Department of Management Science

Designing a Value Framework for Servitised Medtech Solutions: Aligning Offerings with Healthcare Providers' Perceptions

by

Spyridon Gkikas Panousis

A Thesis Submitted in Fulfilment of the Requirements for the Degree of Doctor of Philosophy

2025

Declaration of authenticity and author's rights

This thesis is the result of the author's original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.

Signed:

Date:

Acknowledgments

I would like to express my sincere gratitude to those who have supported me throughout my PhD journey. First and foremost, I extend my heartfelt thanks to Professor Alec Morton and Dr. Steve Paton for their invaluable guidance, insight and encouragement throughout this research. Their expertise, support, encouragement and presence have been instrumental in shaping the direction and development of this work. The constructive discussions and thoughtful insights they provided were invaluable in refining and advancing the research.

I am also deeply grateful to the healthcare professionals and medtech participants who generously devoted their time and efforts to engage in insightful discussions about the research topic. Their contributions were essential in enriching this study and providing a broader perspective on the subject matter.

Special thanks to my colleagues and specialists in the healthcare domain, whose opinions on value perception and medtech solutions helped foster a discourse that was both inspiring and enlightening. Their perspectives have been an important source of inspiration for the development of this research.

Finally, my deepest thanks go to my family - my wife Olga and my children Georgios, Eirini-Maria and Ioanna. Their unwavering patience, support and encouragement were a constant source of strength throughout this journey. This work would not have been possible without their love and belief in me. I dedicate this thesis to them with all my heart.

Abstract

The medtech industry is transitioning from a product-centric model to a service-oriented approach, known as servitisation, where companies offer integrated solutions that combine medical devices with value-added services. This shift emphasises delivering outcomes and performance, enhancing customer relationships, differentiation and sustainable revenue. However, for servitised solutions to succeed, they must align with healthcare providers' diverse perceptions of value. Existing value frameworks, which often focus on individual products, do not adequately assess these integrated solutions.

This research adopts a qualitative approach, structured in three phases, to develop a value framework that provides the necessary value criteria to assess servitised medtech solutions. The framework will align these offerings with the key value drivers and expectations of healthcare providers, addressing the current gap in evaluating integrated medtech solutions and guiding companies toward better value creation in healthcare.

In the first phase, a thematic analysis extracts key value criteria from existing healthcare value frameworks, procurement guidelines and health technology assessments (HTAs). Phases 2 and 3 involve interviews with healthcare professionals (HCPs) and executive leaders from a single medtech company, providing empirical data on the value drivers that transform a medical device into an integrated solution, as perceived by healthcare providers.

The findings suggest that an effective value framework for servitised medtech offerings should focus on three core criteria: a) supporting business growth and operational excellence, b) fostering connected care through care pathways and digitalisation and c) enhancing the sustainability of the healthcare ecosystem with a focus on patient-centred care.

This study contributes to existing research by establishing foundational criteria for assessing servitised offerings and identifying key value drivers from healthcare providers' perspectives. These insights can inform decision-making on adopting servitised business models, market segmentation and solution design. However, the study's limitations include the small sample size and data from a single medtech company, which may limit the generalisability of the findings.

Future research could explore how medtech companies design and scale solutions to maximise value, improve patient outcomes and promote healthcare sustainability. Expanding the stakeholder base and using a mixed-methods approach would strengthen the robustness and generalisability of the findings.

Table of Contents

List of Abbreviations

Term	Definition
ACC -AHA	American College of Cardiology / American Heart Association
AdvaMed	Advanced Medical Technology Association
AI	Artificial Intelligence
ASCO	American Society of Clinical Oncology
B2B	Business-to-Business
BOO	Build - Operate - Own
BOT	Build - Operate - Transfer
CBA	Cost-Benefit Analysis
CCA	Cost-Consequence Analysis
CEA	Cost Effectiveness Analysis
CEO	Chief Executive Officer
CMA	Cost-Minimisation Analysis
COO	Chief Operations Officer
CT	Computed Tomography
CTO	Chief Technology Officer
CUA	Cost-Utility Analysis
CUR	The Health Problem and Current Use of Technology domain in EUnetHTA Core Model
DALYs	Disability-Adjusted Life Years
DL	Deep Learning
EaaS	Equipment-as-a-Service
ECO	The Economic Evaluation domain in EUnetHTA Core Model
EFF	The Effectiveness domain in EUnetHTA Core Model
EMA	European Medicines Agency
ESG	Environmental, Social and Governance
ETH	The Ethical analysis domain in EUnetHTA Core Model
EU	European Union
EUnetHTA	European Network for Health Technology Assessment
FDA	Food and Drug Administration
GDPR	General Data Protection Regulation
HB-HTA	Hospital-Based Health Technology Assessment
HCP(s)	Healthcare Professional(s)
HRQoL	Health-Related Quality of Life
HTA	Health Technology Assessment
$ICER_a$	Institute for Clinical and Economic Review
$ICER_b$	Incremental cost-effectiveness ratio
ICU	Intensive Care Unit
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
IT	Information Technology
KPI	Key Performance Indicator
LEG	The Legal aspects domain in EUnetHTA Core Model

LOS	Length of Stay
LY	Life Years Gained
MCDA	Multicriteria Decision Analysis
MEAT	Most Economic Advantageous Tender
Medtech	Medical technology
MRC	Medical Research Council
MRI	Magnetic Resonance Imaging
MSKCC	Memorial Sloan Kettering Cancer Centre
NCCN	National Comprehensive Centre Network
NHB	Net Health Benefit
NHS	National Health System
NICE	National Institute for Health and Care Excellence
OOP	Out-of-Pocket
OR	Operating Room
ORG	The Organisational aspects domain in EUnetHTA Core Model
PET/CT	Positron Emission Tomography (PET) and Computed Tomography (CT)
PROM	Patient Reported Outcomes
QALYs	Quality-Adjusted Life Years
QoL	Quality of Life
ROI	Return On Investment
SAF	The Safety domain in EUnetHTA Core Model
SOC	The Patient and Social aspects domain in EUnetHTA Core Model
TA	Thematic Analysis
TEC	The Description and Technical Characteristics of Technology domain in EUnetHTA Core Model
VBH	Value-Based Healthcare
VBP	Value-Based Procurement
WHO	World Health Organisation

Definitions of key terminology employed in this study

Term	Definition
CT scanner:	A CT scanner (Computed Tomography) is a medical imaging device that uses X-rays to create detailed cross-sectional images of the body. It rotates around the patient, capturing multiple angles to generate 3D images of organs, bones and tissues. CT scanners are widely used to diagnose conditions in oncology, cardiology, neurology and musculoskeletal medicine, as well as to guide medical procedures.
Disability - Adjusted Life Years (DALYs):	A Disability - Adjusted Life Year (DALY) reflects the loss of one year of optimal health. The total DALYs for a particular disease or health condition are calculated by adding the years of life lost due to early death and the years spent living with disability caused by existing cases of the condition within a population.
Healthcare ecosystem:	The healthcare ecosystem is a complex and interconnected network of individuals, organisations and services that collaboratively deliver healthcare. It includes a broad spectrum of stakeholders including healthcare providers (hospitals, clinics), healthcare professionals (doctors, nurses, technicians), patients managing their health, payers (insurance companies, government programs), pharmaceutical and medtech companies that develop and distribute medical products, regulatory bodies such as the FDA, that ensure safety standards, technology providers offering digital health solutions and support services like laboratories, diagnostics and pharmacies.
Healthcare professionals (HCPs):	A healthcare professional is a trained and licensed individual who plays a vital role in delivering medical care. This group includes doctors, nurses, pharmacists, medical physicists, biomedical engineers, as well as management and administrative experts, all of whom contribute to the diagnosis, treatment and care of patients.
Healthcare Provider:	The organisation or facility delivering care (e.g. hospitals, clinics). Healthcare providers are the institutions or businesses that offer healthcare services.
Health-Related Quality of Life (HRQoL):	It is an individual's or a group's perceived physical and mental health over time.
Incremental Cost-Effectiveness Ratio ($ICER_b$):	Incremental Cost-Effectiveness Ratio ($ICER_b$) is used to assess the cost-effectiveness of one healthcare intervention compared to another. It is a way to quantify the additional cost

	associated with a gain in health benefits, typically measured in quality-adjusted life years (QALYs).
Mammography unit (2D, 3D, stereotaxis and stereotactic mammography):	A mammography unit uses X-ray imaging to detect breast cancer, producing mammograms for both screening and diagnosis. Two-dimensional (2D) mammography captures flat images, which may obscure abnormalities due to tissue overlap. In contrast, three-dimensional (3D) mammography, also known as Digital Breast Tomosynthesis, takes multiple images from different angles to create a 3D reconstruction. This method improves detection, particularly in dense breast tissue, and reduces the need for follow-up imaging. Stereotactic mammography is a specialised form of mammography that employs a three-dimensional coordinate system (stereotaxis) and X-rays to guide a needle to a specific area of the breast, enabling precise biopsies of suspicious lesions.
Medtech industry, sector or domain:	The medtech industry, sector, or domain includes companies involved in the development, manufacturing and sale of medical devices, along with a broad network of supporting service and supply businesses.
MRI/MR scanner:	An MRI scanner (Magnetic Resonance Imaging) is a medical imaging device that uses strong magnetic fields and radio waves to create detailed images of the body's internal structures. Unlike CT scanners, MRI does not use ionising radiation. Instead, it relies on the magnetic properties of hydrogen atoms in the body's tissues to produce high-resolution images. MRI is particularly useful for visualising soft tissues, such as the brain, muscles, ligaments, and organs like the heart and liver. It is commonly used in neurology, orthopaedics, cardiology and oncology to diagnose conditions such as brain tumors, spinal cord injuries, joint abnormalities, and heart disease.
PET/CT:	A PET/CT scanner combines Positron Emission Tomography (PET) and Computed Tomography (CT) to provide detailed images of both the structure and function of organs and tissues. This hybrid system offers doctors a comprehensive view, integrating metabolic and anatomical information in one scan, which is particularly valuable in oncology for accurately locating tumors, planning treatment and monitoring its effectiveness.
Quality-Adjusted Life Years (QALYs):	The Quality-Adjusted Life Year (QALY) is a universal metric used to assess the burden of disease, considering both the

	quality and duration of life lived. QALY scores range from 1, indicating perfect health, to 0, representing death.
Value criteria:	Value criteria are the specific standards or benchmarks used to evaluate and measure the value of a product, service, or solution. They outline the key factors that are deemed important when assessing value. In this study, value criteria are used to guide the evaluation of medical devices or solutions. These criteria help identify what matters most in determining the value of a product or solution and serve as the foundation for assessing value elements and value drivers.
Value elements:	Value elements are the individual factors that contribute to the overall value of a product, service, or solution. These can include tangible aspects (e.g. a device's features or functionality) as well as intangible aspects (e.g. patient experience or service quality). Value elements are the building blocks of value and are assessed based on the established value criteria. In this study, these elements are what make up the core value of medical devices or medtech solutions and are evaluated against the value criteria.
Value drivers:	Value drivers are key elements that directly influence the creation or enhancement of value in a product or service. In this study, value drivers are defined as the factors that specifically contribute to transforming a basic medical device offering into a more comprehensive medtech solution offering. These value drivers are not merely individual features, but rather strategic elements such as service integration, clinical outcomes, or workflow optimisation, that, when combined, elevate a medical device from a stand-alone product to a complete, value-added solution in healthcare settings. These drivers can be leveraged to optimise or increase the overall value of a medtech offering.
Value themes:	Value themes are broad concepts or key ideas that capture the overall value proposition of a product, service, or solution. They are derived from a thematic analysis and represent the central messages that resonate with stakeholders about what makes the offering valuable. These themes inform the value elements, criteria and drivers identified in the analysis. In this study, value themes are derived from the thematic analysis conducted during the analysis of value frameworks (Phase 1) and from the interviews with participants (Phases 2 and 3). They summarise the core aspects of value as understood by stakeholders.

List of Figures

List of Tables

1. Introduction

1.1 Background and context

Since the start of the 21st century, innovations in healthcare, such as molecular diagnostics and personalised medicines, have had a dramatic effect on patient longevity and quality of life. Simultaneously, financial constraints, an aging population, the rise of chronic diseases and a patient consumerism approach - where patients actively choose and manage their healthcare based on personal preferences, available information and cost considerations - have placed significant pressure on healthcare systems (L. W. Lee et al., 2024; Patrício et al., 2020; Rodriguez Llorian & Mann, 2022; Schmitt, 2012). Aiming to re-engineer care delivery, the healthcare industry has introduced the term 'value' and 'value-based healthcare'. Value-based healthcare focuses on improving health outcomes while maintaining or lowering health costs (A. P. Brady et al., 2020; T. Lee, 2010). In the emerging value-based healthcare environment, the Medical Technology (medtech) industry seeks to create more value, by adding a service component to the products it provides. The aim is to provide integrated solutions that combine products with additional services to create innovative offerings (Macdonald et al., 2016). This approach, known as servitisation, involves companies adding services to their products to create extra value (Vandermerwe & Rada, 1988). Businesses may choose this model for various reasons, including marketing advantages, financial gains and strategic benefits. By adopting servitisation, companies aim to stand out in the market, increase their profits and enhance their competitiveness. Ultimately, they are looking to offer more value to their customers (Green et al., 2017; Valtakoski, 2017).

To examine what value means in health technology, value assessment frameworks and methods have been developed with the aim of evaluating both healthcare options and supporting evidence-based decisions (Oortwijn et al., 2017). Such value frameworks have been adopted as decision-support tools to assist policy-making, healthcare treatments and investment decisions (Sorenson et al., 2017). Frequently, the value of a health technology is derived by the application of complex formulas and calculations and traditionally includes criteria such as clinical outcome and impact, safety, quality and cost effectiveness. Recently,

there has been increasing interest in the inclusion of additional considerations such as ethical, legal and social issues to capture a multistakeholder conception of value (Garrison et al., 2017; Sorenson et al., 2017).

1.2 Research problem

Servitisation offers manufacturers the opportunity to differentiate themselves, strengthen customer relationships and increase firm value by shifting from a product-centric to a service-oriented model. This transition involves delivering integrated solutions that combine products and services to offer comprehensive value. However, the success of servitisation relies heavily on understanding how customers perceive the value of these integrated solutions (Gebauer et al., 2006; Huang et al., 2022; S. Lee et al., 2016; Valtakoski, 2017).

In the medtech industry, aligning servitised solutions with healthcare providers' perceptions of value is crucial. Providers now expect solutions that enhance patient outcomes, control costs and optimise care delivery (EY, 2023). Yet, these stakeholders have diverse and subjective views on what constitutes value. Medtech companies must identify and respond to the specific value drivers that healthcare providers prioritise in the shift from product offerings to integrated solutions. Without a clear understanding of these drivers, companies risk delivering solutions that do not meet expectations, thus undermining the potential benefits of servitisation.

While existing value frameworks in healthcare support decision-making, they primarily focus on pharmaceutical products and healthcare interventions or individual medical devices rather than the integrated solutions that are central to servitisation (Mandelblatt et al., 2017; Sorenson et al., 2017). These frameworks fail to account for the complexities of evaluating the value of servitised offerings in the medtech industry. As such, there is a significant gap in understanding the value drivers that shape healthcare providers' perceptions of these offerings.

To succeed, medtech companies must thoroughly understand the key value criteria that align with healthcare providers' perceptions of value. A specialised framework is needed to assess

the value of servitised medtech solutions, helping companies align their products and services with the goals and challenges faced by healthcare providers. To address this issue, this study examines the value criteria that form a framework for evaluating servitised solutions, ensuring alignment with the key value drivers and expectations of healthcare providers. The central research question is:

What value criteria should be included in a framework to evaluate servitised medtech solutions, ensuring alignment with the needs and expectations of healthcare providers?

