, accessible, and high-quality healthcare environment. Central to this vision is universal health coverage — ensuring that every individual, regardless of economic status, can access quality health services without financial hardship. The nation is dedicated to developing a resilient healthcare system capable of adapting to changing needs and unforeseen challenges. Through strategic investments in public health infrastructure and innovative technologies, Malaysia aims to deliver effective and sustainable care. These efforts, which are guided by value-based practices, will also bolster the country's responsiveness to health needs and emergencies. Embracing a person-centered approach, Malaysia aspires to make affordable, quality health services accessible to all citizens.

The core of this vision is an open and innovative health ecosystem that leverages technological advances to improve service efficiency and effectiveness. Furthermore, Malaysia aims to continuously improve its healthcare system, making it one that is highly valued by its people, fostering trust and ownership.

However, our current health system faces several challenges that impact the alignment of healthcare provision with its visionary goals. These challenges include:

Demographic transition: Malaysia is experiencing an aging population, with an expected shift towards an 'aged' society by 2030, where 15% of the population will be over 60 years old.[1] This demographic change requires a strategic focus on geriatric care and management of non-communicable diseases (NCDs), which are more prevalent in older populations.

Rise of non-communicable diseases (NCDs): There is high prevalence of diabetes (18.3%), hypertension (30%), and hypercholesterolemia (38.1%) in Malaysia. These conditions are major risk factors for cardiovascular diseases (CVD).[2] The healthcare costs associated with managing CVDs are substantial, emphasizing the importance of prevention, health education, and promoting healthy lifestyles.

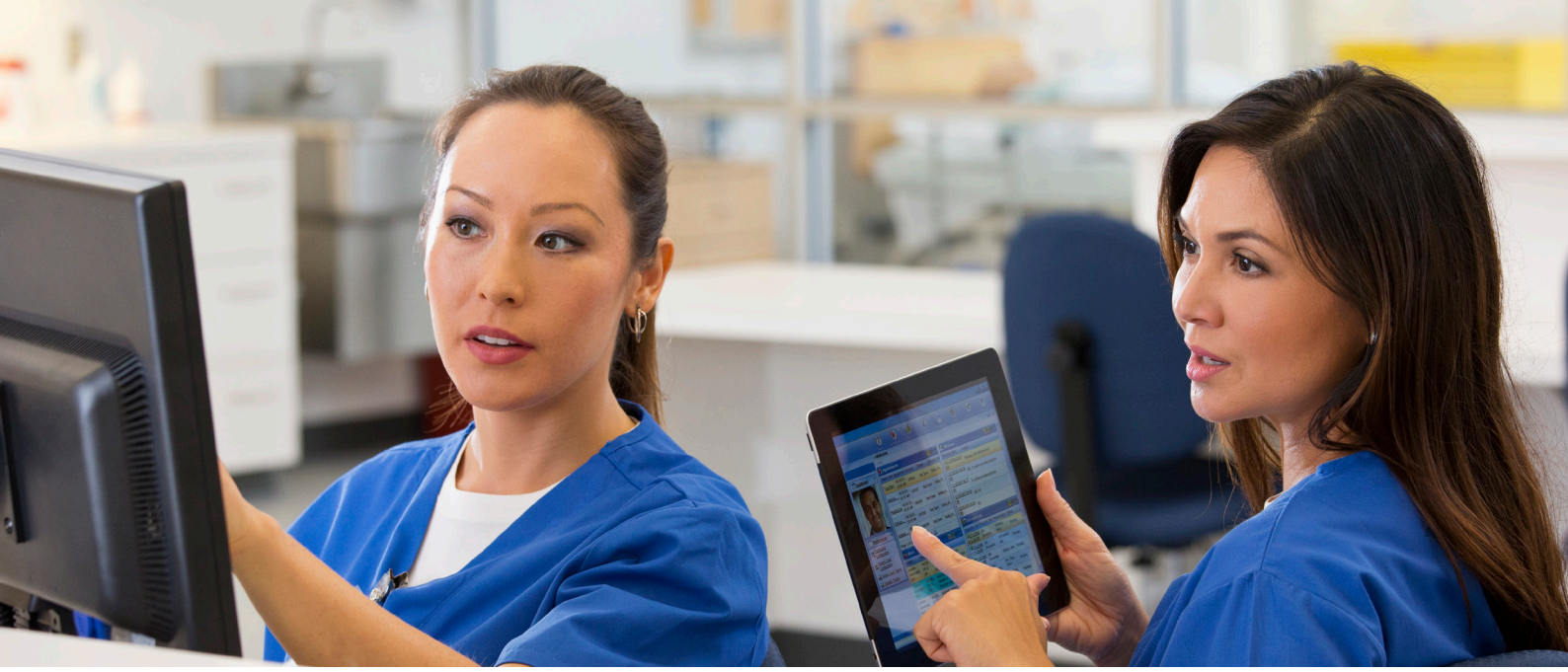
Geographic and socio-economic health disparities: Disparities in healthcare access and quality exist between urban and rural areas, as well as among different socio-economic groups. Rural areas often face limited access to healthcare facilities and a shortage of healthcare professionals.[3] While most people would seek care in public healthcare facilities, these facilities may lack access to advanced medical devices readily available in private facilities. This situation exacerbates inequities and affects health outcomes.

Healthcare affordability and accessibility: Ensuring affordability and equitable healthcare access for all remains a challenge, especially for advanced treatments and medications. These often remain out of reach for low- and middle-income families.[4,5]

Financial constraints in the public sector: The public sector faces financial constraints that impact its ability to procure selected medical devices, particularly those critical for patient care and monitoring. A comparison of the spending on devices versus pharmaceuticals can provide insights on resource allocation and impact on patient access to health technologies.

Infectious diseases and public health emergencies: The emergence of novel communicable diseases such as COVID-19, and the resurgence of communicable diseases such as measles, alongside the ongoing burden of diseases such as HIV, tuberculosis and dengue, pose significant challenges for the healthcare system.[6]

Healthcare system capacity and sustainability: The increasing demand for healthcare services, combined with resource constraints and workforce shortages, strains Malaysia's healthcare system. This leads to suboptimal health outcomes.



Integration of technology and innovation: Malaysia's healthcare system faces challenges in integrating technology and innovation.[6,7] Adoption of digital health records, telemedicine, and AI-driven diagnostic tools is crucial for enhancing healthcare efficiency and patient outcomes. However, the lack of local data and challenges in harmonizing data across healthcare settings hinder seamless data exchange, meaningful analysis, and integration of these technologies.

Disparity between technology assessment and adoption: A key challenge is the gap between evaluating new medical technologies and their actual adoption in clinical practice. End users may lack the understanding of how to incorporate these technologies into patient care, limiting their potential benefits. While there is existing guideline on the economic evaluation of health technologies,[8] the lack of a structured value assessment framework complicates the development of clinical guidelines and coverage decisions. This disconnect hampers the integration of innovative healthcare solutions and negatively affects the quality and equity of healthcare delivery.

Strategic directions

To address these challenges, a multifaceted approach is essential. This approach should include strengthening healthcare infrastructure, promoting preventive healthcare, ensuring equitable access to healthcare services, and harnessing technological advancements. By tackling these areas, Malaysia can advance towards realizing its vision of a comprehensive, accessible, and high-quality healthcare system for all citizens.

The indispensable roles of medical devices in a modern, effective, and inclusive health system

In the dynamic landscape of Malaysia's healthcare system, the role of medical devices has become increasingly apparent as the nation faces diverse health challenges. Defined as articles, instruments, apparatus, or machines used in the prevention, diagnosis, or treatment of illness or disease or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose, medical devices[9] are vital in facilitating adaptation to the changing demographics, urban-rural divides, and rising chronic disease burdens.

Supporting an aging population: Malaysia's aging demographic necessitates specialized medical devices tailored to the elderly. Innovations in mobility aids, home monitoring systems, and telemedicine devices are crucial. These technologies provide timely and appropriate care, allowing older individuals to maintain their independence while addressing their health needs.

Managing chronic diseases: The growing prevalence of NCDs such as diabetes, hypertension, and cardiovascular diseases highlights the need for medical devices. Devices such as glucose monitors, blood pressure cuffs, and home dialysis equipment facilitate the shift towards prevention and primary care.

These tools empower patients to actively manage their health at home, reducing hospital visits and enhancing quality of life. They also enable early identification of potential health risks, promoting timely interventions and reducing healthcare resource utilization. This approach not only enhances patient outcomes but also supports a more sustainable and efficient healthcare system.

Reducing geographical and socio-economic health disparities: Bridging the healthcare access gap between urban and rural areas, as well as disparities linked to socioeconomic differences, is critical. Portable diagnostic tools and mobile health technologies bring essential healthcare services to remote populations. This ensures that rural communities receive comparable healthcare services as those in urban areas. Promoting the procurement and use of effective medical devices in public facilities improves access to innovative technologies, ensuring underserved populations receive quality care, regardless of location or economic status.

Enhancing healthcare affordability and accessibility: Medical devices such as portable ultrasound machines, and advanced imaging systems improve healthcare affordability and accessibility. They enhance diagnostic accuracy, treatment efficiency, and patient outcomes. These devices allow for early and precise diagnosis, enabling timely interventions that can prevent more severe and costly health issues. By improving the efficiency and effectiveness of medical treatments, they ensure that high-quality healthcare is accessible to a larger population.

Optimizing resource allocation for public healthcare: Integrating effective devices, such as multifunctional portable ultrasound machines and diagnostic kits, can streamline operations. These devices reduce the need for multiple specialized tools and lower long-term costs. Value-based assessments guide strategic procurement decisions, ensuring that investments in these technologies enhance patient care, prevent complications, and lead to significant savings while optimizing resource utilization.

Equipping for public health emergencies: The role of medical devices is critical during public health emergencies and infectious disease outbreaks. The COVID-19 pandemic highlighted the vital contributions of medical devices in managing such crises. The rapid deployment and innovation of medical devices such as diagnostic kits, ventilators, and protective gear were instrumental in diagnosing, treating, and preventing the spread of the virus. This demonstrate how crucial medical devices are in strengthening healthcare resilience.

Capacity building in healthcare infrastructure: As Malaysia continues to expand its healthcare infrastructure, incorporating advanced medical devices in hospitals and clinics is essential. Cutting-edge surgical equipment, diagnostic imaging devices, and laboratory instruments are vital for delivering comprehensive, high-quality healthcare services that meet the evolving needs of the population.

Leveraging digital health technologies: Integrating digital health technologies such as AI-driven diagnostic tools, telemedicine, and electronic health records can greatly improve the efficiency and effectiveness of healthcare services. These technologies assist in early disease detection, enable personalized treatment plans, and contribute to better patient outcomes.

Tailoring devices to local health needs: Developing medical devices designed to address Malaysia's unique health challenges, such as tropical diseases or specific genetic conditions, is vital. This requires a focus on research and development tailored to the specific health needs of the Malaysian population.

In summary, medical devices are integral to the evolution of Malaysia's healthcare system. They provide innovative solutions for managing chronic diseases, supporting the aging population, bridging healthcare access gaps, enhancing affordability, and responding to public health emergencies. Continued investment in medical devices alongside policies that foster innovation and accessibility, will be key to realizing a modern, effective, and inclusive healthcare system in Malaysia.

Figure 1: Roles of medical devices in addressing Malaysia's healthcare challenges

Innovation in medical devices

Innovation in medical devices, spans a broad spectrum, from simple tools to complex equipment and diverges notably from pharmaceutical development in its focus and developmental process.[10] Unlike pharmaceuticals, which rely heavily on extensive research and clinical trials to demonstrate efficacy and safety, medical device innovation is rooted in engineering, focusing on both radical breakthroughs and continuous incremental improvements. While efficacy and safety are prioritized in both fields, the process for medical devices integrates a wider range of technologies, including materials science, digital technology, and bioengineering. This reflects the diverse and evolving nature of medical devices.[10]

Characteristics of the innovation process: The innovation process for medical devices is emergent and non-linear. It is shaped by various factors such as funding, user feedback, and evolving healthcare system needs.[11] The process includes organizational, technological, product, and service innovations, with real-time adjustments to address practical challenges. This agile and iterative approach ensures devices are continuously refined based on user experiences and clinical demands.

Key differentiators in medical device innovation: Medical device innovation presents several distinctive challenges and characteristics that set it apart from other types of medical innovation:

Organizational factors: The performance and utilization of medical devices depend heavily on the context of use. This includes the operator's competence, training, experience, and how well the device is integrated into healthcare settings.[12]

Diagnostic impact: Many medical devices serve diagnostic purposes, and their impact on patient outcomes is closely tied to the end-users' ability to interpret the information they provide. This interdependence complicates the assessment of a device's direct contributions to health outcomes, as its value is linked to user expertise and the decision-making processes.[13]

Learning curve and rapid technological advancements: New medical devices may present steep learning curves, complicating adoption and value assessment. Frequent updates and short product life cycles[14] challenge healthcare providers and regulators to keep up with advancements while ensuring effective use. The rapid evolution of medical devices calls for updated regulatory frameworks and value assessment processes. Establishing a separate pathway for innovative devices could facilitate smoother market entry and timely patient access to cutting-edge technologies, while ensuring safety.

Broad spectrum and regulatory evidence challenges: The diverse range of medical devices necessitates adaptive and flexible regulatory frameworks, as a one-size-fits-all approach is impractical. Unlike pharmaceuticals, Randomized Controlled Trials (RCTs) are often not feasible for devices due to their varied applications, iterative design improvements, and real-world usage conditions. This results in distinct evidence requirements tailored to the classification and risk level of the device. Medical devices are classified by their risk level: low-risk devices (Class A) follow a simpler approval process, while moderate-to-high-risk devices (Class B, C and D) undergo more rigorous evaluations. Regardless of the classification, all medical devices in Malaysia must adhere to strict safety and performance standards demonstrated through clinical and non-clinical evidence, ensuring that these devices are safe, effective and suitable for use in healthcare settings.

Complex value assessment and cost considerations: Assessing the value of medical devices is challenging within traditional Health Technology Assessment (HTA) and value frameworks, which are more suited to pharmaceuticals. These frameworks often overlook the integration of devices within clinical workflows, their multiple indications and their varying impacts on health outcomes.[14] Beyond acquisition costs, assessments should include maintenance, consumables, and other recurring expenses to provide a comprehensive view of the device's economic impact.

In summary, medical device innovation is a complex and multifaceted process. It requires a tailored approach to development, assessment, and integration into healthcare systems. Addressing these unique challenges through continued innovation aligned with regulatory and market strategies is essential for advancing the capabilities and impact of medical technologies. By fostering an environment that encourages innovation and adaptability, Malaysia can improve its healthcare system's effectiveness, inclusivity, and responsiveness to the needs of its population.

Figure 2: Key differentiators in medical device innovation

Importance of understanding the value of medical devices

Understanding the value of medical devices is critical for their optimal integration into Malaysia's healthcare system, ensuring that they contribute effectively to healthcare quality, affordability, and accessibility. The significance of this understanding is multi-dimensional, impacting various aspects of healthcare delivery and societal well-being.

Impact on healthcare quality: The value assessment of medical devices directly influences the quality of healthcare provided. By evaluating the efficacy, safety, and clinical outcomes of medical devices, healthcare providers can make informed decisions on technology adoption. This ensures patients receive the most effective and advanced care, supported by devices that meet high performance and quality standards. Accurate value assessments help select technologies that genuinely enhance patient care, elevating overall healthcare quality. Some devices used in procedures such as stent insertions or hip replacements may have irreversible long-term impacts, making the initial value assessment particularly critical for both patients and stakeholders.

Contribution to healthcare affordability and accessibility: Assessing the value of medical devices requires evaluating their impact instead of just the acquisition cost. This approach enables the healthcare system to make informed choices about which technologies deliver the best return on investment. In a resource-constrained environment, such assessments are crucial for maximizing the impact of healthcare spending. Ensuring that medical devices are affordable and accessible is key to equitable healthcare, enabling all population segments to benefit from advanced medical technologies, irrespective of their financial status.

Resource allocation and clinical decision-making: A deep understanding of the value of medical devices facilitates optimal resource allocation within the healthcare system. It helps policymakers and healthcare providers prioritize investments in technologies that offer the most meaningful benefits to patients and the system. Additionally, this knowledge influences clinical decision-making, guiding healthcare professionals in selecting the most suitable devices for various medical conditions and treatments.

Enhancement of patient outcomes: Improving patient outcomes is the primary objective of any healthcare system. A comprehensive value assessment of medical devices considers both clinical advantages and improvements in patients' quality of life. High-value devices are those that offer meaningful improvements in patient outcomes, such as shorter recovery times, fewer complications, and enhanced life quality. Such assessments ensure that the adoption of new medical technologies translates into tangible health benefits for patients.

Alignment with public health and societal goals: The value assessment of medical devices should also consider broader societal impacts. This includes alignment with public health objectives and societal well-being. Medical technologies that enable early disease detection, reduce the need for invasive procedures, or support chronic disease management not only improve individual health outcomes but also boost public health efficiency and societal productivity. These broader considerations ensure that the adoption of medical devices support overarching public health strategies and societal goals, reinforcing the sustainability of the healthcare system.

Understanding the value of medical devices is pivotal in shaping a healthcare system that is modern, effective, and responsive to the population needs. It ensures that technological advancements translate into real-world benefits, enhancing the quality, accessibility, and efficiency of healthcare services across Malaysia.

Figure 3: Importance of understanding the value of medical devices

The concept of 'value'

Assessing the value of medical and healthcare interventions, including medical devices, requires a comprehensive definition of 'value'. In this context, 'value' is a multidimensional concept that encompass aspects such as utility, social significance, emotional and spiritual meaning, and monetary expenditure.[15] Fully comprehending this concept necessitates exploring these various dimensions that constitute value.

Multidimensional nature of value:
Value can be perceived in several ways:[15]

***Exchange and use value*:** This perspective views value by the monetary sacrifice individuals are willing to make to acquire and use a product.

***Symbolic value*:** From another angle, value acts as a sign, focusing on the symbolic meanings that goods carry.

***Experiential value*:** Value can also be seen as an experience, reflecting the personal and emotional experiences associated with a product or technology.

Lack of global consensus on value definition:
There is no universally accepted definition of value for medical technologies.[16] This lack of consensus complicates how value is determined and applied in health technology decision-making. Traditional methods, such as cost-effectiveness analyses which measures incremental cost per quality-adjusted life years (QALYs), often fail to capture the full spectrum of values important to various stakeholders. This limitation is particularly evident in the evaluation of medical devices.

Incorporating diverse stakeholder perspectives:
It is vital to acknowledge that different stakeholders perceive value differently:

***Payers*:** Emphasize cost-effective, evidence-based interventions.

***Healthcare providers*:** Prioritize the efficacy and efficiency of diagnostic and treatments.

***Patients*:** May value technologies that improve their health and align with personal health goals; however, this perceived value varies with socio-economic status, health literacy, and financial capacity, adding complexity to defining value in healthcare.

Despite these diverse perspectives, stakeholders share an understanding of the importance of broader social outcomes, such as productivity, though these are often difficult to quantify.

Bridging gaps with Value Assessment Frameworks (VAFs): Given the varied perspectives on value, there is a pressing need for tools such as Value Assessment Frameworks (VAFs) that provide a structured approach to evaluating the value of health technologies. VAFs accommodate diverse stakeholder views and guide the decision-making process in healthcare. These frameworks typically quantify benefits and costs, considering factors such as clinical efficacy, patient outcomes, safety, and quality of life improvements.

Developing a comprehensive value assessment framework: Developing a robust VAF requires an understanding of the multifaceted nature of 'value' in healthcare. This includes considering not just the clinical and economic aspects, but also the personal and societal impacts of medical technologies. Such a framework supports informed decision-making to ensure medical devices deliver maximum value in terms of patient outcomes, resource utilization, and alignment with broader healthcare goals. By adopting comprehensive VAFs, the Malaysian healthcare system can ensure that decisions regarding medical devices are made in a way that optimizes outcomes for patients, providers, payers, and society as a whole.

Current assessment practice in Malaysia's health system

In Malaysia, value assessment of medical devices is a critical component of healthcare management, particularly under the Ministry of Health. While regulatory oversight by the Medical Device Authority (MDA) ensures that medical devices meet essential safety, quality, and performance standards for market entry, the broader evaluation of their value is conducted through Health Technology Assessment (HTA).

HTA is applied to selected medical devices upon request, focusing on technologies with significant impact on patient care, healthcare costs, or policy decisions. HTA serves as a cornerstone for value-based healthcare by systematically evaluating prioritized medical technologies beyond their regulatory compliance. This process examines clinical effectiveness, cost-effectiveness, and organizational implications, as well as social and ethical impacts. By integrating these multidimensional evaluations, HTA provides a comprehensive framework for decision-making, guiding policymakers in the optimal allocation of healthcare resources.

Unlike regulatory assessments, which primarily focus on ensuring that devices are safe and meet performance benchmarks, HTA addresses the broader question of whether a medical device delivers meaningful value within the context of the healthcare system. This includes assessing its impact on patient outcomes, budgetary considerations, and equity in healthcare access.

Health Technology Assessment (HTA) in Malaysia: HTA is a key tool in Malaysia's healthcare system for appraising medical technologies, including medical devices. The Malaysian Health Technology Assessment Section (MaHTAS), under the Ministry of Health, is the primary agency conducting these assessments. MaHTAS ensures that evaluations are relevant, evidence-based, and aligned with national healthcare priorities. These assessments inform decision-making, guiding policy formulation, technology adoption, and resource allocation across the healthcare sector.

Types of assessments conducted by MaHTAS: Since its establishment in 1995, MaHTAS has evolved to produce various types of assessments:

***Full HTA*:** Involves a complex and thorough review, considering safety, effectiveness, cost and organizational impacts.

***Mini-HTA*:** Addresses current decision problems with a smaller scope of assessment.

***Rapid review*:** Provides quick responses to urgent information needs, emphasizing safety and effectiveness.

***Horizon scanning programme*:** Supports early identification and monitoring of new and emerging health technologies for their potential impact on healthcare delivery, patient outcomes, and resource utilization.