To address this, the study explores the following sub-questions:

1. What value criteria are currently applied in existing value assessment frameworks for medical devices?
2. What key value drivers transform a medical device offering into a medtech solution, as perceived by healthcare professionals (HCPs) and medtech professionals?

These sub-questions aim to identify the common value criteria currently used for assessing medical devices within the medtech domain and uncover the value elements expected in servitised solution offerings by healthcare and medtech professionals. The insights gained will help establish the core value criteria necessary for developing a comprehensive framework to assess the value generated by servitised medtech solutions.

This research makes a significant contribution to both academic literature and practical applications by critically examining medtech value frameworks through the lens of servitisation. Instead of assuming that a solution-based approach inherently creates value, the study shifts the focus to investigate which value drivers are actually perceived or expected in a solution offering. These insights are essential for informing the design of servitised business models that better align with the needs and expectations of healthcare stakeholders.

The findings identify the critical value criteria necessary to capture and assess the value generated by servitised medtech offerings, ensuring consistency and providing a basis for more effective value assessment methods. Through a structured methodological approach, the study proposes that a value framework should evaluate medtech solutions by considering

a combination of business needs, patient care and process sustainability. By developing a more specific and actionable framework, this research moves beyond abstract solutions-based strategies and offers practical guidance for successfully implementing servitised offerings in the healthcare sector, while mitigating the risk of superficial or trendy adoption of such approaches.

1.3 Research approach

Grounded in the pragmatist paradigm, which seeks knowledge through the interaction of different worldviews, this study explores the perspectives of HCPs and medtech industry professionals using qualitative methods. The dyad of HCPs and medtech industry professionals serves as an ideal field for investigating value perceptions, as these stakeholders collectively shape the perceived value of medtech solutions.

Medtech vendors typically design solutions based on their understanding of customer needs. However, they may not fully anticipate how these solutions integrate into the customer's ecosystem or account for influences from internal and external stakeholders. Healthcare providers, through their HCPs, are primary recipients of medtech industry solutions, except in cases such as home therapy or consumer medical products like rehabilitation or respiratory care. They play a pivotal role in the healthcare ecosystem by directly delivering patient care and selecting and purchasing medical devices that shape and facilitate these services. Consequently, healthcare providers' perspectives are crucial for understanding how medtech products and services impact patients, who ultimately are the end-users.

1.3.1 Research process

The research process consists of three distinct phases aimed at providing answers to the two sub-questions.

Phase 1: Thematic analysis of existing healthcare value frameworks

During the initial phase, a thematic analysis is undertaken including healthcare value frameworks, value-based procurement (VBP) guidelines, health technology assessment (HTA) procedures and relevant projects centred on the value assessment of medical devices. The

objective is to identify and chart the current value criteria discussed across these various sources within the discourse on healthcare value frameworks. The outcome of Phase 1 is the development of a comprehensive map delineating key value criteria extracted from existing value frameworks.

Phase 2: Semi-structured interviews with Healthcare Professionals

Building on Phase 1, Phase 2 involves conducting semi-structured interviews with a group of HCPs from various healthcare providers. These interviews aim to explore HCPs' perceptions of value concerning medtech servitised offerings compared to traditional medical device offerings. The data collected from these interviews are analysed thematically to identify the unique elements of perceived value specific to medtech solutions as seen by HCPs.

Phase 3: Semi-structured interviews with executive leaders from medtech companies

Phase 3 involves conducting semi-structured interviews with executive leaders, from a medtech company, who are experts in medical device product lifecycle, design and solution architecture. Thematic analysis in this phase validates the findings from Phase 2 within the medtech industry context, translating the identified value elements from the perspectives of HCPs into terms and concepts relevant to the medtech industry. This phase aims to facilitate a collaborative exploration between medtech industry professionals and HCPs, with a primary focus on identifying value elements specific to servitised (solutions) offerings and uncovering potential latent or tacit value components that HCPs may not fully recognise.

The outcomes from Phases 1 to 3 contribute to identifying the value drivers that transform a conventional medical device offering to a servitised one in the eyes of both HCPs and medtech professionals. This knowledge leads to the identification of the value criteria crucial for integration into a value framework tailored to evaluate servitised medtech offerings in healthcare.

1.4 The researcher

The healthcare sector and medtech industry are chosen as the research domain due to their significant professional and academic interest to the researcher. Moreover, these fields are

currently engaged in an intense dialogue regarding value. Value-based healthcare systems are at the forefront of healthcare policies and reforms in various countries. The study is situated within a specific area of healthcare, involving informants in diverse roles within healthcare provider organisations.

At the time of conducting this research, the researcher holds a leadership position in a medtech company. This role provides contextual knowledge, understanding and practical experience pertinent to the inquiry. However, it is recognised that such involvement carries inherent risks, including pre-understandings, preconceptions, biases and predispositions. These factors could potentially influence the researcher's interpretation of data and lead to misrepresentations. To mitigate these risks, several strategies are employed:

- **Authenticity and Inquiry:** The researcher maintains an authentic and inquiring approach throughout the research process, continuously challenging preconceptions.
- **Stringent Data Analysis:** Rigorous data analysis methods are employed to ensure the reliability and validity of findings.
- **Self-Reflection and Discussions:** Ongoing self-reflection and discussions with professional colleagues help to scrutinise assumptions and interpretations.
- **Supervisory Oversight:** Supervisors with extensive experience provide critical feedback and oversight throughout the analysis and concept-building phases, ensuring robustness and credibility.

These measures aim to enhance the credibility and trustworthiness of the research findings, contributing to a detailed understanding of value perceptions in medtech solutions within the healthcare context.

1.5 Thesis outline

The remainder of the thesis is structured as follows.

Chapter 2 reviews the literature on servitisation in the medtech industry, examining the shift from product-based to service-oriented business models. It discusses the drivers, challenges

and strategies behind the transition to integrated solutions, focusing on how products, services and support are combined. The chapter also explores customer value, value and procurement frameworks in healthcare, highlighting the gap in research for a tailored framework to evaluate servitised medtech solutions from healthcare providers' perspectives.

Chapter 3 introduces the introduces the methodological framework, emphasising the pragmatic worldview and the qualitative approach chosen to address the research question. It provides a comprehensive overview of the aim, sample selection criteria, data collection methods, analysis procedures and the expected outcomes across three distinct phases of the research.

Chapter 4 examines Phase 1 of the research, focusing on key value criteria for medical device assessment derived from value frameworks, procurement guidelines and HTA models. It reviews frameworks such as ICER$_a$, EUnetHTA, MEAT, AdvaMed and NICE technology appraisal process. The chapter concludes by synthesising the key value criteria from these frameworks, providing a foundation for the next phases of the research.

Chapter 5 presents the findings from Phases 2 and 3, focusing on the key value drivers that transform a medical device into a medtech solution, as perceived by HCPs and medtech professionals. It begins by analyzing the value elements of a medical device from the perspective of HCPs, highlighting how they assess the value of devices in isolation. The chapter also explores how HCPs perceive the added value in medtech solutions, comparing them to traditional devices. Insights from medtech professionals are also incorporated, offering a broader view of value in integrated solutions. The chapter concludes by defining the key value drivers responsible for this transformation from medical device to medtech solution.

Chapter 6 explores how the identified value drivers of medtech solutions contribute to the development of evaluation frameworks. It synthesises findings from all research phases and outlines the core value criteria for a framework designed to assess medtech solutions.

Chapter 7 reflects on the study's findings and outlines its academic and managerial contributions. It discusses how the proposed value framework for evaluating servitised

medtech solutions advances knowledge in serivisation and highlights its practical implications for HCPs and medtech companies. The chapter also acknowledges the study's limitations and suggests directions for future research.

2. Review of Literature and Theoretical Framework

2.1 Introduction

This chapter reviews the literature on servitisation in the medtech industry, focusing on the shift from traditional product-based models to integrated, service-oriented business models. It aims to provide the theoretical and empirical foundation needed to understand the drivers, challenges and strategies of servitisation, while identifying gaps in existing knowledge that this research addresses.

The chapter begins by examining how medtech companies are transitioning to integrated solutions to meet the demand for value-driven healthcare offerings. It then explores the concept of servitisation and its potential to reshape traditional healthcare delivery. Following this, the review discusses the complexities of integrated solutions, including how products, services and support are combined into holistic offerings. It also outlines the key stages and strategies required for building effective integrated solutions. The chapter further explores the key drivers of servitisation - marketing, strategic, financial - and how these are pushing the industry toward more service-oriented models. It also addresses the challenges of this transition, such as organisational culture, resource allocation and the alignment of business models with customer needs.

A significant portion of the review focuses on customer value, examining how it is defined and assessed in both business and healthcare contexts. The literature on value assessment frameworks in healthcare is discussed, with a focus on how these frameworks inform decision-making for integrated medtech solutions. The review also looks at procurement frameworks that aid healthcare providers in evaluating the full spectrum of value offered by integrated solutions. The chapter concludes by identifying the research gap: the need for a tailored framework to evaluate servitised medtech solutions from the perspective of healthcare providers. This gap highlights the importance of understanding the unique value drivers in medtech servitisation and the implications for both healthcare providers and industry stakeholders.

2.2 Medtech companies shifting towards integrated solutions

The Medtech industry (medtech), characterised by its diverse range of products and services, plays a vital role within the process of medical care, from diagnosis to treatment and long-term patient management. Traditionally, medtech companies focused their business models on the development, marketing and sale of individual products to healthcare providers, such as hospitals and clinics (KPMG, 2024; McKinsey & Company, 2019). These products, including medical devices and diagnostic tests, are designed to meet specific clinical needs. Healthcare providers are facing significant challenges, including personnel burnout and financial constraints. Healthcare workers are experiencing high levels of stress and exhaustion due to long hours, heavy patient loads and emotional strain. At the same time, many healthcare organisations, particularly those in public or underfunded systems, are dealing with budget cuts, limited resources and rising costs, making it difficult to invest in new technologies, recruit staff, or maintain quality care. As a result, there is growing demand for solutions that go beyond stand-alone devices to address these broader issues.

Integrated solutions, which combine technology, data management and user experience, are now recognised as essential for effectively addressing the complexities of modern healthcare. The shift towards comprehensive approaches is crucial for improving clinical workflows and care quality. As a result, medtech companies are adapting their business models to deliver these integrated solutions, recognising that a purely technological approach is no longer sufficient to meet the evolving needs of healthcare providers (Bain & Company, 2018; Bandeiras, 2020; Funk et al., 2017; McKinsey & Company, 2019).

A key component of this evolution is the concept of **servitisation**, introduced by Vandermerwe and Rada (1988), which involves adding services to products to more comprehensively meet customer needs (Weeks & Benade, 2015).This shift from stand-alone products to service-driven offerings reflects a broader trend that has been evolving for over 150 years (Min et al., 2015; Schmenner, 2009). As Schmenner (2009) notes, industries such as transportation and communications have long sought to bundle services with their products, driven by competition and the need to create deeper customer relationships (Schmenner, 2009).

Presently, this model is being increasingly adopted by the medtech sector to address healthcare's complex challenges.

Contemporary business literature highlights a growing trend among leading firms to integrate products and services into cohesive solutions. This trend towards integrated solutions can be traced back to strategies like systems selling within organisations (Davies et al., 2007) and the early Build-Operate-Transfer (BOT) or Build-Operate-Own (BOO) infrastructure projects (T. Brady et al., 2005). Systems selling involves providing products and services tailored to meet customers' operational needs, while BOT and BOO projects typically involve consortiums sharing services and risks to deliver better value. To support their customers in achieving their objectives, firms combining products and services have developed capabilities such as systems integration, operational service, business consulting and financing (T. Brady et al., 2005). This strategic shift towards integrated solutions provisioning has been driven by factors like commoditisation, declining profitability and increasingly complex customer needs (Paiola et al., 2013) and includes intangible activities, such as know-how, support and self-service (Vandermerwe & Rada, 1988).

Over the past three decades, servitisation has evolved into a significant research domain with various academic communities, including service marketing, service management and operations research (Baines et al., 2009). While definitions of servitisation vary slightly, they generally converge on the concept of shifting from selling products to offering integrated solutions that include product-based services (Baines et al., 2009). Importantly, this shift does not render products obsolete but rather emphasises services and end-user (customer) interactions (Kohtamäki et al., 2018).

In the context of medtech, the shift from product-centricity to solutions highlights a long-standing recognition of the value of combining products with services to better serve healthcare providers and patients alike. This shift is driven by evolving healthcare needs, technological advancements and broader systemic challenges. Technological advancements are reshaping the medtech landscape. Innovations, such as artificial intelligence (AI) driven tools and automation of administrative tasks like documentation and billing, reduce the cognitive load on HCPs and allow them to focus more on patient care. Similarly, telemedicine

platforms and remote monitoring devices facilitate decentralised care, improving accessibility and patient outcomes. These technological developments are central to the industry's shift towards holistic solutions that address broader healthcare challenges.

Healthcare systems are progressively adopting a value-based healthcare model, which aims to enhance both the quality and efficiency of care by focusing on patient-centred outcomes and cost-effectiveness. This model shifts the emphasis from the volume of services delivered to the value of care provided. Integral to this shift are VBP frameworks, which prioritise outcomes over mere product costs (Gerecke et al., 2020; Nowak, 2016). In response, medtech companies are transitioning from a product-centric approach to a solutions-oriented model. This transition entails a focus on delivering measurable outcomes and demonstrating both the clinical and economic value of their solutions to ensure high-quality, cost-effective care. To stay competitive, medtech firms are expanding their offerings to include comprehensive services such as technical support, training and managed equipment services that complement their core products. These integrated solutions provide a more holistic approach to addressing healthcare challenges and strengthen the overall value proposition of medtech firms. This strategic shift often necessitates a thorough overhaul of existing business practices, requiring medtech companies to revise their operations and strategies to enhance their value proposition.

2.3 Understanding servitisation

Traditionally, equipment manufacturing companies have concentrated on the production of goods and invested in innovation to enhance their competitive edge. Services such as logistics, installation, maintenance and the provision of spare parts for the manufactured equipment have been viewed as supplementary to the core products (Gebauer & Friedli, 2005). In the initial phases of adopting servitisation, manufacturing firms often regarded this strategy as merely adding a layer of services to their existing manufacturing operations. For example, after-sales services were seen as an extension, with the primary value still attributed to the products themselves (Weeks & Benade, 2015).

The importance of services in the manufacturing industry has grown significantly over time, leading to various models of servitisation that differ based on the extent to which services are integrated into or dominate the value proposition (Baines et al., 2009). The transition towards servitisation typically occurs in three stages, as outlined by Vandermerwe and Rada (1988). Initially, companies operate purely as manufacturers of goods or providers of services. They then evolve into entities that offer both goods and services. Finally, they advance to a stage where they provide comprehensive solutions that include not only products and services but also support, self-service options and expert knowledge (Vandermerwe & Rada, 1988). In this advanced stage, the combination of goods and services is not merely a collection of individual components. Instead, it embodies a cohesive transformation that generates distinct value. As articulated by S. Lee *et al*., this approach represents an 'inseparable transformation that has its own characteristics' (S. Lee et al., 2016).

Gebauer *et al*. (2008) outline three service strategies that businesses can adopt: After-Sales Service Providers (ASPs), Customer Support Providers (CSPs) and Development Partners (DPs). After-Sales Service Providers focus on maintaining the functionality of products throughout their use by offering services such as inspection, repair and managing spare parts. Customer Support Providers, on the other hand, concentrate on enhancing customer operations through high-quality, technically superior products and advanced, proactive services. These services include preventive maintenance, guaranteed operational uptime and tailored training, which are customised to meet specific customer needs. The Development Partners strategy involves a collaborative effort between customers and service providers to create innovative solutions and optimise performance, leveraging the combined expertise of both parties (Gebauer et al., 2008).