Integration in procurement processes: Findings from our primary research indicate that the procurement of medical devices in Malaysia has traditionally been dominated by a price-centric focus. While this approach manages device costs effectively, it often overlooks the broader patient and healthcare system needs. There is a growing recognition of the benefits of a value-based procurement strategy, where HTA plays a crucial role. MaHTAS may be consulted during the procurement process for recommendations. Positive HTA outcomes facilitate funding and adoption, while negative ones limit uptake. HTA insights guide better-informed procurement decisions by focusing on technical specifications, healthcare compatibility, quality standards, and cost-effectiveness, ultimately prioritizing patient outcomes and long-term benefits.

Impact on policymaking:
HTA significantly shapes healthcare policies in Malaysia through value assessments that impacts:

***Resource allocation*:** Strategic allocation of resources ensures that the healthcare system can provide the best possible technologies to the population, based on solid evidence of effectiveness and cost-efficiency.

***Technology adoption*:** Systematic evaluations influence policies on new medical technology adoption, ensuring that only those with proven benefits and reasonable costs are incorporated into the national healthcare system.

***Clinical practice guidelines*:** HTA helps to develop guidelines that standardize care across the country, ensuring they reflect the most effective and valuable treatments available.

Collaboration with stakeholders:
MaHTAS collaborates through multidisciplinary teams through several committees:

***Expert Committee*:** Includes clinicians, allied health professionals, patient representatives, policymakers, representatives from the Ministry of Health (MOH) and health economists, formulating protocols and reviewing evidence.

***Technical Advisory Committee (TAC)*:** Comprises clinicians, allied health professionals, representatives from the MOH, policymakers, clinicians, and health economists, overseeing technical aspects and appraising reports.

***The Council*:** Consists of clinicians (national heads of specialty), high-level officials (directors of various divisions within MOH), allied health professionals, patient representatives, policymakers, academia, health economists and private sector associations, providing final approval on reports and recommendations.

Patient involvement:
Patients and carers are integral to the assessment process and included in assessments whenever possible. Their perspectives are gathered through focus groups and surveys to ensure assessments reflect patient-centric outcomes and values.

Industry involvement:
While not proactively engaged, industry representatives are consulted when specific information on the technology is required.

Selected assessments by MaHTAS:
A variety of assessments have been reported, covering diverse technologies and devices, from intrathecal pumps and capsule endoscopy systems to advanced diagnostic assays and robotic surgery systems[17] **(Table 1)**. These assessments delineate the boundaries of effective medical device use within the healthcare system, highlighting the utility and value of diverse medical technologies.

In summary, value assessment practices in Malaysia's health system through HTA and other methodologies are integral for ensuring that medical devices used are cost-effective and aligned with the broader goals of healthcare quality, accessibility, and innovation.

Table 1. A selected list of assessments performed by MaHTAS covering diverse technologies and devices

Assessment type	Report title	Technology assessed	Year
Full HTA	Molecular Profiling Assays in Early Breast Cancer	Oncotype DX, MammaPrint, Prosigna, EndoPredict tests	2022
	Capsule Endoscopy For Colorectal Cancer (CRC) Screening	First Generation Pillcam® Colon Capsule Endoscopy System (CCE-1), Second Generation PillCam® COLON 2 Capsule Endoscopy System (CCE-2)	2015
	Continous Intrathecal Baclofen (ITB) Infusion For Severe Spasticity And Dystonia	SynchroMed electronic pump by Medtronic	2014
	Intraocular Lens (IOl) Implantation- Hydrophilic Acrylic Versus Hydrophobic Acrylic	Various brands of IOLs	2009
Mini-HTA	Negative Pressure Wound Therapy (NPWT)	Various NPWT devices	2023
	Versajet Hydrosurgery System For Wound Debridement: An Update	VersaJet™ Hydrosurgery System	2022
	Robotic Arm-Assisted Surgery In Total Hip Arthroplasty	Various robotic systems	2022
	Rezūm Therapy For Management of Benign Prostate Hyperplasia	Rezūm Water Vapour Therapy	2021
Rapid review	Baguera Implant in Spine Surgeries	Baguera© (Prosthesis device)	2022
	Trumpet Art Stent	Trumpet art stent	2022
	Geko Device to Prevent Venous Thromboembolism	Geko device	2020
	Flash Glucose Monitoring	Flash Glucose Monitor (FGM)	2020
Horizon scanning	Airway Shield	Airway shield (Proxima Clinical Research)	2023
	Extravascular Implantable Cardioverter-Defibrillator	EV ICD device and system (Medtronic)	2022
	Glucosenz	Glucosenz power-operated, stationary, non-invasive blood glucose measuring device	2020
	EmboTrap II Revascularization Device (stent-clot-retriever)	EmboTrap II Revascularization Device	2017

Challenges and issues in value assessment for medical devices

The assessment of the value of medical devices in Malaysia, while comprehensive, faces unique challenges that significantly differentiate it from the pharmaceutical sector. These challenges require a nuanced understanding to effectively navigate the value assessment process within the complex healthcare landscape.

Limitations in scope of assessment:
While Malaysia's HTA methodologies are robust, they present challenges in capturing the multifaceted value of medical devices. There are often gaps in comprehensive data for newer technologies, leading to potentially incomplete assessments. Moreover, existing methodologies may not fully account for all dimensions of value, such as long-term effectiveness, patient-reported outcomes, healthcare system efficiency or broader societal impacts. This can result in evaluations that do not entirely reflect the true value of the devices.

Incorporating patient perspective and voice:
Integrating patient perspectives remain a limitation in medical device value assessments. Prioritizing the needs and values important to patients and their families is key to a comprehensive evaluation. Patient perspectives offer real-world insights that extend beyond traditional clinical data, contributing to a more holistic understanding of a device's impact.

Balancing cost and clinical performance in a rapidly evolving landscape:
A primary challenge in the medical device sector is assessing the clinical effectiveness of new innovations while considering both cost and performance standards. While budget constraints are a significant factor, healthcare expenses should be viewed as investments, rather than just cost. The rapid pace of technological advancements in medical devices and shorter product lifespans make it difficult to keep assessments current, as newer models frequently replace existing ones. A pragmatic approach is needed — one that considers both cost and real-world impact, ensuring that investments in medical technology yield meaningful benefits and align with the evolving healthcare landscape.

Challenges in clinical evidence and data availability:
Medical devices often have fewer randomized controlled trials (RCTs) commonly seen with pharmaceuticals, making it more difficult to generalize evidence across settings. Conducting RCTs for medical devices is challenging due to issues such as blinding and the development of sham devices. Effective value assessments rely heavily on high-quality data, which is often scarce. Therefore, obtaining sufficient real-world data and adapting assessments to the evidence available is crucial. The lack of comprehensive post-market surveillance further compounds this issue, highlighting the need for ongoing monitoring and data collection.

Variability in adoption of clinical guidelines:
Based on insights gathered from our primary research, inconsistent adherence to clinical guidelines in actual practice poses a challenge in evaluating the value of medical devices. While guidelines aim to standardize care and improve outcomes, variability in their adoption can lead to differences in patient outcomes. This inconsistency complicates the process of gathering high-quality data, hindering the accurate assessment of a device's true value.

Difference from other health technologies:
The efficacy and safety of medical devices are influenced by the learning curve effect, where clinical outcomes depend on the operator's training, competence, and experience. This factor must be considered in the assessment and implementation phases of medical device use.

Need for comprehensive and transparent evaluation processes:
There is a growing demand for more comprehensive and transparent evaluation processes in medical device value assessment. Stakeholders seek greater clarity and involvement in decision-making regarding medical device approvals and reimbursements.

Adapting to the diverse needs of the Malaysian population:
Malaysia's diverse population presents distinct healthcare needs. Ideally, value assessment should be tailored to address differences in cultural, socioeconomic, and health needs. The current one-size-fits-all approach may not effectively meet the requirements of the population.

Implications of current practices in medical device value assessment:
Impact on healthcare delivery: Inadequate evaluation of medical devices can lead to the adoption of technologies that may not provide optimal outcomes, potentially hindering advancements in healthcare delivery.

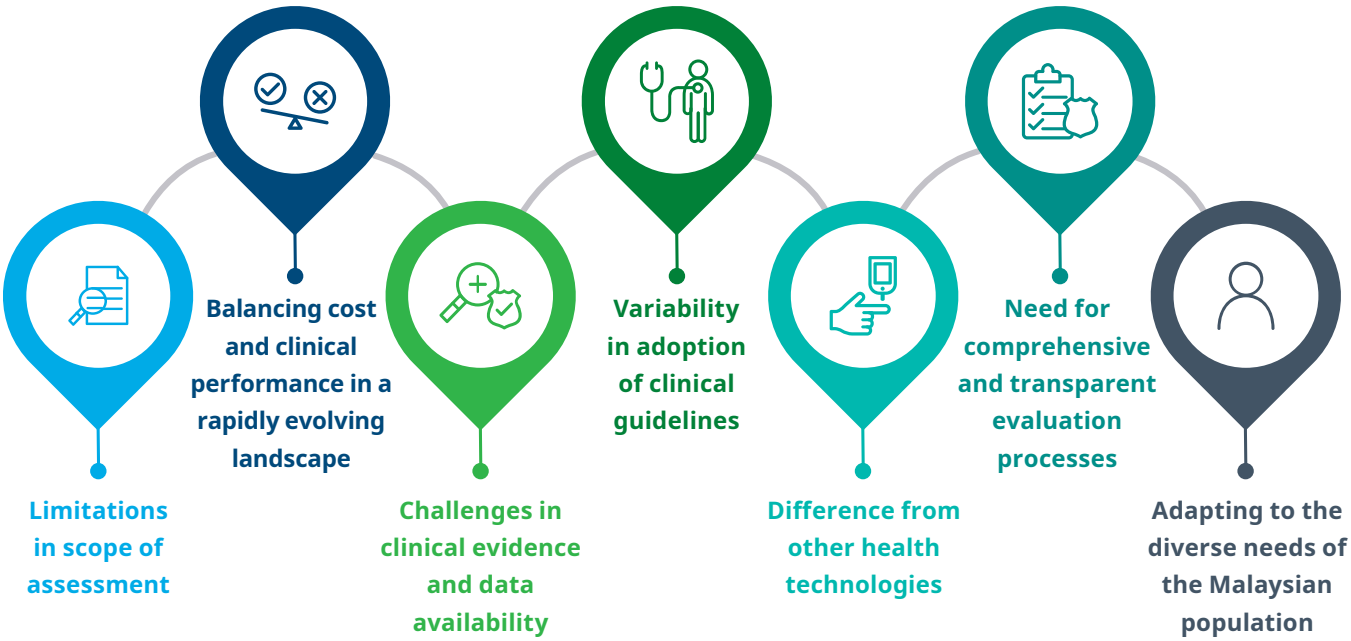
Patient access to new and innovative medical devices: The pace and thoroughness of the value assessment process impact patient access to new and innovative medical devices. However, access is also constrained by funding availability, particularly in the public sector. Funding limitations can delay coverage decisions, hindering timely patient access to cost-effective technologies and beneficial treatments.

Overall efficiency of the healthcare system: Effective value assessment practices are crucial for ensuring that investments in medical devices provide the best value for money, optimizing resource allocation and maximizing health outcomes.

Alignment with Malaysia's healthcare goals: Effective value assessment is essential for achieving high-quality, accessible healthcare for all Malaysians. It supports the broader goals of an inclusive and progressive healthcare system.

Addressing these challenges is vital for enhancing Malaysia's healthcare system and achieving optimal patient outcomes. A tailored approach to value assessment is needed — one that adapts to the rapidly evolving and complex medical device sector, balances cost and clinical performance effectively, and considers the unique needs and circumstances of the Malaysian population.

Figure 4: Challenges in value assessment of medical devices



Case study

Case 1: Pulsed Field Ablation Therapy

Pulsed Field Ablation (PFA) is an advanced treatment for cardiac arrhythmias, particularly atrial fibrillation (AF).[18] It uses pulsed electric fields to selectively ablate cardiac tissue without harming surrounding structures, reducing the risk of complications and improving patient outcomes.

WHAT POTENTIAL ROLE COULD IT PLAY IN OUR HEALTHCARE SYSTEM?

PFA can significantly enhance the healthcare system by:

Improving clinical outcomes: Offering a safer, more effective alternative to traditional ablation methods, leading to fewer complications and better long-term results for AF patients.

Enhancing efficiency: Optimizing procedural efficiency through standardized workflow. Therefore, greatly enhancing operational predictability and ultimately reduce waiting times for AF treatments.

Addressing population health challenges: Providing an effective treatment for the growing number of AF patients, particularly in the aging population. This improves quality of life and reduces healthcare burdens.

Safeguarding financial health: Reducing repeat procedures and complications, leading to quicker recoveries and fewer follow-up visits. This allows patients to return to work and daily activities sooner, easing financial burden and supporting individual economic resilience and family financial security.

WHAT FACET OF ITS VALUE IS IMPORTANT TO BE CONSIDERED?

An often-overlooked facet of PFA's value is its impact on patient quality of life. Current assessments focus on immediate outcomes and costs, neglecting benefits such as reduced complications, fewer repeat procedures, improved patient satisfaction and enhanced financial stability. Incorporating patient-reported outcomes, overall well-being and societal impact is crucial for a more comprehensive assessment.

CHALLENGES AND ISSUES IN VALUE ASSESSMENT

Comprehensive value metrics*:* Neglect of long-term cost-effectiveness, patient-centered outcomes and societal benefits.

- **Potential solution:** Develop metrics that include long-term health outcomes, cost savings, patient-reported outcomes and societal impact to capture PFA's full benefits.

Real-world evidence and longitudinal studies: Lack of real-world and long-term data.

- **Potential solution:** Conduct studies to gather data on PFA's effectiveness, safety, and long-term outcomes to inform policy and reimbursement decisions.

Integration and utilization: Need for investment in equipment, training, and workflow adjustments.

- **Potential solution:** Implement pilot programs at key public hospitals to demonstrate PFA's benefits. Results from these programs can guide decisions for gradually expanding its use to more healthcare facilities. This would involve providing targeted training for healthcare staff and securing incremental funding to support the broader adoption of PFA.

Policy and reimbursement adjustments: Current reimbursement policies may not fully reflect PFA's value.

- **Potential solution:** Advocate for policy changes that recognize long-term savings, patient benefits and financial stability, while adjusting reimbursement models to support innovation.

Case 2: Water Vapor Thermal Therapy

Water Vapor Thermal Therapy (WVTT) is an innovative treatment for benign prostatic hyperplasia (BPH), a common condition in older men that results in an enlarged prostate. WVTT uses steam to ablate excess prostate tissue, relieving lower urinary tract symptoms with minimal invasiveness. An example of this technology is the Rezum™ system.[19] which has been evaluated by MaHTAS.[17]

WHAT POTENTIAL ROLE COULD IT PLAY IN OUR HEALTHCARE SYSTEM?

WVTT can play a transformative role in the healthcare system by:

Enhancing patient safety and comfort: Offering a less invasive alternative to traditional surgical procedures such as transurethral resection of the prostate (TURP), with potentially fewer complications and faster recovery.

Improving clinical outcomes: Demonstrating effectiveness in significantly reducing BPH symptoms, maintaining long-term symptom relief, and preserving sexual function — leading to improved patient satisfaction and quality of life.

Increasing accessibility: Providing a simpler, outpatient procedure that can be performed using local anesthesia in a wider range of healthcare settings, expanding access to effective BPH treatment. This benefits marginalized and underserved populations, aligning with broader societal goals of advancing health equity.

Reducing healthcare costs: Potentially lowering overall cost of BPH treatment through lower retreatment rates, reduced procedure times, shorter hospital stays, and fewer post-operative complications.

WHAT FACET OF ITS VALUE IS IMPORTANT TO BE CONSIDERED?

An important yet often overlooked value of WVTT in Malaysia's healthcare system is its suitability as an effective and safe alternative to existing BPH treatments such as TURP. While TURP is common and effective, WVTT offers a minimally invasive option that can be deployed more easily in outpatient settings, including smaller clinics and community hospitals. This flexibility supports greater access to BPH treatment and contributes to equity in healthcare delivery across Malaysia.

CHALLENGES AND ISSUES IN VALUE ASSESSMENT

Access to rural and underserved areas*:* Assessing the impact of WVTT on improving access to care in remote areas requires a comprehensive approach beyond product evaluation. It necessitates evaluating broader aspects such as patient equity, as setting up a service involves addressing infrastructure, workforce, and operational hurdles to ensure equitable access to care.

- **Potential solution:** Explore a mobile WVTT and conduct pilot studies in rural areas to evaluate deployment feasibility and effectiveness, with a focus on infrastructure and operational metrics such as facility readiness and procedural efficiency. This approach allows urologists to perform procedures in smaller hospitals, with local teams overseeing follow-up care. Collaborate with MOH to establish infrastructure endpoints; if met, this could lead to broader implementation of mobile WVTT units.

Long-term outcome metrics: Lack of focus on long-term patient outcomes and resource utilization.

- **Potential solution:** Develop metrics to assess long-term health improvements, reduction in medication use, and overall patient satisfaction. These indicators are relevant to capture the full value of WVTT, especially in underserved populations.

Patient-centered outcomes: Under-representation of patient-reported outcomes and quality of life improvements.

- **Potential solution:** Incorporate patient surveys and feedback mechanisms to measure the impact of WVTT on daily living, sexual function and overall well-being. This ensures these outcomes are included in the assessment framework, with a focus on rural healthcare needs.

Case 3: Intravascular Ultrasound (IVUS) for Percutaneous Coronary Intervention (PCI)

Intravascular Ultrasound (IVUS) is an advanced imaging technology used during Percutaneous Coronary Intervention (PCI) to provide detailed, real-time images of the coronary arteries' interior. IVUS operates via a catheter with an ultrasound probe, allowing visualization of artery walls and lumen to support precise stent placement and optimization during PCI procedures.[20]

WHAT POTENTIAL ROLE COULD IT PLAY IN OUR HEALTHCARE SYSTEM?

IVUS can play a transformative role in the healthcare system by:

Enhancing clinical precision: Offering detailed visualization of coronary arteries, enabling more accurate assessment of plaque composition and stent placement compared to conventional imaging (coronary angiogram) alone, which reduces the risk of complications.

Improving patient outcomes: Contributing to better long-term outcomes for coronary artery disease (CAD) patients by lowering the incidence of major adverse cardiac events (MACE) and reducing the need for repeat interventions which are associated with higher costs.

Optimizing resource use: Shortening procedure times and hospital stays by enhancing the precision of PCI, thus improving overall healthcare system efficiency.

WHAT FACET OF ITS VALUE IS IMPORTANT TO BE CONSIDERED?

A crucial facet of IVUS's value is its impact on operators and the subsequent impact on clinical outcomes. For many medical devices, their effectiveness depends on the technical expertise of operators, which can be aided by medical devices themselves. In the case of IVUS, the detailed imaging overcomes limitations of coronary angiogram alone, enhancing clinical precision by guiding stent deployment during PCI and avoiding adverse events that require repeat intervention. Current assessments that focus on immediate procedural outcomes and costs neglect how imaging insights by IVUS improve clinical decision-making, thus avoiding longer-term complications, retreatments and costs.

Furthermore, advancements in IVUS through the incorporation of more advanced artificial intelligence (AI) is meaningfully shaping the PCI imaging landscape. AI algorithms can automate procedural steps, enhance guidance during PCI, and streamline IVUS procedures, leading to improved procedural efficiency. These innovations can further amplify the positive impact of IVUS on patient care and hospital efficiencies.

CHALLENGES AND ISSUES IN VALUE ASSESSMENT

Imaging interpretation and expertise: The effectiveness of IVUS is closely tied to the cardiologists' expertise in interpreting the images and making clinical decisions. Variability in skill levels may result in inconsistent outcomes.

- **Potential solution:** Invest in specialized training and certification programs for clinicians to ensure high standards of utilizing IVUS technology in PCI.

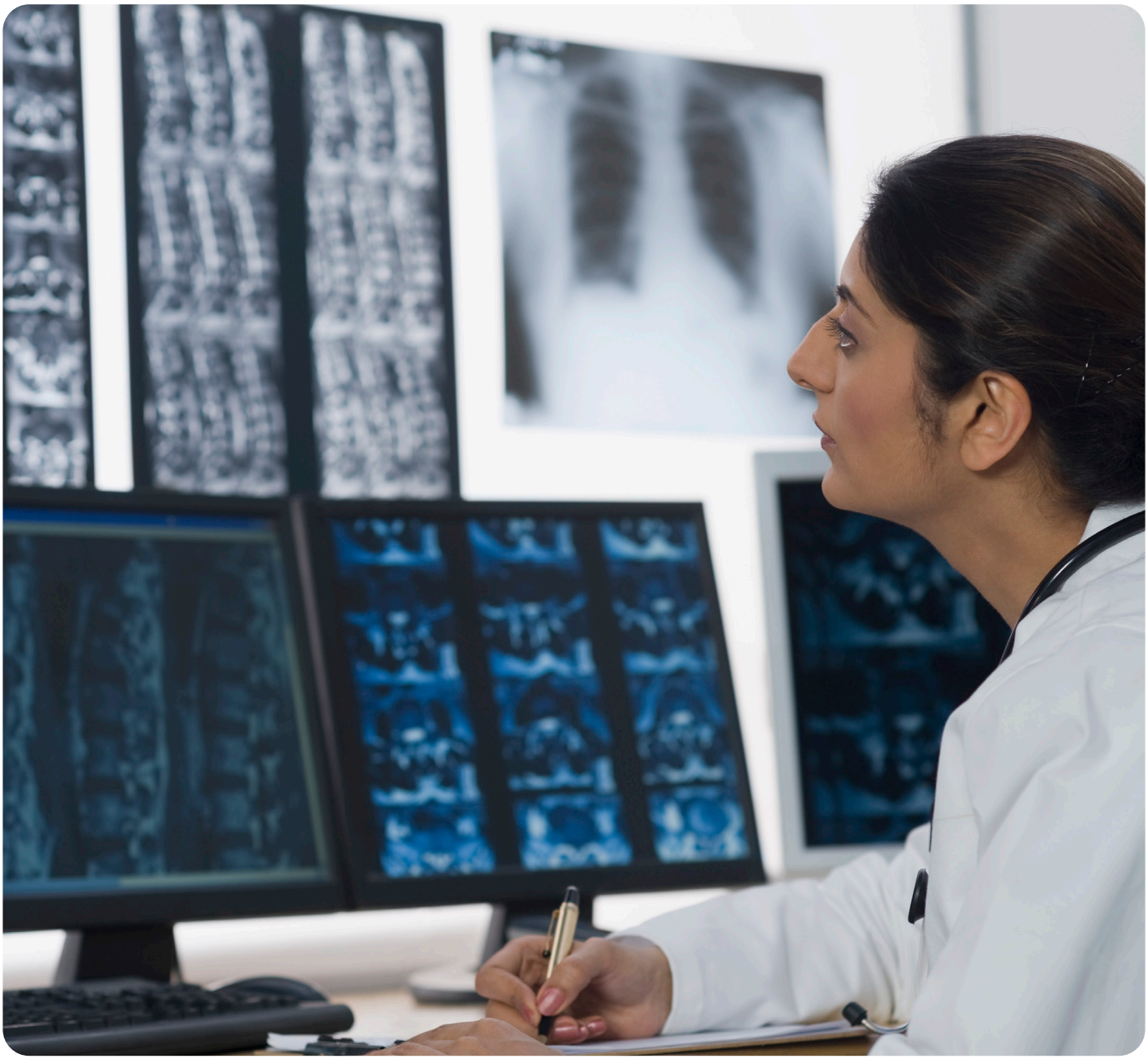
Comprehensive value metrics: Current assessments often emphasize short-term procedural outcomes and costs, neglecting the broader benefits of IVUS to patients, hospitals and healthcare systems.