Wise and Baumgartner (1999) identify four types of servitisation models that businesses can adopt: embedded services, comprehensive services, integrated solutions and distribution control. Embedded services are directly integrated into a product, such as remote monitoring or troubleshooting features. Comprehensive services are offered alongside the product, like financial services or extended warranties. Integrated solutions combine products and services to address broader customer needs, such as in IT services, where hardware, software and consulting are bundled to provide a complete solution. Distribution control involves the

service provider becoming deeply integrated into the customer's operations, often managing the entire distribution and service process, as seen in managed IT services (Wise & Baumgartner, 1999)

2.4 Integrated solutions

The concept of solutions in the literature is defined and interpreted in various ways. According to Windler *et al.* (2014), definitions of solutions can be categorised into three main perspectives. The first views solutions as an integrated mix of products and/or services designed to meet a customer's business needs. The second perspective highlights the importance of co-creating solutions with customers. The third definition characterises solutions as a series of relational processes between customers and suppliers (Windler et al., 2017).

Windahl (2015) elaborates on these relational processes by including several key activities: identifying opportunities for value creation, integrating and customising solution components, implementing these solutions within customer operations and providing support throughout the delivery phase (Windahl, 2015). Building on the definition provided by Ulaga and Reinartz (2011), which describes solutions as offerings that support customer processes with a value proposition aimed at achieving specific outcomes, Windler *et al*. (2014) refine the concept to describe business solutions as product-service bundles that support customer processes through a value proposition aimed at achieving a collaboratively created result (Ulaga & Reinartz, 2011; Windler et al., 2017).

Many definitions of servitisation in the literature share common elements, including the integration or combination of products and services, tailored and customised offerings and a focus on addressing specific customer needs to create meaningful outcomes (Davies, 2004; Nordin & Kowalkowski, 2010; Windahl, 2015). Despite variations in the scope and detail of the services discussed, there is a consensus that combining services with products generates value that exceeds the mere sum of its parts.

Cova and Salle (2008) emphasise the collaborative nature of solution development between suppliers and customers, encompassing commercial, operational, and financial aspects (Cova & Salle, 2008). Lusch and Vargo (2006) further argue that customers are always co-creators of value, with both parties acting as resource integrators. They suggest that actual value emerges through ongoing customer engagement (Grönroos, 2012; Vargo & Lusch, 2004). A solution, therefore, is not only a bundle of products and services but rather a series of relational processes designed to comprehensively address customer needs. This involves everything from requirement analysis and customisation to the integration and deployment of goods and services, as well as ongoing support after deployment (Tuli et al., 2007). Essentially, a solution is designed to resolve a business problem for the customer, aligning with its fundamental purpose and name.

2.5 Key stages and strategies to effective solution building

Identifying and understanding customers' needs and values is a crucial initial step in the solution-building process, as emphasised by various studies in the literature. Pawar *et al*. (2009) propose a three-stage approach to solution development: defining value, designing value and delivering value. They stress the importance of concurrently designing products, services and organisational processes to effectively create value and suggest that collaborations between firms can enhance the delivery of this value (Pawar et al., 2009).

Brady *et al.* (2005) outline a four-phase approach to transitioning from a product-centric to a customer-centric model. Their framework includes strategic engagement, developing a value proposition, systems integration and operational service. They highlight that informal discussions before formal tenders can provide valuable insights into customers' strategic needs and priorities (T. Brady et al., 2005). Similarly, Tuli *et al.* (2007) identify four key steps in the solution process: defining requirements, customising and integrating goods and/or services, deploying the solution and providing post-deployment support. This approach places significant emphasis on post-deployment support, with Storbacka (2011) noting that effective solutions require ongoing tracking and adaptation of requirements as they evolve over time to remain relevant in dynamic environments (Storbacka, 2011; Tuli et al., 2007).

This continuous interaction between suppliers and customers reflects the idea of solutions as part of a long-term relationship rather than a simple transaction. Storbacka (2011) introduces a solution business model framework where solutions are viewed as processes rather than just mere combinations of goods, services and knowledge. This framework consists of four iterative phases: developing solutions, creating demand, selling solutions and delivering solutions. In the development phase, solutions are created based on customer insights and the firm's resources. During the create demand phase, these solutions are communicated to relevant market segments. The sell solutions phase involves converting these solutions into orders and the deliver solutions phase focuses on implementation to ensure long-term value. The framework highlights the importance of a process-oriented and cross-functional approach to the solutions business, with commercialisation and industrialisation occurring concurrently rather than sequentially. It also includes a solution platform that supports the implementation of the solution business, including strategic planning, management systems, infrastructure support and human resource management. These capabilities form the backbone of the solution business.

Solution process models emphasise the importance of ongoing, comprehensive engagement with customers, involving cross-functional teams and multiple managerial layers from both parties. Cantù *et al.* (2012) reinforce the concept of solutions as an ongoing achievement resulting from interactions among the involved actors, stressing that solutions are developed through the dynamic interplay between users and providers (Cantù et al., 2012). Nordin and Kowalkowski (2010) link this iterative interaction to the quality of problem definition, noting that well-defined problems generally require less iterative involvement than poorly defined ones (Nordin & Kowalkowski, 2010).

The design, development, and implementation of solutions can be managed as projects involving both internal and external stakeholders, using Agile or Lean management principles (Badakhshan et al., 2020; Behl & Rajagopal, 2023; Bernardo Junior & Padua, 2023; Weber & Wener, 2004). These methods promote frequent customer interaction to test and validate ideas, quickly identify issues, learn rapidly, and build long-term, trusting relationships with customers.

2.6 Servitisation drivers

Manufacturers have adopted servitisation as a strategy to enhance value towards differentiation and de-commoditisation (Kohtamäki et al., 2018; Raddats et al., 2016). The primary drivers for this shift include marketing, financial and strategic benefits (W. Zhang & Banerji, 2017). Among the key marketing benefits are increased product sales, revenue growth and market share expansion (Brax, 2005; Gebauer et al., 2006; Mathieu, 2001). Additionally, servitisation helps to build, strengthen and extend customer relationships, fostering loyalty, dependency and repeat sales (Malleret, 2006; Penttinen & Palmer, 2007). Manufacturers also create value through tailored offerings that combine products, services and customer knowledge, leading eventually to quality, reputation, branding and corporate image (Cooper & Aiken, 2001; Oliva & Kallenberg, 2003; Windahl & Lakemond, 2010; Wise & Baumgartner, 1999).

Beyond the marketing advantages, servitisation improves margins and profitability (Gebauer et al., 2006; Gebauer & Friedli, 2005). These margins are often more predictable and stable, as they derive from the installed base and ongoing customer services, helping to balance economic cycles (Brax, 2005; Johnstone et al., 2009; Oliva & Kallenberg, 2003; Wise & Baumgartner, 1999). A servitised offering that utilises customer knowledge is expected to boost turnover stability and customer satisfaction (Malleret, 2006; Penttinen & Palmer, 2007).

Servitisation also raises barriers to entry for competitors to a segment or a customer as it is difficult to allow imitation (Gebauer et al., 2006; Oliva & Kallenberg, 2003). Those barriers are even higher with co-production between manufacturers and customers (Gebauer, 2008; Gebauer et al., 2009). Consequently, servitisation provides strategic benefits in differentiation and competitive advantage. This advantage is sustainable, as continuous customer feedback facilitates ongoing improvements and trust-building (Brax, 2005; Gebauer et al., 2006; Oliva & Kallenberg, 2003).

2.7 Challenges and considerations in servitisation

Manufacturers have increasingly embraced servitisation to differentiate themselves, enhance firm value, boost sales and drive profitability and growth. However, literature and current studies have not consistently validated these expectations (Ambroise et al., 2018; Benedettini et al., 2015; Kohtamäki et al., 2018; S. Lee et al., 2016).

The shift from goods-centric to solution offerings presents numerous challenges, including organisational changes, cultural resistance and strategic adjustments. Kinnunen and Turunen (2012) categorise these challenges into five areas: defining a service strategy, adopting a service-oriented organisational culture, establishing a customer-centric organisational configuration, creating and developing market-oriented services and managing service knowledge and communication (Kinnunen & Turunen, 2012). Similarly, Zhang and Banerji (2017) have identified five constructs for the servitisation challenges: organisational structure, business model, development process, customer management and risk management (W. Zhang & Banerji, 2017). Their study indicates a positive correlation between the realisation of marketing, strategic and financial benefits and improved business performance in servitised companies. However, there is some controversy in the literature regarding the relationship between servitisation and business performance (Min et al., 2015). For example, research on Chinese enterprises found no evidence that servitisation strategy promotes profitability and long-term financial performance may even be negatively affected (Min et al., 2015). To explain these varied outcomes, Gebauer, Fleisch and Friedli (2005) introduced the 'service paradox', where investments in service expansion lead to higher costs without proportionate returns. This paradox has driven research into the barriers and success factors of servitisation in manufacturing (Gebauer et al., 2005; Oliva & Kallenberg, 2003).

Benedettini *et al.* (2015) explored the reasons behind the failure of firms to achieve expected financial benefits from servitisation, analysing data from 129 bankrupt manufacturers, 75 of which had adopted service provision (Benedettini et al., 2015). Their findings indicate that servitised companies face increased environmental and internal operating risks. Environmental risks involve uncontrollable changes in the business landscape, while internal risks include company-specific challenges, policies, management capabilities and decision-

making processes. The study suggests that although firms adopt service offerings to mitigate environmental uncertainty (i.e. economic cycles), this does not necessarily reduce business environmental risks. Internal risks, however, become more prominent under servitisation.

Contrary to the predominant manufacturer-focused perspective, Valtakoski (2015) developed a framework highlighting the critical role of the customer in the success of servitisation approach (Valtakoski, 2017). Valtakoski's work indicates that servitisation can fail either because it does not create sufficient value for the customer or because the solution provider may not understand what is valuable for the customer. In the latter case, the solution provider fails to leverage customer knowledge on what value is expected from the solution or the solution offered is marginally or insufficiently valuable (Valtakoski, 2017). Thus, developing a solution that offers low value or does not align with the customer's strategy can result in servitisation failure. Additional reasons for failure include the lack of necessary knowledge from manufacturers to deliver solutions or issues arising during solution implementation.

Nudurupati *et al.* (2016) also emphasise the importance of the customer perspective in transitioning from a product-dominant logic to a servitised model (Nudurupati et al., 2016). Understanding customers' perspective and their diverse needs is critical for a smooth and successful journey of a product-based organisation towards servitisation. Customers often struggle to fully understand their needs or expectations when it comes to servitised solutions (Vaittinen et al., 2018). Huang *et al.* (2022) highlight the role of identifying latent needs as a mediator between servitisation and firm performance (Huang et al., 2022). Latent needs are implicit, often unknown to customers and difficult to express. These needs are context-dependent and can be uncovered through close interactions between businesses and their customers. For example, in the case of a large imaging system like a CT scanner, a radiologist may not explicitly request a more efficient workflow, but they might spend unnecessary time clicking through multiple steps to process images, revealing a latent need for a streamlined interface. Similarly, customers may not directly express a need for seamless integration between different tools or platforms they use, but through engagement, companies may identify this underlying need to reduce friction and improve the overall user experience.

While the challenges of servitisation, such as organisational changes, cultural shifts and risk management, are well-documented, a critical factor influencing success is the ability to align offerings with customer value perceptions. Understanding and responding to the needs of customers is fundamental in overcoming the complexities of servitisation. Identifying these needs, which may not be articulated directly, allows businesses to better tailor their solutions and ensure they provide meaningful value. By understanding how value is perceived and what drives customer satisfaction, companies can refine their servitisation strategies and ultimately enhance their performance, both in the business and healthcare sectors.

2.8 Defining and assessing customer value in business and healthcare sectors

Value perception is a central concept in business markets, pivotal to marketing strategies (Lindgreen & Wynstra, 2005). Despite numerous attempts to define customer-perceived value, the literature reveals significant inconsistencies. Lin *et al.* (2005) demonstrate that different conceptualisation methods applied to the same data can yield varying parameter estimates, potentially leading to misguided marketing strategies and investments (Lin et al., 2005).

Although there has been substantial research on value assessment methods, the composition and creation of value in specific fields, such as business relationships and medtech, remain unclear. Eggert and Ulaga (2002) identify three common elements in value definitions: multiple components, subjective perception and the importance of competition (Eggert & Ulaga, 2002). This implies that value perception varies among customers, influenced by their personal values and judgment criteria (Helkkula et al., 2009). Sweeney and Soutar (2001) propose a 19-item measure for assessing customer perceptions, yet a universally accepted definition of value is still elusive (Chahal & Kumari, 2012).

Kotler (2000) defines customer-delivered value as the difference between total customer value and total customer costs (Kotler, 2000). Neap and Celik (1999) offer an alternative perspective, suggesting that value equals the product's total cost plus a subjective marginal value, which is dependent on the customer's value system (Neap & Celik, 1999). Anderson and Narus (1998) define value as the monetary worth of technical, economic, service and social

benefits received in exchange for the price paid. They argue that value is independent of price changes and is instead related to net benefits, including operating savings (Anderson & Narus, 1998).

Woodruff (1997) identifies that most definitions of value involve a trade-off between what the customer receives (e.g. quality, benefits) and what they sacrifice. It is also noted that value assessment can differ depending on the context, such as during procurement versus product use. Woodruff's Hierarchy Model suggests that customer value is evaluated through a means-end approach, where products and services are acquired to achieve specific goals. This model progresses from evaluating product attributes to assessing value in use and, ultimately, achieving customer goals (Woodruff, 1997). Smith and Colgate (2007) propose a customer value framework that incorporates functional, experiential, symbolic and cost/sacrifice dimensions. Their framework also identifies key sources of customer value across the value chain, including information, products, interactions, purchase environment and ownership transfer (Smith & Colgate, 2007).

In the healthcare industry, the concept of value is integral to re-engineering care delivery. Porter and Teisberg (2006) assert that value, defined as the health outcome per dollar spent, is the central goal uniting all stakeholders in the healthcare system. They argue that value-based healthcare focuses on improving outcomes while managing costs, challenging the traditional reliance on quality alone. According to Porter and Teisberg, competition in healthcare should address medical conditions comprehensively, including prevention, diagnosis, treatment and management (M. Porter & Teisberg, 2006).

The shift towards value-based healthcare indicates that the medtech industry should align with this model, moving beyond traditional product sales to cover the entire care cycle. Medtech companies must move beyond incremental improvements and volume-based models to focus on delivering 'genuine' value. This transition offers opportunities for innovation, emphasising patient outcomes and evidence-based benefits. Addressing these needs requires a deep understanding of value from the perspective of all healthcare stakeholders, ultimately leading to enhanced patient care and more effective healthcare solutions.

Customer value is a key concept in both business and healthcare, but its application is especially crucial in healthcare, where the shift to value-based care is transforming decision-making. As discussed in the previous section, understanding customer value requires a detailed approach, considering subjective and context-dependent factors. In healthcare, this complexity is heightened by the diverse perspectives of stakeholders, including patients, providers and payers, each defining value differently (Morton & Cornwell, 2009). The rise of value-based care, which focuses on improving outcomes while managing costs, has led to the development of value assessment frameworks that aim to standardise how value is measured across healthcare domains, from pharmaceuticals to medical devices. These frameworks help guide decisions, shape care delivery and influence the adoption of new technologies.