- **Potential solution:** Develop comprehensive metrics that capture the value of IVUS, such as its impact on clinical decision-making, procedural success rates, and long-term patient outcomes. Incorporate these metrics into value assessment frameworks to reflect its full benefits.

Integration into clinical practice: Integrating IVUS into routine clinical practice requires investment in equipment, training, and workflow adjustments.

- **Potential solution:** Promote IVUS integration through pilot programs supported by government initiatives and funding. Demonstrate the long-term benefits and cost savings to encourage widespread adoption.

Note: *The technologies discussed in this section were selected based on their potential impact on the healthcare system and their relevance in illustrating key concepts related to the value assessment of medical devices, as covered in earlier sections of the paper. They may not necessarily reflect the input or viewpoints of a particular contributor or organization.*



Recommendations for advancing value assessment of medical devices

As we transition from the detailed exploration of value assessment challenges in Malaysia's healthcare system, it becomes clear that strategic enhancements are necessary to align with technological advancements and evolving stakeholder expectations. This chapter presents a series of recommendations drawn from our comprehensive review of literature, stakeholder interviews, and analysis of current practices. These recommendations are proposed as strategic directions to guide stakeholders in refining and advancing the value assessment practice for medical devices. Each suggestion is presented as a well-considered option rather than a directive, encouraging serious consideration and potential adaptation to local contexts.

Recommendation 1: Establish key value domains for comprehensive value assessment

The complexity of medical device innovation and their diverse impacts on health systems necessitate a structured value assessment approach. We propose the consideration of a set of key value domains that encompass the multifaceted values inherent in medical devices. These domains were derived from extensive research and validated by global best practices. They include areas such as disease impact, device specifics, innovativeness, clinical outcomes, and other critical factors such as patient-centered outcomes (see details in ***Appendix S1***).

STRATEGIC INSIGHT:

- Stakeholders are encouraged to review and adapt these proposed domains as necessary to capture the full spectrum of value that medical devices offer. This adaptation may involve prioritizing certain domains based on Malaysia's healthcare goals or specific population needs.
- Customization of value assessment criteria to fit the Malaysian context is crucial. This includes incorporating stakeholder perspectives, prioritizing domains based on local preferences, and setting cost thresholds.

Recommendation 2: Enhance evidence generation and development of research ecosystem

The generation of robust clinical evidence for medical devices presents challenges. These include the complexities in conducting randomized controlled trials (RCTs) and the need for comprehensive post-market surveillance. Enhancing the evidence generation ecosystem involves improving research infrastructure, fostering stakeholder collaboration, standardizing data collection, promoting transparency, and establishing processes for maintaining and sharing evidence. A robust data infrastructure is essential to address gaps in data availability.

STRATEGIC INSIGHT:

- Establish mechanisms to encourage active participation from medical device manufacturers in the development of real-world data by providing incentives such as preferential procurement opportunities. This incentivization stimulates their commitment to conduct studies that rigorously monitor device performance post-marketing, ensuring compliance with safety and effectiveness standards comparable to their originator counterparts.
- Assess Malaysia's healthcare infrastructure readiness to support real-world data initiatives, considering data accessibility, and technological capabilities. Address any limitations through process improvements and educational efforts for successful real-world evidence (RWE) generation.
- Develop alternative evidence generation methodologies that are tailored to the characteristics of medical devices. These could include adaptive trial designs, RWE studies, and observational research.

- Foster partnerships between healthcare institutions, industry, and research organizations to facilitate clinical trials and evidence generation. Such collaborations bring necessary resources and expertise to overcome challenges in this area.
- Introduce a structured framework requiring manufacturers to submit initial and periodic reports on real-world usage, adverse events, and efficacy outcomes. This framework could be integrated into the existing regulatory process, providing a continuous assessment pathway that aligns with international best practices. Stakeholder engagement, including healthcare providers and patient groups, will be crucial in monitoring and evaluating the impact of these devices in real-world settings.
- Emphasize the integration of RWE for a comprehensive understanding of medical device performance in real-world settings. Traditional assessments based on published data may overlook the full impact of devices. Meanwhile, incorporation of RWE allows for a more personalized evaluation that aligns with local patient needs.
- Establish data governance frameworks to ensure the reliability and transparency of evidence. Develop mechanisms to manage unpublished or potentially biased data from industry-sponsored studies, improving the accessibility and reliability of the evidence base.

Recommendation 3: Foster transparent and consultative stakeholder engagement in value assessment processes

Our findings highlight the significance of transparent and robust practices in stakeholder engagement for effective value assessment. By embracing transparency and involving stakeholders in a consultative manner, diverse perspectives and expertise can be integrated, contributing to more balanced and thorough evaluations.

STRATEGIC INSIGHT:

- Stakeholders can consider establishing more structured and continuous engagement processes. This could involve forming dedicated working groups with a broad range of perspectives, from healthcare providers to patients. These groups can steer the assessment process, ensuring inclusivity and providing rich and diverse insights.
- Involve relevant stakeholders early in the assessment process. Patient involvement clarifies uncertainties about technology impact on quality of life and incorporates diverse perspectives. Meanwhile, engaging policymakers through structured processes — either after positive recommendations, or at earlier key stages for high-potential technologies, can bridge the gap between assessment outcomes and funding approvals, promoting smoother adoption of technologies.
- Provide educational resources in layman's terms and collaborate with patient groups to inform patients about new technologies. Ensure transparency regarding all treatment options, beyond those available in the public sector. This will support patient autonomy and access to comprehensive information despite resource constraints.
- Strengthen advocacy for specific therapeutic areas to encourage the adoption of new technologies, especially in underrepresented areas such as rare diseases.
- Draw on methodologies from established organizations such as the Institute for Clinical and Economic Review (ICER), the Health Information and Quality Authority (HIQA) and Schmeer's Stakeholder Analysis Guidelines, and adopt a systematic approach for stakeholder collaboration (see details in ***Appendix S2***).

Recommendation 4: Implement strategies for framework adoption and progress evaluation

Implementing a value assessment framework successfully requires careful planning, ongoing evaluation, and readiness to make iterative improvements. This recommendation focuses on strategic execution and continuous evaluation of framework effectiveness over time.

STRATEGIC INSIGHT:

- Stakeholders can consider pilot testing new frameworks in controlled settings to gauge their effectiveness before broader application. Establish clear metrics for regular performance evaluations to maintain framework relevance and effectiveness as healthcare needs and technologies evolve.
- Ensure systematic and transparent evaluation processes for consistent and thorough medical device assessments. Based on various international best practices, we have synthesized a guiding framework to support systematic implementation and continuous improvement for the adoption process (see details in ***Appendix S3***).

Recommendation 5: Address rapid technological advancements

The rapid pace of technological advancements in medical devices calls for a dynamic and responsive approach to value assessment. Strategies must be in place to manage the evolving nature of medical device innovation to ensure timely and relevant assessments.

STRATEGIC INSIGHT:

- Create pathways for manufacturers to proactively provide updates on evidence. Leveraging their knowledge of product pipelines, manufacturers can contribute to horizon scanning activities voluntarily, supporting timely integration of new evidence into assessment frameworks.
- Develop flexible assessment protocols that can be quickly adapted to new technologies and iterations of existing devices. This will enable the healthcare system to keep pace with innovation without compromising the rigor of value assessments.
- Include alternative evaluation approaches, such as cost-consequence analysis, to better reflect the diverse impacts and benefits of medical devices on patient health and quality of life.

Recommendation 6: Strengthen training and capacity building

Specialized training programs for stakeholders involved in the assessment process are essential to ensure effective participation and evaluation. Capacity building will ensure stakeholders have the necessary skills and resources to conduct thorough and accurate evaluations.

STRATEGIC INSIGHT:

- Implement training programs for healthcare professionals, policymakers, and other stakeholders involved in value assessments. These programs should cover methodologies, regulatory requirements, and practical skills needed for effective evaluation.
- Focus on capacity building within the HTA body to address workload challenges faced by limited staff handling multiple assessments. Strengthening this capacity is crucial to meet the growing demand and complexity of assessments.
- Encourage collaboration with academic institutions and international organizations to develop and deliver training modules. This collaboration will ensure that the training is comprehensive and aligned with global best practices.

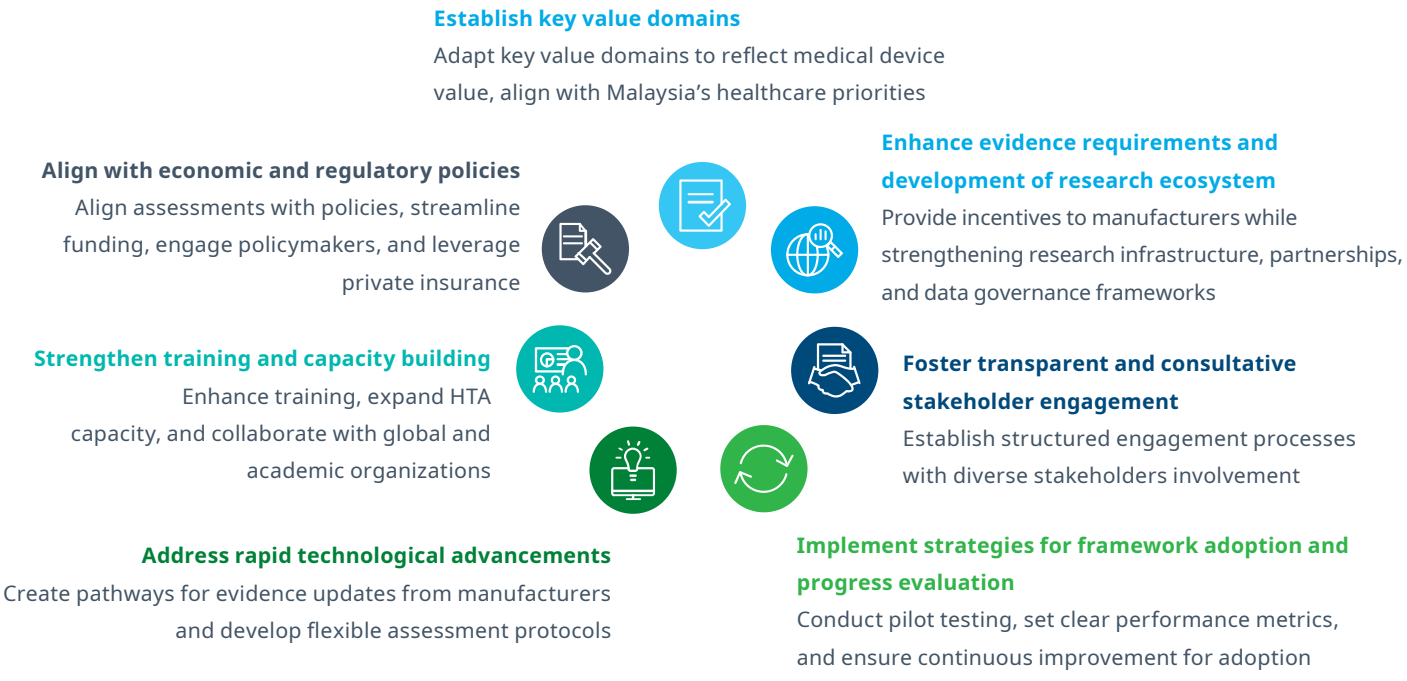
Recommendation 7: Align with economic and regulatory policies

National policies, such as the National Strategic Plan for Non-Communicable Diseases and the Medical Device Act, significantly impact the assessment and adoption of innovative medical devices. These policies shape the regulatory environment and influence the integration of new technologies into the healthcare system. Bridging the gap between HTA or clinical guidelines recommendations and funding, becomes paramount to ensure access to advanced technologies, especially within the context of universal health coverage.

STRATEGIC INSIGHT:

- Conduct regular reviews of national policies and their implications on medical device assessments. Align assessment frameworks with current and emerging policies to facilitate seamless integration of new devices.
- Engage policymakers to advocate for regulatory reforms that support innovation while ensuring patient safety and effectiveness.
- Align value assessment outcomes with funding and procurement processes to establish a clear link between assessment results and funding decisions. This will ensure that valuable technologies are effectively communicated and integrated into the healthcare system.
- Streamline funding processes to reduce inefficiencies and delays in reimbursement approvals, expediting access to innovative treatments. This creates a more efficient pathway to secure funding for technologies with positive assessment recommendations or Clinical Practice Guidelines (CPGs) endorsements, bridging the gap between assessment outcomes and patient access.
- Leverage private insurance reimbursement mechanisms and co-payment models to address funding gaps, particularly in the private sector. This can improve access to innovative technologies without overwhelming public resources.

Figure 5: Recommendations for advancing value assessment in medical devices



Looking forward

As Malaysia navigates its healthcare challenges, the role of medical devices in addressing these complexities remains pivotal. Implementing these recommendations will ensure that the evaluation of medical devices is robust, inclusive, and aligned with the healthcare system needs. Continuous evolution and adaptation of value assessment frameworks will be essential to keep pace with technological advancements and evolving healthcare demands.

Conclusion

This white paper initiates the discussion on medical device value assessment, setting the stage for further dialogue and advancements. However, an important consideration remains: the gap between value assessment outcomes and funding mechanisms. Positive assessments should lead to dedicated funding for adopting innovative medical technologies, ensuring equitable access and supporting the sustainable growth of Malaysia's healthcare landscape.

For healthcare sustainability, the system must be responsive and resilient. HTA should evolve beyond its traditional role in evaluating and regulating access, to actively shaping the system, fostering innovation, and enhancing agility. This approach will promote efficient resource use and broaden access to advancements, keeping Malaysia's healthcare system innovative and effective in meeting its population's needs.

Glossary

Chronic disease management	A long-term approach to treating and managing chronic diseases to improve quality of life and reduce healthcare costs, involving regular monitoring, medication management, and lifestyle changes.
Demographic transition	The shift from high birth and death rates to lower birth and death rates, typically associated with improved living standards, better healthcare, and economic development.
Disease burden	The impact of a health problem on a population, measured by financial cost, mortality, morbidity, or other indicators.
Economic evaluation	The comparative analysis of alternative courses of action in terms of both their costs and consequences, often used in the context of health technology assessment to determine the value for money of medical interventions.
Evidence-based evaluation	An approach to decision-making in healthcare that integrates the best available scientific evidence with clinical expertise and patient values.
Health financing transformation	The process of changing the way healthcare is funded to improve efficiency, equity, and sustainability, often involving reforms in insurance systems, payment models, and resource allocation.
Health Technology Assessment (HTA)	A systematic evaluation of properties, effects, and impacts of health technology, including medical devices, pharmaceuticals, and procedures, used to inform decision-making in healthcare.
Innovation in medical devices	The process of developing new or significantly improved medical devices that offer enhanced functionality, improved patient outcomes, or greater efficiency in healthcare delivery.
Incremental cost-effectiveness ratio (ICER)	A statistic used in cost-effectiveness analysis to summarize the cost-effectiveness of a healthcare intervention, calculated as the difference in costs between two possible interventions, divided by the difference in their effectiveness.
Learning curve	The process of gaining proficiency and efficiency in a new task or technology over time, which impacts the initial performance and outcomes of medical device usage.
Malaysian Health Technology Assessment Section (MaHTAS)	Malaysian Health Technology Assessment Section, a division within the Ministry of Health responsible for conducting HTAs in Malaysia.
Medical Device Authority (MDA)	Medical Device Authority, a division within the Ministry of Health approving the use of and regulating the safety, quality, and performance of medical devices.
Medical device	Any instrument, apparatus, implement, machine, appliance, implant, reagent, software, material, or other similar or related article intended for medical purposes, used for diagnosis, prevention, monitoring, treatment, or alleviation of disease.

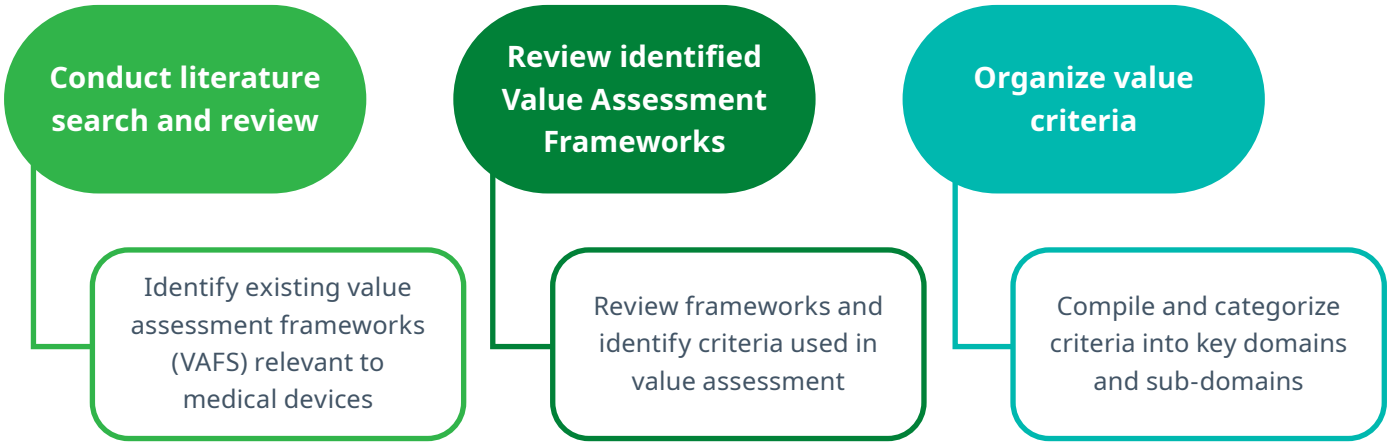
Non-communicable diseases (NCDs)	Chronic diseases that are not passed from person to person, such as heart disease, cancer, diabetes, and chronic respiratory diseases.
Patient-centered outcomes	Health outcomes that are important to patients, reflecting their preferences, needs, and values, and typically measured by factors such as quality of life, satisfaction with care, and functional status.
Patient-reported outcomes (PROs)	Health outcomes directly reported by the patient, without interpretation by clinicians or others, typically collected through questionnaires or interviews.
Procurement processes	The procedures and activities involved in acquiring medical devices and other healthcare technologies, including needs assessment, specification development, supplier selection, and purchase.
Public health emergencies	Situations or events posing an immediate threat to public health, requiring urgent and coordinated response efforts to mitigate health impacts.
Public health strategies	Planned actions and policies aimed at improving the health of populations, focusing on prevention, health promotion, and addressing health disparities.
Quality-adjusted life year (QALY)	A measure of the value of health outcomes, which takes into account both the quantity and the quality of life generated by healthcare interventions.
Real-world evidence (RWE)	Clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of real-world data (RWD), such as electronic health records, claims and billing activities, and patient registries.
Regulatory challenges	The difficulties and complexities associated with complying with regulatory requirements for the approval and market entry of medical devices.
Stakeholder engagement	The process of involving individuals, groups, or organizations who may affect or be affected by a decision, project, or policy, in order to gain their input and foster collaborative decision-making.
Sustainability in healthcare	Practices and policies that ensure healthcare systems can maintain high-quality care delivery over the long term without compromising financial, environmental, or social resources.
Telemedicine	The delivery of healthcare services through telecommunications technology, allowing for remote diagnosis, treatment, and consultation.
Urban-rural health disparities	Differences in health outcomes and access to healthcare services between urban and rural populations, often due to factors like availability of healthcare facilities, economic conditions, and lifestyle differences.
Value assessment framework (VAF)	A structured approach used to evaluate the value of health technologies, including medical devices, by considering multiple criteria such as clinical outcomes, cost-effectiveness, patient-centered outcomes, and broader societal impacts.

Appendix S1. Value Assessment Framework

One of the key recommendations in this paper is a recommended set of domains (i.e., a value assessment framework) to guide the value assessment of innovative medical devices for Malaysia's healthcare system.

To facilitate this, we conducted a comprehensive literature search and identified 10 existing value assessment frameworks (VAF) on health technologies (including medical devices). We reviewed each of these frameworks to understand the criteria utilized for evaluation of the health technologies.