2.9 Value in healthcare

The transition to value-based care, which emphasises outcomes and cost efficiency, has made defining and assessing value a critical aspect of healthcare decision-making. This shift necessitates standardised frameworks that help all stakeholders evaluate what constitutes value in treatments, technologies and services. To support this shift, value assessment frameworks have emerged, helping to define, measure and communicate value in a standardised way. While not a new concept, these initiatives have spread rapidly, especially in the USA (Doshi & Willke, 2017; Sorenson et al., 2017). Prominent frameworks include those proposed by the American College of Cardiology (ACC)/American Heart Association (AHA), the American Society of Clinical Oncology (ASCO), the Institute for Clinical and Economic Review ($ICER_a$), Memorial Sloan Kettering Cancer Center (MSKCC) and the National Comprehensive Center Network (NCCN) (Doshi & Willke, 2017).

While these frameworks provide essential guidelines for decision-making, they must balance diverse stakeholder interests, which can sometimes complicate the ability to standardise value definitions. The complexity arises from the varied missions and objectives of the entities proposing these frameworks, as well as the diverse methodologies used to measure and communicate value (Doshi & Willke, 2017). Frameworks focus on areas like oncology (ASCO, MSKCC, NCCN) and cardiac care (ACC/AHA) or have a broader scope including medical devices and health interventions ($ICER_a$). Their aims and target groups are also diverse; some of them

such as ASCO and NCCN are geared towards supporting patients and physicians making more informed (evidence-based) shared decisions, whereas others, like $ICER_a$, oriented towards payers and their negotiations with the manufacturers (Sorenson et al. 2017; Mandelblatt et al. 2017). The analytic techniques employed by the different frameworks are also diverse, including conventional methods such as Cost-Effectiveness Analysis (CEA) or new methods based on Multicriteria Decision Analysis (MCDA) (Mandelblatt et al., 2017).

Value frameworks aim to standardise and enhance transparency in healthcare decision-making, supporting well-informed prioritisation in drug prescriptions and other interventions, devices or practices (Garrison et al., 2018; Mandelblatt et al., 2017). Since they predominantly focus on pharmaceuticals and place less emphasis on medical devices, physician and hospital services are rather neglected, and new technologies are marginally involved with the epicentre lying on the existing technologies. This fact is incompatible with the high spending on physician and hospital services as well as the innovation in modern technologies. The lack of proper data for these latter categories, due to the unavailability of randomised clinical trials, contributes to this imbalance (Garrison et al., 2018; Ollendorf et al., 2019; Solow & Pezalla, 2018).

While frameworks aim to simplify decision-making, the complexity of healthcare, with its numerous stakeholders, makes it challenging for these frameworks to fully capture the diverse perspectives and associated costs. It is crucial to assess whether a framework addresses value from the viewpoints of all relevant parties - patients, payers (public and private), providers, technology manufacturers and society at large. Moreover, even a patient-centred framework must account for variations in patient preferences and value assessments, which can differ significantly between healthy and ill states.

Frameworks like ASCO and NCCN aid in patient-level decision-making, helping patients and their providers (i.e. physicians) select the therapeutic option that maximises health benefits. On the other hand, $ICER_a$ focuses on payer decisions regarding coverage and pricing by comparing the costs and health gains of products, primarily pharmaceuticals and to a lesser extent, devices. The narrow perspective often employed can obscure important aspects from other stakeholder viewpoints (Garrison et al., 2016, 2017). In healthcare, patient

heterogeneity and diversity lead to individualised value expectations influenced by the impact on length and quality of life, willingness and affordability to sustain costs and cognitive biases from the patients, their providers or payers/insurers.

Most value frameworks rely on an economic perspective, using CEAs as evaluation techniques. Garrison *et al.* (2017) suggest incorporating additional value elements beyond costs and health outcomes, such as Life Years Gained (LYs), Quality of Life Improvements (QoLs), commonly combined in QALYs (Quality-Adjusted Life Years) and Cost savings within the health system (Garrison et al., 2017). Additional value elements related to productivity or time value are less frequently considered in HTA. These elements aim to capture and evaluate the value of a patient's time spent receiving medical care and the impact of absenteeism. Similarly, HTAs sometimes measure cost savings outside the health system, such as nonmedical costs related to the transportation of relatives and family carers, reflecting a societal perspective (Garrison et al., 2016, 2017).

Garrison *et al.* (2017) introduce five additional value elements. Reduction in Uncertainty pertains to the value derived from knowing a technology or medicine is effective, which helps patients in planning and managing risks. Insurance Value refers to the peace-of-mind associated with protection against health loss, ensuring access to innovative treatments. Value of Hope reflects patients' willingness to accept higher risks for treatments that offer potential survival benefits, particularly in end-of-life scenarios. Real Option Value involves the appreciation of treatments that extend life, allowing time to benefit from future therapies. Lastly, Scientific Spillovers denote the value placed on technologies that advance knowledge and innovation, potentially benefiting future patients (Garrison et al., 2016, 2017). Literature from economics, clinical and ethical domains can introduce new value elements. Other examples include adherence-improving factors, which reflect the value derived from a patient's adherence to therapy. A technology that promotes better adherence can yield greater benefits as well as equity and equality in health.

Integrating multiple value elements into a single metric remains a complex task. Traditional approaches, such as CEAs, provide valuable insights but often rely on limited metrics - primarily focusing on cost and health outcomes - that can fall short when making

comprehensive healthcare decisions. To address this gap, MCDA has been developed as an alternative approach. MCDA allows decision-makers to incorporate a broader range of criteria, such as patient preferences, quality of life and long-term outcomes, in addition to cost-effectiveness. This method works by assigning value weights to each criterion, helping to promote transparency and facilitate more informed decisions (Phelps & Madhavan, 2017). MCDA models begin by defining the decision problem and structuring relevant criteria (Morton et al., 2018). Decision-makers then assign weights to these criteria, evaluating alternatives based on their weighted scores, which are used to guide decision-making. This approach enhances transparency by explicitly showing the trade-offs among different value attributes. Moreover, as Phelps and Madhavan (2017) highlight, MCDA facilitates the testing of alternatives, improves data efficiency, supports decision convergence and mitigates cognitive biases in practical decision-making.

A new challenge arises regarding who sets the value weights. The 5Ps perspectives - Public, Providers, Payers (insurers), Patients, Producers (Medtech or Pharma) - may prioritise different value elements or assign different weights (Muir et al., 2023; Phelps & Madhavan, 2017). International Society for Pharmacoeconomics and Outcomes Research (ISPOR) recommends expanding the testing and application of MCDA models, advancing their use and regularly comparing their outcomes with those of traditional CEA and similar models (Neumann, 2019; Willke, 2019). As the debate continues over how best to assign value to different health interventions, the perspectives of the 5Ps underscore the inherent tension in aligning frameworks with the diverse needs and priorities of all stakeholders.

As the sector shifts toward value-based care, evolving frameworks will be crucial in aligning decision-making across patients, providers, payers and policymakers to improve outcomes and control costs. Ongoing debates emphasise the need for further research, as the complexity and diverse perspectives of stakeholders create a dynamic environment, with the patient at the center of efforts to optimise value (Morton et al., 2018). An application of these evolving frameworks is in the procurement of medical technologies, an area where traditional evaluation methods often fall short in capturing the multifaceted value of innovations. In this context, value-assessment tools specifically designed for procurement decisions play an

essential role. These frameworks not only address clinical effectiveness but also consider broader factors, such as long-term outcomes, societal impact and cost-effectiveness.

2.10 Procurement frameworks or guidelines with value assessment focus

As healthcare transitions from volume-based to value-based models, procurement frameworks have become increasingly essential for ensuring that technology investments align with the broader goals of value-based care. These frameworks not only help capture the complex and diverse needs of various stakeholders, such as payers, providers, clinicians, patients, policymakers and employers, but also ensure that technology choices reflect comprehensive value (M. D. Miller 2017). By addressing the diversity of medical technologies and their distinct impacts, these frameworks play a key role in improving decision-making processes across the healthcare sector. Importantly, they also recognise the differences between medical technologies and biopharmaceutical products, which require unique value-assessment approaches (AdvaMed & Deloitte, 2023).

Several initiatives have emerged to help stakeholders assess the full value of medical technologies. For example, the Advances in Medical Technology Association (AdvaMed) proposes expanding the dimensions of value considered in procurement decisions to better meet the needs of diverse stakeholders. These dimensions include: Clinical Impact, Non-Clinical Impact, Care Delivery Revenue and Cost Impact and Public/Population Impact, as well as Environmental Impact (AdvaMed & Deloitte, 2023; Miller & Woodcock, 2017). The development of these value aspects takes into account the following considerations: a) the diversity of medical technologies, b) the integral role of medical devices in complex care processes (e.g. surgical procedures), c) the rapid innovation cycles that can render value conclusions obsolete, d) the varying roles that technologies play in treatment selection and intervention and e) the appropriateness of different methods for evidence generation.

A key milestone in this evolution is the 2014 EU Public Procurement Directive (2014/24), which aims for innovation while incorporating environmental and social considerations into procurement policies. Central to this Directive is the Most Economically Advantageous Tender (MEAT) methodology, which requires contracting authorities to evaluate tenders based on an

optimal balance of price, quality and a range of qualitative, technical and sustainability criteria across the entire product lifecycle. The MEAT criteria include product and service quality, technical excellence, accessibility, inclusive design, social and environmental impacts and innovation. Furthermore, the expertise and experience of the personnel responsible for executing the contract are also considered, as their competence can significantly influence the success of the procurement process. Other factors may include post-purchase services, technical support and specific delivery conditions (e.g. timelines and execution processes).

In alignment with this approach, MedTech Europe, in collaboration with The Boston Consulting Group (BCG) and procurement specialists, introduced the MEAT Value-Based Procurement initiative. The goal of this initiative is to guide healthcare institutions, hospitals and procurement authorities in adopting value-based decision-making processes. To operationalise the MEAT model within the EU Public Procurement Directive framework, a comprehensive system was developed, incorporating a structured framework, an Excel-based tool and detailed guidelines. This system emphasises value-based procurement, highlighting the significance of medical technology in promoting discussions around value in healthcare systems (Gerecke et al., 2015). The MEAT framework provides criteria for a holistic value assessment, which are categorised into four distinct layers: a) Outcomes, b) Costs, c) Benefits to key stakeholders and d) Broader societal impact. These criteria can be tailored to meet the specific requirements of different users.

These frameworks are designed to capture the broader and long-term value of medical technology procurement, moving beyond mere price-based evaluation and instead advocating for the use of both quantitative and qualitative measures to assess the total healthcare costs and the value generated throughout the entire lifecycle of medical technologies.

2.11 Conclusions and research gap identification

The existing literature highlights the significant organisational, strategic and cultural challenges that companies face when adopting servitisation. While the potential benefits, such as enhanced differentiation, improved customer relationships and increased firm value,

are well-documented, uncertainty remains regarding the actual impact of servitisation on business performance and profitability.

A core aim of servitisation is to create value beyond product features by addressing customer needs comprehensively. However, aligning these integrated solutions with customer expectations and ensuring they deliver tangible value remains complex. Understanding how customers perceive the value of integrated solutions is crucial for successful servitisation strategies (Green et al., 2017).

The inherent subjectivity of customer value complicates the alignment of value propositions with buyer perspectives. While sellers may design propositions based on what they perceive as important, these often fail to resonate with the specific needs of buyers. For servitisation to succeed, firms must have a deep understanding of the value drivers influencing buyers' decision-making processes, particularly as they shift from product-centric to service-oriented offerings. Firms that fail to align their solutions with what customers truly value or do not fully grasp their latent needs are likely to struggle. Therefore, for servitisation to be a successful business model, it is essential to focus on understanding and addressing customer value perceptions effectively. This approach ensures that solutions are both relevant and valuable, leading to better performance and long-term success.

The medtech industry is undergoing a paradigm shift from a product-centric model to a service-oriented approach, offering integrated solutions that combine medical devices with related services and support. Given the increasing complexity of these solutions, it is essential for industry players to proactively assess how healthcare providers (buyers) perceive the value of integrated solutions. This requires identifying key value elements and ensuring alignment with healthcare providers' goals, challenges and domain-specific trends. The shift towards value-based healthcare necessitates that medtech companies align their offerings with what truly matters to healthcare stakeholders, that is improving patient outcomes while managing costs. Traditional models, which focus on volume and product features, are no longer sufficient. To meet the evolving needs of the healthcare system, medtech companies must deliver a broader range of value, from functional benefits to experiential and symbolic aspects.

By doing so, the medtech industry can make informed decisions about whether to pursue a servitised business model and what specific solutions to design.

Traditional procurement models in the medtech industry are often ill-suited to evaluate the full impact of integrated solutions. Buyers typically rely on narrow criteria such as upfront cost, when selecting suppliers, undervaluing solutions that offer long-term benefits like operational efficiency or improved patient outcomes. Sellers, on the other hand, often adopt a broader, solutions-oriented approach that considers both capital and operational expenditures. However, discrepancies between the buyer's and seller's value perceptions can hinder the adoption of these solutions. For example, a vendor might offer a solution that reduces energy consumption and maintenance costs, but if these benefits are not prioritised by the buyer, the solution's true value may be overlooked.

Value frameworks in healthcare have been introduced to support better decision-making for stakeholders like patients, providers and payers. However, existing frameworks often focus narrowly on evaluating individual medical devices rather than integrated solutions. In this context, a solution is more than just a collection of products and services; it is a customised integration designed to meet specific customer needs.

Despite substantial literature on servitisation and value assessment in healthcare, there is a significant gap in frameworks dedicated to evaluating servitised offerings in the medtech industry. Most existing frameworks focus on product evaluations or generic service models, neglecting the unique complexities and value propositions associated with integrated medtech solutions. This gap points out the need for a tailored framework that addresses the specific elements of value creation, delivery and sustainability in medtech servitisation.

The study explores the value drivers in medical technology (medtech) solution propositions, particularly focusing on what generates added value when transitioning from stand-alone medical devices to integrated solutions. By identifying these drivers, the research seeks to establish the value criteria needed to build a comprehensive framework for evaluating servitised offerings in the medtech industry. The central research question is:

What value criteria should be included in a framework to evaluate servitised medtech solutions, ensuring alignment with the needs and expectations of healthcare providers?

This framework will equip medtech companies with the tools to assess the viability of adopting a servitisation business model, focusing on creating value for healthcare providers. It will guide companies in designing, communicating and delivering integrated solutions that align with healthcare providers' evolving needs and expectations. By clarifying the embedded value of these offerings, the framework will strengthen the alignment between medtech companies (sellers) and healthcare providers (buyers). Furthermore, the empirically grounded framework will support strategic decision-making and facilitate the effective implementation of servitisation strategies within the medtech industry.

The research gap identified in this study centres on the limited understanding of specific value drivers in medtech solution propositions, particularly in the shift from stand-alone medical devices to integrated solutions. While servitisation has been studied in other industries, its application within the medtech remains underexplored. Existing literature lacks a comprehensive framework that identifies the unique value criteria for servitised medtech offerings and how these align with healthcare providers' expectations. Additionally, no structured approach exists to guide companies in assessing, designing, communicating and strategically implementing these solutions in response to evolving market demands. Addressing this gap is essential for medtech companies to meet healthcare providers' needs and maximise the value of their integrated offerings.

3. Methodological framework

3.1 Introduction

This chapter outlines the methodological framework of the study, emphasising the adoption of a pragmatic worldview to gain context-driven insights into the value perceptions of medtech solutions. A qualitative approach was chosen to explore the complexities of these perceptions.

The chapter outlines the research process, which is divided into three phases, with each phase building upon the previous one to answer the research questions. Each phase begins with the objectives and rationale, followed by the criteria for sample selection and concludes with a description of the expected outcomes. In phases 2 and 3, two groups are involved: HCPs using medtech solutions and executive leaders from a medtech company with expertise in product design and solution development. This dual sample aims to provide complementary perspectives on the perceived value of servitised offerings.

Data collection is carried out through semi-structured interviews, allowing flexibility while maintaining consistency. These interviews focus on exploring value perceptions of medtech solutions, particularly in comparison to traditional medical devices.

The chapter also outlines the analysis procedures, using thematic analysis to identify and categorise key themes from the interview data. This process supports the development of a tailored framework for evaluating servitised medtech solutions.

Finally, this chapter sets the stage for the following chapters, which will present the research findings.

3.2 Philosophical approach

The ways in which value and its creation are conceptualised significantly shape the research methodologies employed in academic studies. Scholars engaged in traditional streams of

value research have predominantly utilised qualitative methods to explore the dimensionality of value. These methods often involve exploratory research and case studies, that facilitate the development of conceptual frameworks and theories. These frameworks and theories are subsequently validated through empirical studies.

A key assumption underlying this research is that customers act as rational evaluators, continuously and independently assessing offers to determine those with the highest benefits-to-sacrifices ratio. This perspective aligns with a positivist approach, that seeks to identify causality in human behaviour and make predictive assertions. Consequently, researchers have focused on examining the correlations between various value elements and other business parameters such as performance and growth.

Additionally, researchers have developed measurement scales to assess customers' value perceptions (Chahal & Kumari, 2012). The positivist approach views reality as objectively given and researchers adhering to this perspective strive to identify causal relationships and interactions among variables. They test theories using numerical data, with the goal of producing law-like generalisations (Saunders et al., 2016).

However, the concept of value is polysemous and thus a universal or generalised measurement is not feasible, as a positivist approach might dictate. When value is considered subjective and contextual, involving at least two main parties - the firm and the customer - each party may phenomenologically determine value differently based on their experiences, mentalities and aspirations, in other words their own 'reality' (Karababa & Kjeldgaard, 2014). This perspective aligns more closely with interpretivism and subjectivism, where reality is understood as a socially constructed perception and an organisation is seen as a socially constructed product (Bryman & Bell, 2015). In this paradigm, the conceptions, perceptions and experiences of social parties drive the understanding of reality or the subject under research. The interpretivist approach is inherently value-bound; the researcher immerses themselves in the world of the object under study and strives to understand the research participants' viewpoints. Simultaneously, the researchers' own values and beliefs are integral to the research process (Saunders et al., 2016).

Understanding value from the customers' perspective is crucial for firms to build appropriate and effective solutions. The challenge for researchers is to comprehend how value is perceived in specific settings, whether this value is contextual, measurable, or generalised. Instead, the focus should be on addressing practical issues in real-world contexts, that leads to John Dewey's work on the relationship between theory and practice (Dewey, 1929; Fendt et al., 2008). Fendt *et al.* (2012) argue that a theory-praxis gap in management academia diverts researchers from asking the right questions and solving relevant management problems. They propose pragmatism as an alternative to the dominant ontological assumptions in management theory, which often resemble those used in the natural sciences.

Pragmatism, associated with thinkers such as Charles Sanders Peirce, John Dewey and William James, views reality as ever-changing based on actions (Dewey, 1929; James, 1907; Peirce, 1905). Truth, in pragmatism, is rooted in practice - truth is what works. In this philosophical theory, truth is what benefits life in practice, with actions taking precedence over theory and experiences prevailing over ideas and principles (Goldkuhl, 2012; Ormerod, 2006). Pragmatism emphasises the importance of focusing on the context in which individuals live, shaping perceptions of the world through actions and objectives rather than abstract theories. It seeks to generate practical knowledge by addressing urgent contemporary issues and translating that knowledge into actionable outcomes (Fendt et al., 2008).

For pragmatists, research begins with a problem (Saunders et al., 2016) and truth emerges from a process of unlimited practical inquiry, involving the confrontation of different viewpoints (Fendt et al., 2008). According to Dewey, inquiry is considered a form of experience and research is viewed as a type of inquiry (Morgan, 2014). This process follows a cyclical pattern of belief and action, where a problem is identified, actions are taken based on existing beliefs and these actions subsequently shape reflections on those beliefs. Fendt *et al.* (2012) explain that truth evolves through the synthesis of differing perspectives, becoming the foundation for the next phase of dialectical progress.

The current challenge for businesses is to define what value means within their industry, how it is generated and how it can lead to improved offerings. Companies need to identify the value creation process from the customer's perspective (Davies, 2004). Since the perception

and creation of value vary across industries, services and solutions may also differ not only between industries but also across product categories, such as consumer and capital goods. The investigation and identification of value elements, along with the conditions for their creation, should be conducted through a reflective process. Both academic literature and practical applications must engage in a dialogue, integrating perspectives through a process of thesis, antithesis and synthesis involving all relevant stakeholders.

A pragmatic approach might be seen by some as an easy shortcut, avoiding deeper philosophical debates on truth and reality while allowing the flexibility to use multiple methods (Fendt et al., 2008). However, this perspective is overly simplistic. Pragmatism is not only a methodological convenience but rather a theory of meaning and truth (Denzin, 2012; Morgan, 2014). It views the process of acquiring knowledge as continuous, employing various approaches and methodologies that align with the intended purpose (Goles & Hirschheim, 2000). Pragmatism is not limited to practical solutions, nor does it avoid the question of whether knowledge is context-specific or universally applicable (Morgan, 2007). Instead, it emphasises the transferability of knowledge and the importance of communication between researchers with differing worldviews, focusing on the broader purpose. In the ongoing discourse about value, from Aristotle's distinctions (between use-value and exchange-value) to classical economic theories and modern marketing and management approaches, pragmatism offers a suitable framework for building dialogue and advancing knowledge (Stomper, 2018).

Pragmatic researchers are not constrained by the dichotomy of quantitative versus qualitative methods; instead, the research problem dictates the appropriate methods (Onwuegbuzie & Leech, 2005). This practicality has sparked interest among researchers, who often connect mixed methods with pragmatism as a paradigm of choice (Morgan, 2014), combining the benefits of qualitative and quantitative methods. This trend is attributed to the common claim that quantitative methods align with positivism while qualitative methods relate to interpretivism - a view broadly discussed and challenged in literature that sees qualitative and quantitative methods as complementary (Creswell, 2013; Thomas, 2003). In value literature, a deductive approach is commonly used when theories built from academic literature are tested in the field. Equally, data collection from the field can drive the development of

conceptual frameworks through an inductive approach (Saunders, Lewis and Thornhill, 2016). Throughout the study of a problem, both approaches might be deployed within the cyclical pragmatist approach and its dialectics. Data collection may lead to amendments or new conceptual frameworks, which are then tested and validated, generating knowledge in an abductive way.

In summary, the pragmatic approach is not about cutting corners but about addressing real-world problems with the most suitable methods. It emphasises the importance of dialogue and the synthesis of opposing views, providing a pathway for generating actionable knowledge that bridges the gap between theory and practice.

3.3 Why a qualitative approach?

The qualitative approach is chosen for its suitability in exploring the intricate phenomenon of value perception, specifically in medtech solution offerings. Unlike quantitative methods that emphasise measurement and generalisation, qualitative research allows for a profound exploration of participants' lived experiences and the meanings they attribute to these experiences.

To understand how HCPs perceive the value of medtech solutions and use this insight to create a comprehensive value framework for evaluating such solutions, it is essential to engage closely with stakeholders in their natural environments, where their perceptions are formed. Given the diversity in participants' perspectives and preconceptions, the research seeks to comprehensively capture and illustrate the impact of these variations on value perception.

In focusing on HCPs' perspectives, the study intends to uncover the nuances of value perception from those who directly engage with medtech solutions, meaning the perspective of those who experience this value (Vaismoradi et al., 2013). Despite the multitude of theoretical approaches to perceived value, this research focuses on a specific setting to examine the details of value perception and to explore implications for value framework architecture.

To achieve this, the qualitative approach aligned with a pragmatic stance, enables the researcher to gain insights through the real-life situations, actions and consequences of HCPsregarding their perceptions of medtech solutions. By collecting and analysing participants' meanings and perceptions, the study generates a dataset from which thematic insights are derived. This approach acknowledges the multiplicity of realities among participants, emphasising the need to immerse deeply into their worlds to grasp the origins of their perceptions.

However, this closeness to participants' worlds could be seen as a risk to the research's objectivity. In this study, the researcher, coming from the industry, is well-informed and aware of the segment context. This context represents the 'domain wisdom' or 'inherited background', based on Wittgenstein's term, as described by Marc Stierand and Viktor Dörfler in their work on intuition in personal creativity (Stierand & Dorfler, 2014). Rather than posing a problem, this insider view is seen as an advantage, as sharing a similar inherited background with HCPs allows for intersubjective discussion (Stierand and Dörfler, 2014), where both the researcher and research participants are embodied insiders shaping meanings and insights together (Cunliffe, 2011). Furthermore, the occupational habits stemming from the insider's expertise allows for the incorporation of expertise-based intuition into the analysis (Stierand and Dörfler, 2014). Still, the purpose is to give voice to the informants and not to affirm existing concepts or pre-assumptions (Gioia et al., 2013). Continuous and rigorous self-reflection, introspection and iterative discussions help in bracketing pre-understandings.

In conclusion, a qualitative approach is essential for capturing the complex, subjective and context-dependent nature of value perception in the medtech industry. It enables deep engagement with participants, facilitating a detailed understanding of their perspectives and deriving insights that are both theoretically robust and practically applicable. The study's adoption of pragmatic perspective provides a solid foundation for exploring value, ensuring that its findings can contribute meaningfully to the development of effective value assessment frameworks within the medtech industry.

3.4 Overview of the research design

The research is structured into three (3) phases, as shown in Figure 3.1. Each phase's outputs inform the subsequent phase, while collectively contributing to answering the research sub-questions. Specifically, Phase 1 addresses the first sub-question, while Phases 2 and 3 provide an answer to the second research sub-question.

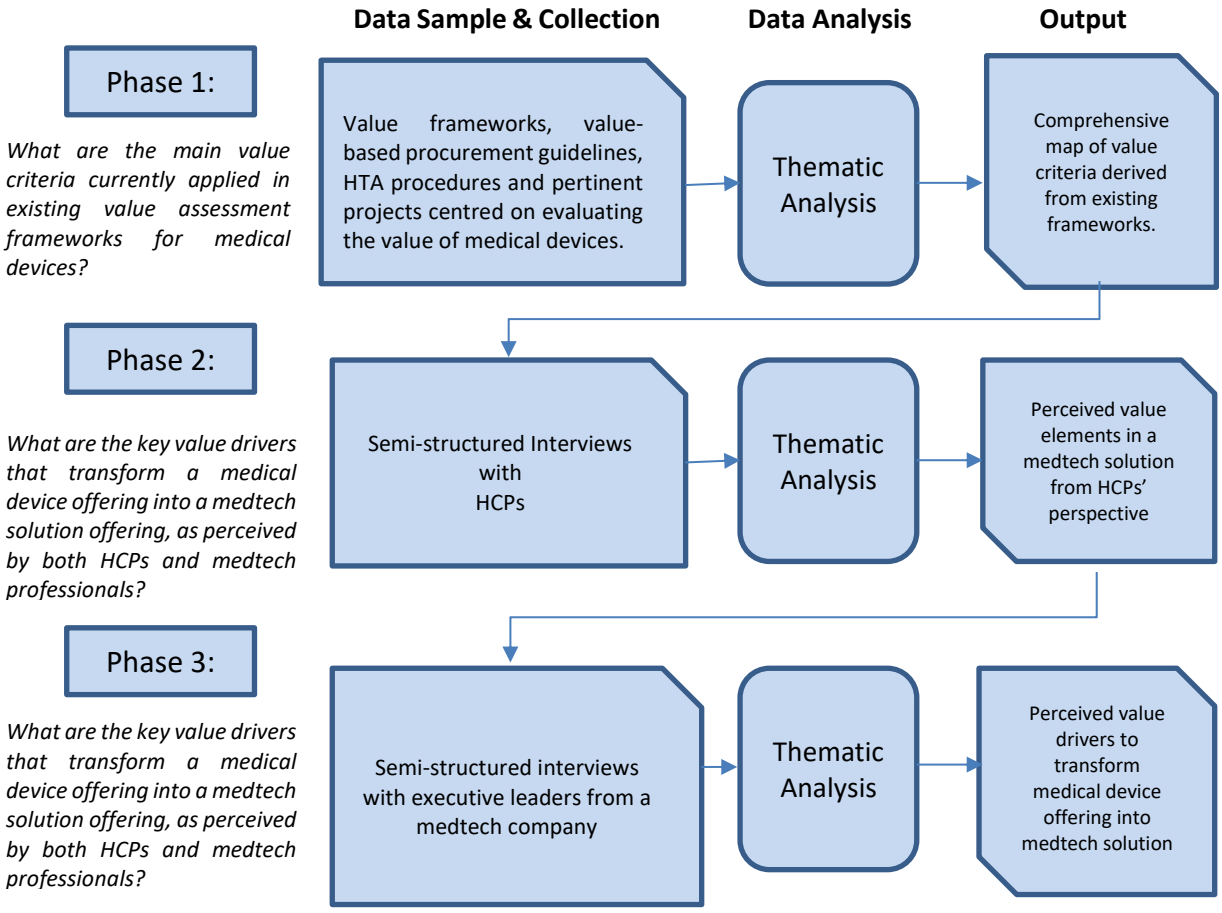

Figure 3.1: The three phases of the research design

3.4.1 Phase 1

3.4.1.1 Objectives and justification

The objective of this phase is to map the value criteria emerging from value frameworks and the current discourse on healthcare technology assessment and procurement guidelines. Although value frameworks are relatively new, they aim to address the need to measure value in a multi-stakeholder environment like healthcare. These sources provide valuable data for creating an initial value criteria map.

The value of medical technology extends along a continuum that begins with its assessment during its introduction to the medical market and continues through its selection, use and concludes with its impact on patients. By studying the value criteria driving evaluations throughout this lifecycle, meaningful insights can be obtained. These evaluations occur within the practitioners' world - HTA agencies, regulatory bodies, policymakers, insurance funds and healthcare providers during procurement processes - providing current perspectives and lessons learned from practical applications. Moreover, the HTA process adheres to regulatory standards ensuring safety and quality, commonly determining pricing or reimbursement rates by public sector payors and procurement processes by providers. This ensures the comprehensive monitoring of the continuum, as illustrated in Figure 3.2 below.

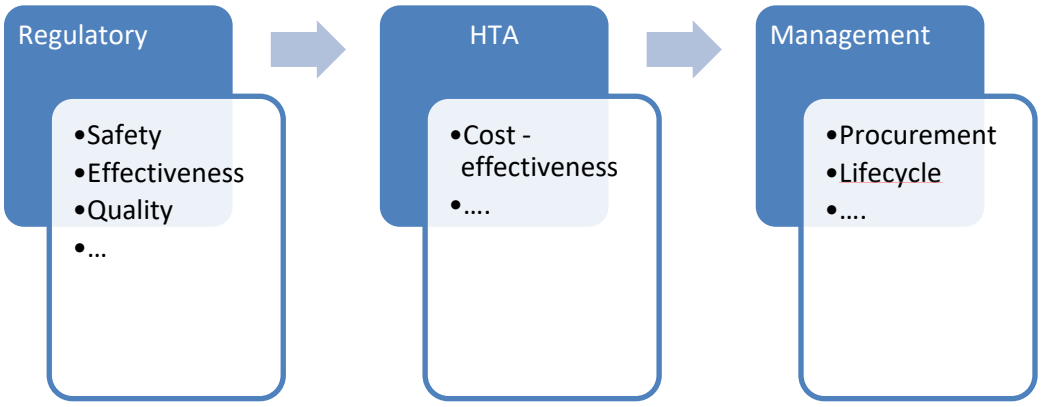

Figure 3.2: The continuum in the medical devices assessment

Currently, numerous Health Technology Agencies worldwide employ various methods in their assessment processes. The shift from a volume-based healthcare model to one driven by value creation has led to the development of frameworks to measure value. As discussed in Chapter

2, these value frameworks vary, often with different or even contrasting purposes, methods, or development processes. Generally, they fall into two major categories: frameworks designed to assist decisions between patients and physicians and frameworks intended to support payment or reimbursement decisions.