Figure S1: Process of synthesizing relevant VAF literature



List of reviewed value assessment frameworks

1. Pichon-Riviere A, Garcia-Marti S, Oortwijn W, Augustovski F, Sampietro-Colom L. Defining the value of health technologies in Latin America: developments in value frameworks to inform the allocation of healthcare resources. International Journal of Technology Assessment in Health Care. 2019 Jan;35(1):64-8.
2. Morgan RL, Kelley L, Guyatt GH, Johnson A, Lavis JN. Decision-making frameworks and considerations for informing coverage decisions for healthcare interventions: a critical interpretive synthesis. Journal of Clinical Epidemiology. 2018 Feb 1;94:143-50.
3. Goetghebeur MM, Cellier MS. Can reflective multicriteria be the new paradigm for healthcare decision-making? The EVIDEM journey. Cost Effectiveness and Resource Allocation. 2018 Nov;16:1-1.
4. Alonso-Coello P, Schünemann HJ, Moberg J, Brignardello-Petersen R, Akl EA, Davoli M, Treweek S, Mustafa RA, Rada G, Rosenbaum S, Morelli A. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. bmj. 2016 Jun 28;353.
5. Avalere Health-FasterCures. Patient-Perspective Value Framework (PPVF) Version 1.0. 2017 May 2017.
6. Radaelli G, Lettieri E, Masella C, Merlino L, Strada A, Tringali M. Implementation of EUnetHTA core model® in Lombardia: the VTS framework. International Journal of Technology Assessment in Health Care. 2014 Jan;30(1):105-12.
7. Golan O, Hansen P, Kaplan G, Tal O. Health technology prioritization: which criteria for prioritizing new technologies and what are their relative weights?. Health policy. 2011 Oct 1;102(2-3):126-35.

8. Youngkong S, Baltussen R, Tantivess S, Mohara A, Teerawattananon Y. Multicriteria decision analysis for including health interventions in the universal health coverage benefit package in Thailand. Value in health. 2012 Sep 1;15(6):961-70.

9. Advanced Medical Technology Association, Deloitte Consulting LLP. A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem. January 2023. AdvaMed.

10. Freitas L, Vieira AC, Oliveira MD, Monteiro H, Bana e Costa CA. Which value aspects are relevant for the evaluation of medical devices? Exploring stakeholders' views through a Web-Delphi process. BMC Health Services Research. 2023 Jun 8;23(1):593.

Based on the review, we extracted and re-organized these criteria to formulate a proposed set in **Table S1** below, which we believe would be a good starting point for the journey of a value-based assessment for innovative medical devices.

Table S1: Important domains and sub-domains with examples of assessment metrics for medical device value assessment

Domains	Sub-domains	Examples of metrics
Disease impact	• Disease burden • Disease severity • Unmet needs	• Years of life lost • Disability-adjusted life years • Economic burden • Availability of treatment options
Device specifics and innovativeness	• Level of innovation • Criteria specific to medical device being evaluated	• Novelty of technology (e.g., groundbreaking, incremental improvement) • Sensitivity • Specificity • Portability
Clinical outcomes	• Efficacy and effectiveness • Safety and tolerability • Other clinical benefits	• Response rate • Survival rate • Adverse events • Symptom relief • Hospitalization rate • Post-procedural recovery period • Post-procedural complication rate
Functional, disease-specific and quality of life outcomes	• Functional outcomes • Disease-specific outcomes • Quality of life outcomes	• Functional patient-reported outcomes (PROs) (e.g., mobility, pain management scales) • Disease-specific PROs (e.g., Asthma Control Test, Diabetes Health Profile) • HRQoL instruments (e.g., EQ-5D, SF-36)
Patient voice and preferences	• Acceptability to patients and caregivers • Patient preference and experience • Impact on patient's active engagement in self-care	• Patient compliance rate • Patient satisfaction scores • Changes in patient empowerment or health literacy with the assistance of the device

Domains	Sub-domains	Examples of metrics
Patient-centered economic impact	• Productivity lost from work or caregiving responsibilities • Economic impact on family and • caregivers	• Days of productivity gained or lost • Early return-to-work rates • Changes in employment status • Economic burden on caregivers
Organizational impact and efficiency	• Implementation feasibility and system capacity • Acceptability to healthcare providers and stakeholders • Efficient time and resource utilization • Workload to healthcare providers and their exposure to physical or chemical agents	• Device integration time • Compatibility with existing systems/resources • Facility and personnel readiness • Reduction in administrative burdens • Reduction in procedure time • Occupational hazard assessment
Population health and health system alignment	• Impact to population/public health • Alignment with overall healthcare goals/priorities, guidelines, political/social context	• Improvement in population health indicators • Compatibility with national health policies, clinical practice guidelines
Ethical and social impact	• Equity and equality in accessibility to service • Social/ethical implications	• Accessibility in rural and urban areas • Social acceptance and cultural appropriateness
Environmental impact	• Environmental impact	• Carbon footprint reduction • Sustainable materials usage
Cost and affordability (other than direct cost of device)	• Cost of set-up, training, implementation, maintenance, operation	• Setup costs • Personnel training expenses • Implementation and operational costs • Maintenance expenditures
Manufacturing quality	• Manufacturing quality	• Compliance to manufacturing standards • Quality assurance measures
Manufacturer reputation	• Manufacturer reputation	• Track record of manufacturer • History of product recalls or safety issues • Adherence to industry regulations and standards
Availability of technical and logistical supports	• Technical support readiness • Logistical reliability	• Availability of technical support personnel • Proximity of service centers or repair facilities • Reliability of supply chain and distribution channels
Steepness of learning curve	• Skill mastery • User-friendliness	• Time required for proficiency • Intensity of training sessions
Local data generation commitment	• Post-marketing surveillance • Real-world evidence generation	• Investments allocated towards local data generation initiatives • Implementation rate of local data generation plans

Appendix S2. Stakeholder engagement best practices

Recognizing the importance of incorporating diverse perspectives and expertise, we propose a systematic approach (**Table S2**) aimed at fostering more structured and meaningful collaboration with stakeholders.

Our recommendations are developed based on several established methodologies, including:

- Institute for Clinical and Economic Review (ICER)'s Processes for Conducting Value Assessments[21]
- Health Information and Quality Authority (HIQA)'s Guidelines for Stakeholder Engagement in Health Technology Assessment in Ireland[22]
- Schmeer's Stakeholder Analysis Guidelines[23]

Phase	Description
Define clear purpose of stakeholder engagement	• Articulate the objectives of stakeholder engagement in the assessment process, such as: » Gather insights on the performance and impact of specific medical devices in diverse healthcare settings. » Identify stakeholder perspectives on the value and effectiveness of medical devices in addressing specific healthcare challenges. » Inform decision-making processes related to the procurement, adoption, and utilization of medical devices within the Malaysian healthcare system.
Establish a working group	• Form a working group to oversee and guide the value assessment process, comprising individuals with diverse perspectives and expertise to ensure comprehensive coverage of all relevant aspect: » Representatives from the organization or agency leading the value assessment initiative, providing oversight and strategic direction. » Experts from various disciplines involved in the value assessment process, such as health economics, clinical research, health policy, procurement, and clinical practice. » Project managers and coordinators responsible for coordinating activities. » Technical experts with specialized knowledge in areas relevant to the assessment, such as medical device technology, health economics and outcomes research, and value-based procurement.

Phase	Description
Identify and compile list of potential stakeholders	• Compile and review existing information related to the topic or purpose of the value assessment and the corresponding medical device or therapeutic area to identify stakeholders with a connection: » Review existing literature, reports, and documentation related to the value assessment and the specific medical device or therapeutic area. • Utilize stakeholder mapping techniques to identify individuals and organizations involved or impacted by the value assessment process. Examples of stakeholders to consider include: » Healthcare providers involved in the procurement, implementation, and utilization of medical devices within healthcare facilities. » Policy experts and decision-makers involved in healthcare policymaking and resource allocation. » Payer bodies responsible for healthcare financing and reimbursement decisions. » Patient advocacy groups or patient representatives who have insights into patient preferences, needs, and experiences related to medical device use. » Industry representatives from medical device manufacturers, distributors, and suppliers. » Representatives from regulatory bodies responsible for overseeing medical device registration, quality assurance, and safety standards. • Consult with experts and key stakeholders already engaged in similar assessments or initiatives: » Leverage professional networks and contacts to gather insights and recommendations on potential stakeholders.
Decide on a maximum number of stakeholders	• Strive for a balanced representation of stakeholders by capping number of participants while ensuring comprehensive coverage of all pertinent viewpoints: » Consider the scalability of the engagement process, balancing inclusivity with practicality to maintain manageable group sizes for effective communication and decision-making. » Evaluate the resources available for stakeholder engagement activities, including personnel, time, and budget constraints, to determine the feasible number of participants.
Conduct stakeholder prioritization	• Compile the identified stakeholders into a comprehensive list, categorizing them based on their roles, affiliations, and relevance to the value assessment process. • Prioritize stakeholders based on their level of influence, expertise, potential impact on the assessment outcomes, and degree of involvement in the value assessment process. • Create tiers or categories for the stakeholders and tailor engagement strategies to each tier, such as: » Tier 1 (Key decision-makers and opinion leaders): Receive more frequent and detailed communication and engagement opportunities, including one-on-one meetings, targeted workshops, and regular updates on the progress and outcomes of the value assessment process. » Tier 2 (Stakeholders with significant expertise or interest): Engage in focused discussions, advisory committees, or working groups where they can provide specialized insights relevant to specific aspects of the value assessment framework. » Tier 3 (Broader stakeholders with general interest): Participate in broader surveys, online forums, or periodic feedback sessions to gather general input and perspectives on the overall implementation and outcomes from the value assessment process. • Continuously assess and reassess the composition of stakeholder tiers throughout the value assessment process, adjusting priorities and engagement strategies based on evolving needs and circumstances.

Phase	Description
Develop comprehensive stakeholder engagement plan and timeline	• Create a comprehensive roadmap for the overall stakeholder engagement process: » Define the information to be obtained through each stakeholder engagement, such as gathering input on device performance, assessing user experiences, or feedback on value criteria. » Select appropriate engagement methods and channels tailored to each stakeholder group and their preferences. » Develop clear communication protocols to guide interactions between the assessment team and stakeholders, including channels for submitting inquiries, providing feedback, and sharing updates. » Allocate sufficient resources, including personnel, budget, and technology, to support effective stakeholder engagement activities and ensure their successful implementation. » Outline key milestones and deadlines for each phase of the stakeholder engagement process, including preparatory activities, engagement events, data collection periods, and analysis timelines.
Provide clear information for participation	• Clearly communicate with stakeholders, providing information on their participation: » Communicate with stakeholders in a transparent and concise manner, outlining their role and responsibilities in the value assessment process. » Clearly articulate the expectations for stakeholder participation, including the level of involvement required and the anticipated time commitment. » Provide detailed information on the nature of their involvement, such as attending meetings, contributing feedback, or participating in data collection activities. » Ensure stakeholders understand the purpose and objectives of the value assessment, as well as the potential impact of their participation on decision-making processes. » Offer multiple channels of communication to accommodate stakeholders' preferences and ensure accessibility to information throughout the engagement process.
Provide training for alignment and capability-building	• Offer training to enable stakeholders to understand the assessment's fundamental aspects: » Develop tailored training sessions or workshops focusing on the methodologies used in the value assessment process, such as health economics, clinical research, or qualitative analysis techniques. » Customize training materials to align with stakeholders' backgrounds and expertise levels, ensuring that content is relevant and accessible to all participants. » Provide hands-on training opportunities, including practical exercises or case studies, to reinforce key concepts and enhance stakeholders' understanding of the assessment methodologies. » Educate stakeholders on logistical considerations such as formatting requirements and page limits for individual comment opportunities.