Similarly, VBP frameworks and guidelines have been developed by medtech organisations with the aim to go beyond the traditional value criteria of HTA frameworks, such as clinical and safety outcomes, to address a broader spectrum of value considerations (AdvaMed & Deloitte, 2017). These frameworks provide robust evaluation grounds for integrated products and services that meet the diverse needs of stakeholders across the healthcare landscape.

Phase 1 of the present study identifies a comprehensive array of value criteria, creating the material for sensitising field interviews for Phases 2 and 3.

3.4.1.2 Sample selection

The data sample for Phase 1 consists of frameworks addressing the value assessment of medical devices, guiding the identification of value criteria for introducing, assessing and procuring medical technology in clinical practice.

A purposive sampling approach is employed to select relevant frameworks (HTA, value frameworks and value-based procurement) to access up-to-date data on value criteria. The selection aims to gather information with rich content and insightful perspectives (Patton, 2002). Criteria for sample selection are that:

- Frameworks must address medical devices and not solely pharmaceuticals or interventions.
- Frameworks must be recent (between 2014 and 2024), implemented and applied in different geographies.

In addition to these criteria, it is important to consider the broader discourse - whether recent or ongoing - that discusses, analyses, or shapes these criteria. Since value frameworks, HTA frameworks and procurement guidelines often emerge from consensus-building among various stakeholders, examining the value considerations raised during this process provides

valuable insight. To identify broadly applicable value criteria for fieldwork, the sample includes research projects and initiatives at the European level, focusing on medical device assessment. Notable projects include:

- **The MedtecHTA Project:** Aimed at improving the methods and practices of HTA for medical technologies, focusing on economic, clinical and patient-related outcomes.
- **The AdHopHTA Project:** Developed a toolkit to optimise hospital-based HTA, promoting effective and sustainable use of medical technologies.
- **The INTEGRATE-HTA Project:** Focused on developing methods to assess complex technologies, considering broader socio-economic and ethical implications.

An abductive approach is followed, iterating between the Phase 1 sample and the resulting criteria map, to identify value criteria (Strandvik et al., 2012). If similarities are found among the frameworks, they highlight the pluralistic nature resulting from diverse methodologies and objectives. The sample enrichment process concludes once a saturation of value criteria is achieved.

3.4.1.3 Output of Phase 1

The output of Phase 1 is a value criteria map derived from current frameworks addressing medical device assessment. This map serves to guide, rather than solely dictate, the collection and gathering of empirical data through interviews in the subsequent phases.

3.4.2 Phase 2

3.4.2.1 Objectives and justification

The objective of this phase is to gather insights from HCPs in various roles within a healthcare provider to understand the key factors that drive value when transforming a traditional medical device into a comprehensive medtech solution.

These roles include management, technical and clinical positions. The empirical study, conducted through interviews, seeks to explore how HCPs perceive the value creation by medtech companies in relation to their activities. Given that this perception often arises cumulatively from distinct aspects and stakeholders within healthcare providers, it is crucial

to capture these diverse views. These views may stem from various motives, such as clinical effectiveness, patient satisfaction, process improvements, revenue maximisation and regulatory compliance, leading to differing and sometimes contradictory perceptions. Therefore, this phase explores the diversity of these perceptions, collaborating with key stakeholders within healthcare provider organisations to extract patterns in value perception concepts. The output of Phase 1, as outlined in Section 3.4.1.3, serves as an initial value map to facilitate discussions.

3.4.2.2 Sample selection

Since the study does not aim for generalisation to a broader population, purposive sampling is employed in Phase 2 to capture the diverse perceptions and characteristics of HCPs relevant to the research sub-question (Bryman and Bell, 2015).

To refine the HCP sample, the research scope is focused on healthcare providers that operate imaging diagnostic centres equipped with at least one Computed Tomography (CT) and one Magnetic Resonance (MR) system. In private healthcare providers, the typical business model centres around offering diagnostic imaging services, with high-cost CT and MR systems playing a pivotal role both clinically and technologically. These systems significantly impact both costs and revenues, addressing a wide range of clinical needs and commonly receiving reimbursement from healthcare funds. They also require substantial capital (CAPEX) and operational (OPEX) investments. For public healthcare providers, the research similarly includes imaging departments in public hospitals and healthcare facilities, where the scope of services is comparable.

The sample in Phase 2 includes 13 HCPs from 12 healthcare provider organisations, representing both private and public sectors, as well as academic and general clinical facilities. These participants are key decision-makers with significant experience, directly involved in the design, assessment, selection, procurement, use and management of imaging medical devices. Their extensive background in evaluating and selecting medical technology, along with their involvement in its various phases, is essential for identifying what HCPs value in imaging solutions. This approach ensures access to knowledgeable informants and adequately reflects the broader healthcare ecosystem.

In many studies, customers are often viewed as single informants, such as a purchasing manager or Chief Executive Officer (CEO), rather than as representatives of a multi-stakeholder organisation or group affected by the technology. However, it is vital to examine the value perceptions of multiple members within these groups. Engaging with various stakeholders within individual diagnostic centres - and in two cases, decision-makers at the headquarters, including Chief Technology Officers (CTOs), Chief Operations Officers (COOs) and Head Radiologists - allows for the capture of both collective and individual value perceptions, shaped by distinct motivations and goals (Macdonald et al., 2016).

The majority of participants (10 out of 13) were employed by healthcare providers in Greece at the time of the interviews, though they also possessed international experience and knowledge. Three participants worked for multinational healthcare providers, with roles spanning multiple European countries, including Greece. Incorporating participants with international experience adds variability and complementary perspectives, potentially reflecting processes or practices shaped by differing legislation and cultural norms. This diversity enhances the transferability of the findings (Eisenhardt 1989; Yin 2003). Table 3.1 provides details on the participants, their titles and selected characteristics.

Table 3.1: List and background of Phase 2 participants

Interviewees	Title - Role	Background and experience	Years of experience in healthcare services	Nationality	HCP organisation (Public/Private)	Type of institution
hcpintw#1	Radiologist	Academic, leadership (head of department), research background, medical technology assessment, clinical leadership and excellence.	40	Greece	Public	University/ Teaching hospital
hcpintw#2	CEO/COO	Financial and business background, leadership, decision-making in the selection, procurement and investments in imaging technology.	35 (including medtech industry)	Turkey	Private	Diagnostic Imaging chain with international footprint
hcpintw#3	CEO/COO	Technical and business background, leadership, decision-making in the selection, procurement and investments in imaging technology.	30 (including medtech industry)	Turkey	Private	Diagnostic Imaging chain with international footprint
hcpintw#4	Chief Technology Officer (CTO) /Biomedical Engineer	Technical background, leadership, decision-making in the selection, procurement of imaging technology, asset management and services contracting.	20 (including medtech industry)	Hungary	Private	Diagnostic Imaging chain with international footprint
hcpintw#5	Radiologist	Clinical leadership, imaging technology expertise, primary and secondary care clinician, selection and use of imaging technology.	20	Greece	Private	Diagnostic imaging chain with dominant position in Greece
hcpintw#6	Radiologist	Clinical leadership, specialised expertise (luminary healthcare facility), secondary care clinician, assessment and use of imaging technology.	20	Greece	Public	Specialised hospital
hcpintw#7	Medical Physicist	Extensive involvement in the specification, evaluation and procurement of imaging systems.	25	Greece	Public	University/ Teaching hospital

Interviewees	Title - Role	Background and experience	Years of experience in healthcare services	Nationality	HCP organisation (Public/Private)	Type of institution
hcpintw#8	Technologist/ Radiographer	Former hospital CEO with extensive background in the hospital and healthcare sector, clinical auditor, healthcare management, medical imaging devices, dosimetry, radiation protection, formulation of strategies to enhance quality services for patients.	40	Greece	Public	Public and Private Hospitals
hcpintw#9	Chief Technology Officer CTO/Biomedical Engineer	Teaching and research in biomedical engineering and cardiovascular technology, HTA, validation of medical devices, medical software design and engineering, information technology consulting, negotiation of reimbursement prices of healthcare services and medical devices.	26	Greece	Public	University/ Teaching hospital
hcpintw#10	Technologist/ Radiographer	Senior radiographer, experience in imaging modalities and nuclear medicine, private and public sector experience.	30	Greece	Public	University/ Teaching hospital
hcpintw#11	Medical Physicist	Radiation protection specialist with involvement in the specification, evaluations and procurement of imaging devices.	28	Greece	Private	Private hospital with leading market position
hcpintw#12	Clinician/ Medical Doctor	Surgeon, specialised in orthopaedics, extensive clinical and scientific work, former policymaker, medical services director.	30	Greece	Public	General hospital
hcpintw#13	Chief Technology Officer CTO/Biomedical Engineer	Senior biomedical engineer, director of biomedical technology department, Healthcare Technology Assessment consultant, medical devices procurement expert, quality manager.	33	Greece	Public	Specialised hospital

3.4.2.3 Interview structure

Data is gathered through in-depth, semi-structured interviews with HCPs. Participants are contacted via phone or email and invited to participate in the study. The interviews, conducted over four months either in person or on a digital platform, each lasted between 50 and 70 minutes. With the interviewees' consent, sessions are recorded and transcribed. Additionally, participants are given an off-the-record period to express views that are not recorded. The interviews are conducted in either Greek or English, depending on the participants' preferences. The interview guide is organised into three main areas, covering a total of nine questions (Table 3.2).

Table 3.2: Structure and objectives of Phase 2 interviews

Interview area	Seeks to:
Part 1	• Examine the major value elements identified by the interviewee that shape their perception of the value associated with a medical device.
Part 2	• Assess the respondent's initial understanding of the solution offering concept. • Encourage reflection on the differences between a solution and a medical device offering. • Identify a set of value elements that define a solution offering as perceived by the HCPs.
Part 3	• Elicit deeper insights into constructing a tool capable of assessing a solution offering and foster the emergence of ideas and suggestions regarding the value criteria it should include.

The first part of the interview aims to explore participants' perceptions of value regarding medical devices. Respondents are invited to articulate what value means to them in the context of imaging devices, such as CT or MR systems. Specifically, they are asked:

'Recently, there has been a discussion about value-based healthcare. What does value mean to you in relation to medical devices, such as imaging systems (e.g. CT, MR, PET/CT)? How do you perceive value from medical technology and what aspects of a product bring you value?'

This open-ended question seeks to uncover the criteria HCPs use to assess medical devices, providing insights into their value judgments rather than generating numerical data. By consistently referencing imaging medical devices across interviews, this question establishes a baseline for identifying key value elements, which will later help assess how these elements may evolve in the context of a solution offering. The question also helps assess participants' familiarity with existing value frameworks and procurement guidelines by prompting a discussion on value criteria and asking for the aspects of a product that deliver value. Participants are shown the map of value criteria from Phase 1 and asked:

'The main value criteria of the value frameworks and procurement guidelines can be summarised in a criteria map. Do you think they reflect the value perception in your domain? What would you add or remove? Which ones are the most relevant or important to you?'

This map serves as an initial set of value criteria for medical devices, acknowledging that it is not exhaustive. This approach fosters a deeper discussion of value perceptions and encourages participants to provide additional insights.

The second part of the interview shifts focus to the concept of a medtech solution offering. Participants are asked to describe how they perceive the concept of a solution and how it differs from a stand-alone imaging medical device. Specifically:

'Medtech companies claim to offer solutions. How do you define 'solution'? What additional elements does a 'solution' include beyond the (imaging) product?'

This question seeks to evaluate respondents' comprehension of the solution offering and how it differs from a traditional medical device offering. It encourages participants to reflect on how solutions compare to stand-alone devices and explore the value elements they associate with each. Follow-up questions include:

'How do you perceive value from a solution? What value elements would you like to see added to a solution or service offering compared to a product? What value elements are relevant or important for a solution-based offering?'

The map of value criteria from Phase 1 is used to guide this discussion and facilitate comparisons between medical devices and solution offerings. The goal is to identify the value elements defining a solution offering from the perspective of HCPs.

The third part of the interview examines the need for expanded value assessment frameworks that include elements beyond those of a medical imaging device. Participants are asked about their willingness to adopt such tools in their daily operations and decision-making processes:

'Do you think there is a need for an 'expanded' value assessment framework that incorporates elements of value beyond the health gains of a medical product or device?'

This discussion aims to generate insights into developing a comprehensive evaluation tool for solution offerings and encourages participants to propose relevant value criteria. The interview structure is designed to facilitate a thorough and productive discussion, incorporating additional questions and clarifications as needed to ensure all criteria are explored.

3.4.2.4 Output of Phase 2

The output of Phase 2 focuses on identifying the value elements of a medtech solution offering as perceived by HCPs, in contrast to the value elements associated with a traditional, stand-alone medical device offering.

3.4.3 Phase 3

3.4.3.1 Objectives and justification

The objective of this phase is to elaborate and further capture the value elements of a medtech solution offering through insights from medtech professionals. The interaction between healthcare providers and medtech companies influences both the structure and content of these solutions. A solution is viewed as a set of relational processes between customer and supplier (Tuli et al., 2007), where the form and content of servitised offerings continuously evolve to meet the needs of both parties (Ferreira et al., 2013). Different servitisation strategies involve varying types and content of services added to core products.

Customers often expect solutions to customise, combine and integrate products and services to address needs and requirements that may not be initially clear to them. Sometimes, a solution includes ongoing processes for identifying customer needs (Tuli et al., 2007).

This phase involves empirical study through interviews with leaders and managers in various roles within a major medtech organisation. These interviews are designed to expand upon and refine the findings from Phase 2, providing a deeper understanding of the value elements in medtech solutions.

3.4.3.2 Sample selection

In Phase 3, a purposive sampling approach similar to that used in Phase 2 is applied within a major medtech company. Interviews are conducted with senior management across various business functions, including sales, operations, services, finance and strategy. The sample comprises 12 individuals from the medtech company, each possessing extensive experience in medical technology and its management. These interviewees are well-acquainted with the solutions offering concept and bring international experience and insights from diverse healthcare markets. The profile of the participants is detailed in Table 3.3.

Consistent with Phase 2, this phase aims to gather comprehensive and diverse insights from within a leading medtech organisation that is actively engaged in the healthcare ecosystem. The goal is to capture responses and reflections from professionals operating within the medtech corporate environment, representing various roles and perspectives within the industry. By focusing on a single major organisation, rather than multiple companies, the approach seeks to provide a synthesised view of how the business model of solutions offering aligns with value elements. The purposive sampling strategy is designed to enhance understanding and capture nuanced perceptions rather than to achieve statistical generalisation. The emphasis is on exploring perceptions and reflections rather than on obtaining a representative statistical sample.

By concentrating on a major medtech organisation, the research seeks to gain a deep, detailed understanding of value elements from a corporate viewpoint. This thorough exploration is essential for creating a comprehensive framework that accurately captures the dynamic and

multifaceted nature of medtech solutions. It ensures that the framework is based on real-world experiences and insights from industry leaders. Consequently, this phase is pivotal for refining and validating the value elements identified in earlier phases, guaranteeing that the final framework criteria are robust, practical and aligned with industry best practices.

Table 3.3: List and background of Phase 3 participants

Interviewees	Title - Role	Background and experience	Years of experience in medtech organisation	Nationality
medintw#1	Modality Manager	Biomedical engineer, Product sales, Product expertise in Imaging modalities (Computed Tomography, Nuclear medicine), Modality leadership, Commercial leadership, international experience (> 20 countries).	7	Romania
medintw#2	Modality Manager	Electronic engineer, Product sales, Product expertise in Imaging modalities (Magnetic Resonance), Modality leadership, Commercial leadership, international experience (> 20 countries).	20	Poland
medintw#3	Modality Manager	Biomedical engineer, Field (Service) Engineer, Application training specialist, Product expertise in Imaging modalities (Mammography & Xrays), Modality leadership, International experience (> 20 countries).	18	Poland
medintw#4	Modality Manager	Biomedical engineer, Application specialist, Product expertise in Surgery and Imaging modalities (Vascular and Surgical), Modality leadership, International experience (>20 countries).	4	Greece
medintw#5	Strategy and Marketing Manager	Finance, Health economics, Modality leadership, Product expertise in Imaging, Product and Business marketing, Sales, Commercial operations, Finance leadership, International experience (> 20 countries).	22	Poland
medintw#6	Service Manager	Biomedical engineer, Field (Service) Engineer, Product expertise in Imaging modalities (Vascular systems), International experience (>4 countries).	22	Greece
medintw#7	Commercial Financing Manager	Accounting, Commercial finance, Banking sector, Design financing solutions for medtech customers, Leadership, International experience (> 20 countries).	8	Romania
medintw#8	Service Sales Manager	Biomedical engineer, Services leadership, Commercial expertise, Service operations, International experience (> 20 countries).	18	Greece
medintw#9	Clinical Education Manager	Biomedical engineer, Account management, Product expertise in Imaging modalities, Commercial and Sales leadership roles, Clinical education leadership, International experience (>20 countries).	13	Poland
medintw#10	Clinical Education Leader	Medical physicist, Application specialist, Clinical education leadership, International experience (> 20 countries).	4	Greece

Interviewees	Title - Role	Background and experience	Years of experience in medtech organisation	Nationality
medintw#11	Director of Project Management	Safety, Environmental and Quality engineer, Healthcare Project Manager, Product quality leadership, Lean leadership, International experience (>20 countries).	17	Hungary
medintw#12	Top Accounts Director of Service	Environmental engineering, Management & Marketing at production engineering, Value Business Management, Business development, Strategic account management, Driving service delivery in strategic accounts, international experience (> 20 countries).	12	Poland

3.4.3.3 Interview structure

The interviews with medtech professionals are designed to last between 45 minutes and one hour, allowing for detailed and comprehensive discussions. With participants' consent, these sessions are recorded and transcribed for accurate analysis and reference. Participants also have the option to speak off-the-record if they prefer. The interviews are conducted either in person or via a digital platform, in Greek or English, depending on the interviewees' background and preference. Participants are initially asked to describe their current business models within their medtech organisation, with a particular focus on whether they adopt a solutions offering approach. This preliminary inquiry aims to establish a foundational understanding of the concept of a solution as a servitised business model, setting the stage for a deeper exploration of the associated value elements. Participants are prompted with the following question:

'Please describe your medtech company's current business model, including its influence on product type (premium, value, performance, low-cost), operational support levels (basic, enhanced), sales approach (direct, indirect, digital), integration of clinical support, brand influence and whether comprehensive solutions are offered to customers'.

The responses provide a basis for understanding the concept of a solution as a servitised business model and guide the discussion on value drivers. The central question is designed to elicit insights into how value elements impact business models and market strategies, framed within the context of value-based healthcare, which pressures medtech companies to manage costs due to lower reimbursements and tighter budgets. The question is as follows, with the set of value elements identified in Phase 2 provided for reference:

'As governments and health insurers aim to control costs through lower reimbursements and tighter budgets, there is an ongoing discussion about value-based healthcare. In this context, medtech companies, like yours, offer solutions. We asked a sample of healthcare professionals about the value elements of a solutions/services offering compared to a product and summarised their responses. How do these value elements impact your business model or go-to-market strategy? Which value element has the greatest effect and how does it influence your approach?'

These questions encourage respondents to share their perspectives and provide specific examples from their professional experiences regarding the design and implementation of a solutions offering approach. Through these discussions, participants illustrate the benefits, barriers and challenges associated with adopting a servitised path.

Interviewees are also invited to suggest modifications to the list of value elements from Phase 2 and to share their opinions on its adequacy and applicability. This collaborative approach enriches the data collected and ensures that the research provides a comprehensive view of the current landscape in medtech solution offerings.

The semi-structured nature of the interviews, combined with the open-ended questions and interactive feedback process, facilitates a detailed understanding of how medtech professionals navigate and optimise value elements within their business models. This approach provides valuable insights into the practical implications of transitioning to a servitised value framework.

3.4.3.4 Output of Phase 3

Phase 3 offers insights from medtech professionals on the value elements of medtech solutions, enhancing understanding of the shift from medical devices to medical solution offerings. The output identifies the key drivers that enable this transformation.

3.4.4 Data analysis - Thematic analysis

This study collects data throughout all phases aiming at opening a window to the reality of people and their ecosystem, meaning healthcare and medtech professionals. Despite seeming contradictory, the notions of reality and perception converge around the concept of value since people recognise as value what they perceive as value, and this reflects their reality. Conversely, by examining their reality and understanding their genuine assessment of value, the constituents of their perceived value can be discerned.

The reality depicted in qualitative data, along with its richness and depth, can potentially be obscured by its sheer volume or complexity, thereby becoming what Miles (1979) termed ‘an attractive nuisance’ (Miles, 1979). Miles, Huberman and Saldana (2014) outline a series of

steps common to many qualitative analysis methods, including coding or thematic assignment, pattern identification and the gradual development of inferences and explanations through reflective elaboration (Miles et al., 2014). This study employs an iterative process of thematic analysis to identify units of meaning within the data - specifically, value criteria or elements. The iterative nature of this process ensures that analysis continues until no new value criteria or elements emerge from the data, signalling saturation.

Thematic analysis (TA), despite being relatively understated in its recognition as a method, includes diverse approaches categorised by Braun and Clarke (2019) into 'coding reliability', 'codebook' and 'reflexive TA' (Braun et al., 2019). These approaches differ significantly in how themes are conceptualised and identified within the data, reflecting distinct underlying paradigms and philosophical orientations.

Coding Reliability TA views themes primarily as domain summaries that reflect and encapsulate participants' contributions at a semantic level. Researchers identify specific areas or domains within the data, typically related to the research question and develop themes that serve as condensed summaries of these domains. This approach often involves multiple coders to ensure reliability and accuracy, with coding consensus evaluated using measures such as Cohen's kappa, a statistical tool to quantify the level of agreement between coders (J. Cohen, 1960; O'Connor & Joffe, 2020). The process is structured around a coding frame or codebook, which may be developed either before or during data collection, drawing on theoretical insights. The coding frame or codebook contains extensive details, including code definitions, descriptions, identification instructions and possibly examples, facilitating unbiased coding by coders unfamiliar with the subject matter. This approach, strongly linked to Boyatzis (1998), employs a positivist logic that bridges qualitative and quantitative paradigms (Boyatzis, 1998). Despite its qualitative techniques, the underlying philosophy resembles hypothesis testing, as the codebook is developed early and applied systematically to identify themes in the data.

Similarly, Codebook TA adopts a structured approach where themes are pre-conceptualised as summaries of domains before analysis begins. Like Coding Reliability TA, this approach seeks to fit data within predefined themes rather than allowing themes to emerge organically

from the data. However, Codebook TA offers greater flexibility in adjusting codes and themes throughout the research process without the requirement for consensus or strict reliability assessments. It aligns with qualitative methodologies and is often employed pragmatically to swiftly examine specific subjects and address focused research questions.

In contrast, Reflexive TA conceptualises themes as patterns or meanings that emerge through active engagement and interpretative work by the researcher (Braun & Clarke, 2006). This approach embraces the researcher's reflexivity, subjectivity and interpretative choices as integral to the analysis process (Braun & Clarke, 2013). Themes are the output of data interpretation after an active engagement and analytic work of the researcher. Consequently, the researcher's deep immersion in the data, the active choices and decisions, the values, experiences or even positionings inform the reflexivity and the analysis. Reflexive TA operates along several continua, including from inductive to deductive approaches, from experiential to critically oriented data interpretations and from critical realist to constructionist theoretical perspectives (Braun et al., 2019). This flexibility does not mean a lack of theoreticality but instead a broad possibility to choose the theoretical location of the research, resonating with qualitative inquiry. The coding process in Reflexive TA is iterative and open-ended, facilitating ongoing refinement and development of themes that capture central organising concepts and meanings within the data.

Braun *et al.* (2017) explain that thematic analysis is a technique used to identify, analyse and report patterns or themes within data. They also offer a six-phase guide for carrying out this analysis, as shown in Figure 3.3, reproduced from Braun and Clarke, (2006)(Braun & Clarke, 2006). This study employs thematic analysis within the Reflexive TA approach, understanding themes as insights or recurring ideas that surface through the researcher's immersive involvement and interpretive exploration. The resulting themes reflect the researcher's deep immersion in the data, informed by their values, experiences and perspectives.

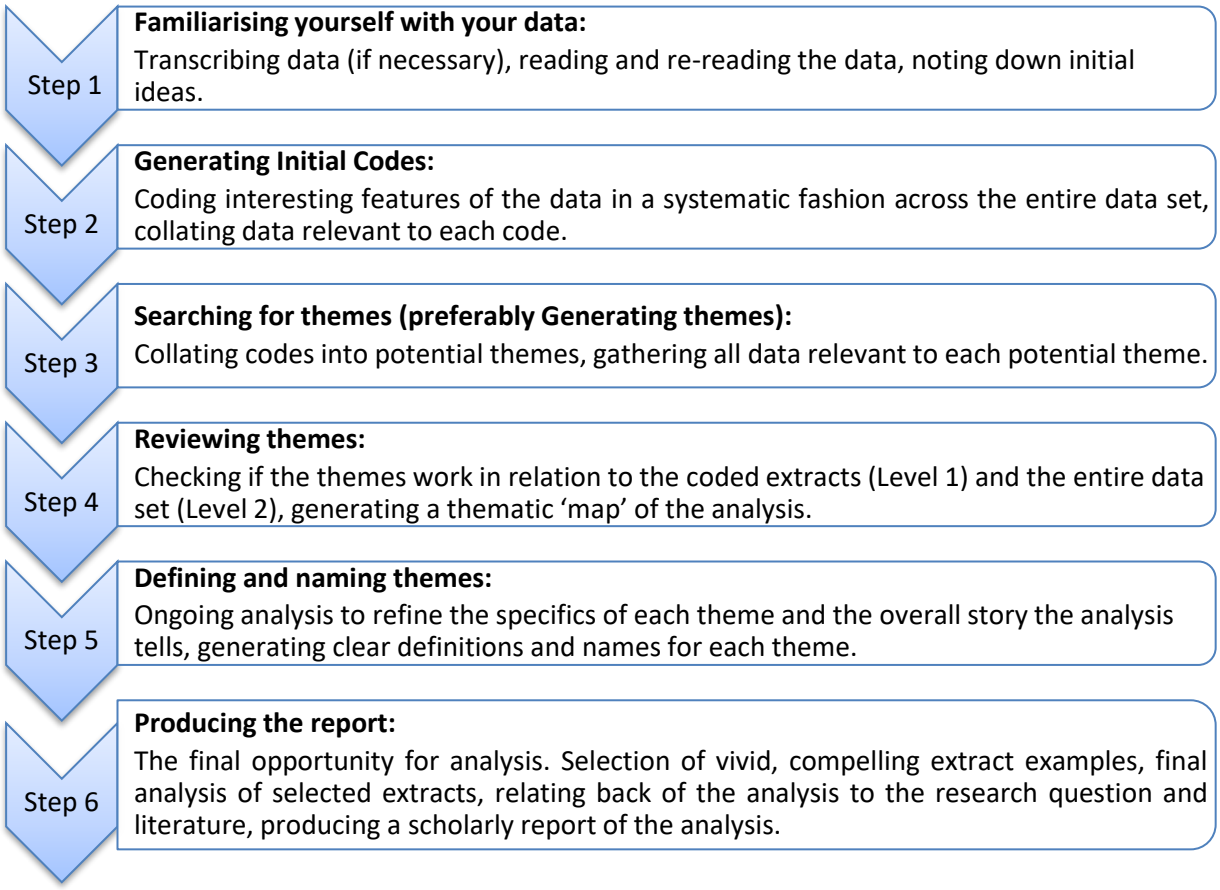

Figure 3.3: Summary of the six phases of thematic analysis

In Phase 1, the dataset comprises established frameworks in value, procurement and HTA, as well as related discourse from research projects and initiatives within the medtech value assessment domain. Thematic analysis is applied to identify a range of value-related criteria. While Phase 1 involves frameworks structured with criteria for assessing medical devices or interventions, the objective is not to develop a codebook for Phase 2, but rather to explore whether meaningful themes emerge that are relevant to the research question. The significance of these themes is determined by the researcher's judgment and justification, rather than their frequency or prevalence in the dataset. As Braun and Clarke (2006) assert, the value of a theme is not contingent on its occurrence rate but on its ability to capture something important about the research question (Braun & Clarke, 2006).

Accordingly, the researcher carefully scrutinised the data to identify key themes and sub-themes that encapsulate the core value criteria of the frameworks, focusing on concepts that are central to the phenomenon being studied. Phase 1 employs an approach similar to latent

thematic analysis (Boyatzis, 1998), aiming to develop a spectrum of value criteria to inform Phase 2, rather than simply cataloguing ideas that influenced the development of the frameworks.

Phases 2 and 3 involve semi-structured interviews with participants, which form the dataset from which value elements are extracted. During these phases, transcribed verbal data are analysed to uncover latent content. Thematic analysis is employed to identify recurring ideas, concepts and perspectives within the interview transcripts (Gioia et al., 2013; Yin, 2009) revealing potentially underlying assumptions and predispositions that influence the semantic articulation of the data. This in-depth exploration facilitates the comprehensive identification of value elements related to both medtech and solution offerings, allowing for a more nuanced understanding of the participants' perspectives.

Thematic analysis aims to discern the conceptual content behind articulated opinions to capture perceptions of value. The findings from Phase 1 are used solely to sensitise participants and stimulate discussion; Phase 2 and 3 analyses remain data-driven rather than theory-driven, as interpretations from Phase 1 do not guide the coding or thematic extraction process. Value elements are derived inductively from the data, leveraging theoretical sensitivity gained in Phase 1. In Phase 3, the focus shifts to the responses of participants regarding the outcomes of Phase 2. This analysis forms the basis for interpreting and elaborating the perceived value elements.

Throughout the thematic analysis process across all phases, an initial coding framework with multiple constructs is developed. As the analysis progresses, this framework evolves, leading to the identification of sub-categories of value criteria (as in Phase 1) or elements (as in Phases 2 and 3) and, ultimately, overarching value criteria or elements.

4. Phase 1: Key value criteria in medical device assessment

4.1 Introduction

This chapter examines Phase 1 of the research, focusing on key value criteria in medical device assessment as derived from existing value frameworks, VBP and HTA guidelines with the aim of exploring how these frameworks evaluate medical technologies.

The chapter begins with an analysis of value assessment frameworks used in the United States, with particular focus on the $ICER_a$ framework. This framework is selected for acknowledging the distinct differences between pharmaceuticals and medical devices while asserting that many of its conceptual elements are applicable to the assessment of medical devices. As such, it provides an important foundation for understanding value in healthcare, particularly in the context of cost-effectiveness and clinical outcomes.