Phase	Description
Prepare consultation or interview materials	• Develop relevant materials based on the topic of assessment and framework being adopted: » Create interview protocols and questionnaires tailored to the objectives of the stakeholder engagement. » Ensure that interview materials are comprehensive and cover relevant topics to gather valuable insights from stakeholders. » Review and refine interview materials to ensure clarity, consistency, and alignment with assessment goals.
Conduct stakeholder engagement	• Disseminate background information and interview materials: » Distribute comprehensive background materials to stakeholders, outlining the purpose, scope, and objectives of the assessment. » Ensure clarity in communication regarding the project's goals and expected outcomes to facilitate stakeholder understanding and engagement. • Plan and schedule interviews with identified stakeholders systematically: » Coordinate with stakeholders to set convenient interview appointments and provide clear instructions on the purpose and format of the interviews. » Provide stakeholders with ample notice of the start date for consultation, allowing sufficient time for them to review background materials. • Formally engage stakeholders in a dynamic and inclusive process to foster collaboration and exchange of information throughout the assessment: » Conduct interviews and record comprehensive notes to capture valuable insights and perspectives. » Carefully manage meeting times, ensuring that they are well-structured and efficiently run to optimize stakeholder engagement. » Create channels for ongoing communication and feedback exchange between assessors and stakeholders, enabling continuous dialogue throughout the assessment process. » Implement mechanisms such as regular progress updates, dedicated feedback sessions, and interactive platforms to facilitate effective information exchange and address stakeholder queries or concerns. » Pay attention to possibility of conflicts during meetings and, if the risk is high, consider using an independent chairperson to conduct the meeting impartially. • Practise close follow-up and exchange of feedback: » Provide feedback to stakeholders on the outcomes of their participation in the interview process. » Address any questions or concerns raised by stakeholders following the interviews. » Use stakeholder feedback to refine the assessment process and improve future stakeholder engagement activities. • Ensure fair compensation for stakeholders' time, expertise, and contributions, if necessary.
Document engagement activities and outcomes	• Compile detailed records of all stakeholder engagement efforts, including meetings, consultations, and feedback sessions: » Ensure that all relevant insights provided by stakeholders are accurately captured and integrated into the final assessment report to produce a comprehensive overview of the value assessment process and outcomes.

Appendix S3. Implementation and progress evaluation of framework adoption

To ensure the successful implementation and ongoing progress evaluation of the framework for value assessment of medical devices, clear strategies must guide each stage of the process. This supplementary section provides detailed guidance on systematic execution and continuous improvement for the adoption process of the framework:

Strategies	Description
Enhance awareness on value-based healthcare	• Improve stakeholders' understanding of the importance of value-based assessments. • Organize sessions to explain the framework's purpose and benefits to stakeholders such as policymakers, industry representatives, and patient groups.
Establish timelines for the conduct of value assessment and reports	• Set clear timelines for the conduct of value assessment activities including: » Topic identification and prioritization » Scoping exercises » Data collection and analysis » Stakeholder consultation » Development of reports
Ensure transparency in evaluation process and periods	• Establish transparent evaluation processes and periods, including all relevant stakeholders at every stage. • Offer sufficient opportunities for each stakeholder group to provide comments during each activity to capture balanced perspectives, promote transparency, and enhance the credibility of the value assessment process and its outcomes. • Highlight any significant changes resulting from stakeholder input to avoid concerns of bias or influence and provide opportunities for other stakeholders to comment on substantial modifications.
Enhance patient and public involvement in assessments	• Increase patient and public involvement in all assessments to ensure a comprehensive understanding of patient perspectives and needs. • Seek to expand resources and streamline processes to facilitate greater patient and public involvement in all assessments to drive patient-centered decision-making.
Incorporate industry stakeholder perspectives	• Increase involvement of industry representatives in discussions, particularly during the scoping stage to provide their perspectives on the study scope. • Seek industry input after the technical analysis phase and post-results evaluation to ensure a comprehensive understanding of the medical device descriptions and attributes.
Establish a tiered-assessment approach	• Implement a tiered assessment approach, focusing resources on highly innovative products while streamlining evaluations for minor changes. » High-innovation products such as a new product category or those with significant advancements should be subjected to more in-depth review, with the potential for premium reimbursement to acknowledge their innovation. » Low-innovation products that fall under an existing product category or involve minor modifications would undergo a faster and more straightforward review.

Strategies	Description
Implement systematic domains and criteria for value assessment	• Identify and select the most relevant value domains and criteria based on factors such as the level of assessment (whether at the national or institutional level), nature of the medical device and the health system priorities. This ensures that the metrics of evaluation are appropriate for the specific context and objectives of the assessment process.
Pilot implementation of new value assessment frameworks	• Conduct pilots on a smaller scale when adopting new value assessment frameworks to pressure test their approach before broader implementation. • Allow for revisions and refinements based on the pilot results to optimize the effectiveness of the frameworks.
Regularly evaluate implementation of the value assessment framework	• Regularly assess the value assessment process and criteria of evaluation to ensure that the framework implemented aligns with stakeholder needs and values. • Seek to understand the impact of the value assessment outcomes to determine whether the recommendations effectively address the healthcare needs of the population and healthcare system.
Periodic assess and update reports after publication of outcomes	• Conduct regular reviews even after the recommendation is published, offering stakeholders the opportunity to comment post-value assessment. • Issue new evidence updates when there is new data on key outcomes for a limited subset of domains. • Recommend a full update to the report when new evidence is available for many or most of the originally-assessed domains.

References

1. Nor N, Ghazali S. Malaysia towards an ageing country. GEOGRAFIA Malaysian Journal of Society and Space. 2021;17(3):234-245.

2. Institute for Public Health (IPH), National Institutes of Health, Ministry of Health Malaysia. 2020. National Health and Morbidity Survey (NHMS) 2019: Vol. I: NCDs – Non-Communicable Diseases: Risk Factors and other Health Problems.

3. Atun R, Berman P, Hsiao W, Myers E, Wei AY. (2016). Malaysia Health System Research (MHSR) Volume 1 - Contextual analysis of the Malaysian health system. Boston, Massachusetts: Harvard TH Chan School of Public Health.

4. Tan SC, Poh WT, Yong ACH, et al. Challenges and Strategies for Improving Access to Cancer Drugs in Malaysia: Summary of Opinions Expressed at the 2nd MACR International Scientific Conference 2022. Cancer Manag Res. 2023;15:851-862. doi:10.2147/CMAR.S420890.

5. Vijayasingham L, Jogulu U, Allotey P. Challenges for accessing and financing high-cost medicines in multipayer systems: case studies of multiple sclerosis in Malaysia. Critical Public Health. 2019/01/01 2019;29(1):74-83. doi:10.1080/09581596.2017.1403011.

6. Ministry of Health Malaysia, Strategic Framework of the Medical Programme, Ministry of Health Malaysia (2021 – 2025). 2020.

7. Hira FA, Khalid H, Rasid SZA, Alam MM. A conceptual framework to investigate health professionals' blockchain technology adoption readiness in Malaysia. Open International Journal of Informatics. 2021;9(Special Issue 2):58-66.

8. Malaysian Health Technology Assessment Section (MaHTAS), Medical Development Division. Economic Evaluation for Health Technologies Manual. 2016. https://www.researchgate.net/publication/318209936_Economic_Evaluation_For_Health_Technologies_Manual.

9. World Health Organization (WHO) : Health products policy and standards. 23 May 2024, Accessed 23 May 2024, https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices#:~:text=Brief%20definition%3A%20An%20article%2C%20instrument,body%20for%20some%20health%20purpose.

10. Institute of Medicine (US) Committee on Technological Innovation in Medicine; Gelijns AC, Halm EA, editors. The Changing Economics of Medical Technology. Washington (DC): National Academies Press (US); 1991. (Medical Innovation at the Crossroads, No. 2.) 6, The Dynamics of Medical Device Innovation: An Innovator's Perspective. Available from:

11. Maresova P, Klimova B, Honegr J, Kuca K, Ibrahim WNH, Selamat A. Medical Device Development Process, and Associated Risks and Legislative Aspects-Systematic Review. Front Public Health. 2020;8:308. doi:10.3389/fpubh.2020.00308.

12. Drummond M, Griffin A, Tarricone R. Economic evaluation for devices and drugs-same or different? Value in health. 2009;12(4):402-404.

13. Wurcel V, Cicchetti A, Garrison L, et al. The Value of Diagnostic Information in Personalised Healthcare: A Comprehensive Concept to Facilitate Bringing This Technology into Healthcare Systems. Public Health Genomics. 2019;22(1-2):8-15. doi:10.1159/000501832.

14. Ming J, He Y, Yang Y, et al. Health technology assessment of medical devices: current landscape, challenges, and a way forward. Cost Eff Resour Alloc. Oct 5 2022;20(1):54. doi:10.1186/s12962-022-00389-6.

15. Boztepe S. User value: Competing theories and models. International journal of design. 2007;1(2).

16. Landon SN, Padikkala J, Horwitz LI. Defining value in health care: a scoping review of the literature. Int J Qual Health Care. Nov 12 2021;33(4)doi:10.1093/intqhc/mzab140.

17. Malaysian Health Technology Assessment Section (MaHTAS), Medical Development Division. Evaluation Reports on Various Medical Technologies and Devices. Ministry of Health Malaysia. Accessed 15 March, 2024. https://www.moh.gov.my/index.php/pages/view/4995?mid=1567.

18. Schaack D, Schmidt B, Tohoku S, et al. Pulsed Field Ablation for Atrial Fibrillation. Arrhythm Electrophysiol Rev. 2023;12:e11. doi:10.15420/aer.2022.45.

19. Westwood J, Geraghty R, Jones P, Rai BP, Somani BK. Rezum: a new transurethral water vapour therapy for benign prostatic hyperplasia. Ther Adv Urol. Nov 2018;10(11):327-333. doi:10.1177/1756287218793084.

20. Mahtta D, Elgendy AY, Elgendy IY, Mahmoud AN, Tobis JM, Mojadidi MK. Intravascular Ultrasound for Guidance and Optimization of Percutaneous Coronary Intervention. Interv Cardiol Clin. Jul 2018;7(3):315-328. doi:10.1016/j.iccl.2018.03.002.

21. Institute for Clinical and Economic Review (ICER). ICER Processes for Conducting Value Assessments. 2023. https://icer.org/wp-content/uploads/2023/09/ICER_Processes_For-Publication_092523.pdfx.

22. Health Information and Quality Authority (HIQA). Guidelines for Stakeholder Engagement in Health Technology Assessment in Ireland 2014. https://www.hiqa.ie/sites/default/files/2017-01/HTA-Guidelines-Stakeholder-Engagement.pdf.

23. Schmeer K. Stakeholder analysis guidelines. Policy toolkit for strengthening health sector reform. 1999;1:1-35.

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