Next, the EUnetHTA (European Network for Health Technology Assessment) Model is introduced. This widely adopted European framework offers a comprehensive approach to HTA, covering a broad range of criteria beyond just safety and clinical effectiveness. EUnetHTA evaluates medical devices from multiple perspectives, incorporating aspects such as ethical, organisational, social, legal, financial impact and patient outcomes. Due to its detailed development and extensive range of value domains, EUnetHTA serves as a crucial resource for identifying emerging value criteria relevant to this study.

The chapter continues by exploring additional frameworks and projects that contribute to the landscape of medical technology evaluation. These include the MEAT (Most Economically Advantageous Tender) model, the AdvaMed Framework and a range of European initiatives like MedtecHTA, AdHopHTA and INTEGRATE-HTA. The chapter also includes an overview of the National Institute for Health and Care Excellence (NICE) technology appraisal process, that covers health technologies, including pharmaceuticals, medical devices and interventions. NICE approach is selected for its comprehensive evaluation of both new and established

technologies, making it crucial for understanding how value is assessed within the broader healthcare context.

Finally, the chapter synthesises the key value criteria from these frameworks, emphasising how aspects such as clinical effectiveness, technology quality, operational impact, economic evaluation and patient-centred considerations are prioritised in the assessment process. This synthesis is visually represented in Table 4.7 and the Value Criteria Map in Figure 4.2 and forms the foundation for the subsequent phases of the research.

4.2 The USA value assessment frameworks

In the United States, at least five frameworks have been developed to provide a structured approach to assess and measure value. These frameworks aim to influence treatment decisions made by patients and their physicians, as well as decisions regarding reimbursement. The five major USA value assessment frameworks include:

- The American College of Cardiology and The American Heart Association (ACC-AHA) Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures
- The Conceptual Framework to Assess the Value of Cancer Treatment Options developed by the American Society of Clinical Oncology (ASCO)
- The Institute for Clinical and Economic Review ($ICER_a$) Value Framework
- The Memorial Sloan Kettering Cancer Center (MSKCC) DrugAbacus
- The National Comprehensive Cancer Network (NCCN) Evidence Blocks

These frameworks serve diverse purposes, focusing on specific diseases and catering to different target audiences. For instance, the ACC-AHA framework concentrates on cardiovascular care, while frameworks from ASCO, NCCN and MSKCC DrugAbacus are oncology-focused. The $ICER_a$ framework, in contrast, evaluates a wide range of interventions and treatments without specific disease limitations. Developed by various organisations, each framework seeks to capture value according to the priorities of its intended audience (J. T. Cohen et al., 2017). Frameworks from ACC-AHA, ASCO and NCCN, associated with professional

societies comprising physician members, are designed to facilitate shared decision-making between patients and physicians. On the other hand, $ICER_a$ and MSKCC DrugAbacus frameworks are primarily tools for policymakers and payors, in addition to being accessible to patients and physicians, influencing their respective value outputs significantly. Each framework produces distinct outputs (Dubois et al., 2019; Mandelblatt et al., 2017; Ollendorf et al., 2019; Schnipper & Bastian, 2016; Willke, 2019; Willke et al., 2019):

- ACC-AHA assesses treatment value using levels (high, medium, low, uncertain, not assessed).
- ASCO provides a 'net health benefit score (NHB)', which is a numerical output ranging from -20 to 130 and separately reports drug acquisition costs.
- $ICER_a$ evaluates long-term value for money and short-term affordability (impact to the health system budget), yielding 'care value' and 'health system value' benchmarks (J. T. Cohen et al., 2017).
- MSKCC DrugAbacus calculates a 'value-based price' based on user-selected weighted preferences, compared to pharmaceutical prices.
- NCCN utilises 'Evidence Blocks' to visually represent scores in five domains rated by an expert panel on a scale of 1 to 5.

Methods employed by these frameworks to deliver the output also vary in terms of evidence synthesis and grading, underlying assumptions in the assessments, benefit-cost weighting and scoring and the components considered in value assessments (Sorenson et al., 2017). The frameworks' intended purposes and target audiences largely define what constitutes value within each framework and consequently determine key value metrics. Primarily, frameworks emphasise clinical benefits and associated costs, with some addressing broader aspects such as disease severity, novelty, public health benefits or other contextual considerations. Table 4.1 summarises the primary components of value for each framework.

Table 4.1: Comparative overview of value components of USA frameworks

	ACC-AHA	ASCO	$ICER_a$	MSK Drug Abacus	NCCN
Value criteria	Clinical benefits versus risks Quality of evidence Cost-effectiveness ratio	(Improvement in) overall survival rate Progression-free survival Response rate Toxicity Palliation of symptoms Treatment - free interval (Improvement in) quality of life	Comparative clinical effectiveness Incremental cost-effectiveness Benefits beyond health Special ethical priorities Potential budget impact	Efficacy Tolerability Novelty Research and Development costs Disease rarity Population (health) burden Unmet need Prognosis	Efficacy Safety Quality of evidence Consistency of evidence Affordability

The value criteria can be categorised based on the primary aspects they address in the assessment: Efficacy, Safety, Other Benefits, Contextual Considerations, Affordability and Costs. While most value frameworks focus primarily on pharmaceuticals, the $ICER_a$ framework stands out by recognising the distinct differences between pharmaceuticals and medical devices, acknowledging their unique challenges. However, $ICER_a$ asserts that its conceptual elements remain applicable to medical devices (ICER, 2023).

4.2.1 The $ICER_a$ framework

The $ICER_a$ Value Assessment Framework establishes the conceptual methods for conducting $ICER_a$ reviews of medical tests, treatments and delivery system interventions, such as preventive programs and organisational changes, using a collaborative, evidence-based and population-focused approach. It aims to provide a comprehensive assessment by examining both long-term value for money and short-term affordability, as illustrated in Figure 4.1, reproduced from $ICER_a$ (2023). First released in 2015, it has undergone three updates that integrate public feedback and practical insights. The $ICER_a$ framework prioritises population-

level analysis over individual factors and it concentrates on evaluating evidence to guide broader decisions regarding care guidelines, pricing, insurance coverage and payment methods, rather than facilitating shared decision-making between patients and clinicians.

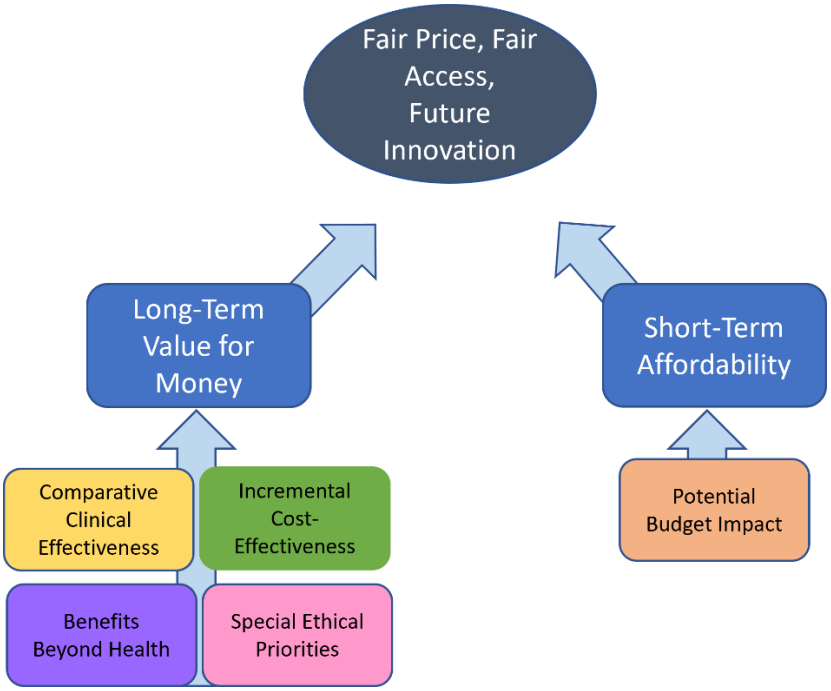

Figure 4.1: Conceptual structure of the $ICER_a$ value assessment framework (ICER, 2023)

Long-term value for money is the cornerstone of the $ICER_a$ value framework, including several key domains: 1) comparative clinical effectiveness, 2) incremental cost-effectiveness, 3) benefits beyond health and 4) special ethical considerations. Long-term value for money seeks to provide a judgment on patient outcomes and costs over an extended period. This may extend to the patient's lifetime, considering that the benefits and associated costs of a new treatment might take years to become evident. This judgment relies on a comparative clinical effectiveness process between two alternative treatments or interventions (Schnipper & Bastian, 2016). Multiple sources and types of evidence, including observational evidence, may be utilised to inform this comparative clinical effectiveness.

However, the $ICER_a$ framework also incorporates non-clinical outcomes in a domain labelled 'benefits beyond health'. This domain aims to acknowledge elements that matter to patients and impact their quality of life but are poorly captured in clinical trials. Such elements may include the complexity of the regimen and real-world adherence and outcomes, the

mechanism of action and potential spillover effects, the caregiver and family impacts, the patients' ability to return to work and their productivity levels and the impact of care options (e.g. the value of hope). Furthermore, assessing value with a long-term perspective requires considering contextual factors, such as the severity of the condition, the availability of other treatments and the ethical, societal and legal priorities. The $ICER_a$ framework ensures these elements are explicitly part of the value discussion and function as guides for using cost-effectiveness thresholds (ICER, 2020).

The latest version of the $ICER_a$ Value Assessment Framework emphasises the broader value dimensions, meaning the benefits beyond health and special ethical priorities focusing these considerations in four key subcategories:

1. **Patients - Unmet need:** This assesses the severity of conditions where current treatments are inadequate. It measures both absolute and proportional health shortfalls, focusing on potential health loss without treatment. Prioritisation is given to conditions that result in early death or have significant lifelong impacts.
2. **Caregivers - Quality of Life improvements:** This evaluates how a treatment impacts caregivers' quality of life, their ability to pursue education, work and manage family responsibilities.
3. **Health Equity - Relevance to disadvantaged communities and access improvement:** This examines the significance of a condition for underserved populations, supported by patient input and demographic data. Additionally, access improvement aspect evaluates whether a treatment's delivery method enhances accessibility for marginalised groups, including considerations of treatment complexity and options for home-based care.
4. **Ethical Considerations:** Ethical priorities, such as addressing unmet needs, reducing health disparities and focusing on interventions that target historical inequities are incorporated into the value assessment process to ensure a fair evaluation of care options.

The 2023 version assesses the same value criteria as the 2020 version but organises them into the four subcategories listed above for greater emphasis. Table 4.2 displays the $ICER_a$ long-term value for money domains and criteria, using the 2020 version as a more detailed

analytical framework. The domains (in bold) and criteria (in italics) are shown as per the $ICER_a$ framework, with descriptions underlining the core of each criterion.

Table 4.2: The $ICER_a$ long-term Value for Money (ICER 2020)

Domains	Criteria	Description
Comparative Clinical Effectiveness		Comparative clinical effectiveness evaluates whether there is sufficient evidence to show that one treatment offers greater health benefits than another for a specific patient group.
Incremental Cost-Effectiveness		The ratio of the cost difference between two interventions, divided by the difference in their effectiveness.
Benefits Beyond Health	*Mechanism of Action*	A potential new mechanism of action can expand treatment options to a wider range of patient populations. Additionally, a novel or distinct mechanism, unlike those currently used, may pave the way for spillover effects into other clinical areas.
	Complexity of regimen	The diverse levels of complexity in a regimen, including various methods of administration, can significantly impact patient adherence and the corresponding outcomes.
	Balance or Timing of Risks and Benefits ('Value of Hope')	Patients may value and make decisions based on the timing of risks or benefits and the associated uncertainty.
Special Ethical Priorities	*Disadvantaged or Underserved Communities*	Interventions targeting disadvantaged communities, which have been historically affected by discrimination or neglect, may warrant special consideration.
	Absolute QALY shortfall	The absolute QALY shortfall is defined as the total future potential health that a patient with a condition will lose without the current treatment. This metric helps prioritise based on the 'burden of disease'. For example, conditions that may cause early death in children will likely yield a high score and be prioritised accordingly.
	Proportional QALY Shortfall	The proportional QALY shortfall is defined as the ratio of health lost to total future health (life expectancy). This proportional calculation aids in prioritising treatments for patients who will lose a sizable percentage of their life due to the health condition. For instance, the proportional QALY

Domains	Criteria	Description
		shortfall score may be similar for children and the elderly facing the same conditions.
	Caregiver and Family Impacts	The impact of an intervention on caregivers and family should be considered, as it is not included in the economic models of the framework. This evaluation is primarily qualitative, since incorporating this impact into an economic model might produce results that, while technically correct, are not ethically or socially acceptable.
	Return to Work and/or Productivity	The effect on patients' ability to return to work and their productivity.

While the long-term perspective is particularly important, the evaluation of short-term affordability, and thus short-term effect on the healthcare system, complements the value assessment by examining the impact of a new intervention or treatment on the budget and planned health expenditures. Short-term analysis reveals the necessary measures for the healthcare system to accommodate the new treatment. These measures may involve pricing, coverage, or other priorities that payers or political authorities need to consider. $ICER_a$ has selected a five-year horizon to capture both the benefits and costs of new technology. For pharmaceuticals, the budget analysis result is compared with a threshold (currently the US economy's growth rate) and if this threshold is exceeded, discussions are initiated on measures needed to ensure affordability.

Devices pose challenges in their development, evaluation and usage, and thereof require adjustments to $ICER_a$'s standard value framework. While the fundamental principles of the framework remain unchanged, the approach to evaluating devices differs. For example, randomised controlled trials (RCTs) may not always be possible during early evaluations due to ethical or practical limitations. Moreover, as devices undergo iterative updates and practitioners face learning curves, assessing the available evidence becomes more complex. Evaluating long-term cost-effectiveness is also difficult, as evolving devices impact costs, effectiveness and the types of patients treated. These factors further complicate budget impact estimates, making it harder to set accurate growth targets. Consequently, $ICER_a$ adapts its methods to account for these unique aspects of devices within the overall value framework (ICER, 2023).

4.3 The EUnetHTA Model

The European Network for Health Technology Assessment (EUnetHTA) was formed by eighty institutions from 28 European member states with the aim of supporting collaboration in HTA activities across Europe. This collaboration intended to reduce overlaps and duplication of efforts while producing more efficient assessments, thereby delivering more value to healthcare systems at the European, national and regional levels. In other words, EUnetHTA's project aimed to address the question of how to create, facilitate and promote sustainable HTA cooperation in Europe. This objective and motivation towards the harmonisation of HTA activities in Europe led to the development of the HTA Core Model (De Folter et al., 2018; EUnetHTA Joint Action, 2016).

The HTA Core Model provides a set of main elements or domains to be considered in an HTA. This enables a standardised approach across various organisations, allowing for similarly standardised reporting and, primarily, setting the path for a common HTA framework. The scope of the HTA Core Model includes diagnostic technologies, medical and surgical interventions, pharmaceuticals and screening technologies. This scope, which explicitly includes medical devices, along with the plurality of organisations involved in the project, make the EUnetHTA Model a valuable source of value criteria for this research.

The HTA Core Model is structured around three main components:

- **HTA Ontology**: Defines the questions the HTA should answer.
- **Methodological Guidance**: Explains how to find the answers to those questions.
- **Reporting Structure**: Details how to report those answers.

The HTA ontology seeks to identify the areas of assessment, meaning those areas where value exists within a technology under consideration. The HTA Model divides HTA information into nine domains, as outlined in Table 4.3. Each domain comprises topics and each topic is further divided into issues. These issues represent the questions that should be addressed throughout an HTA project. The combination of a domain, topic and issue defines the standardised unit of the HTA Model, known as an assessment element.

Table 4.3: HTA Core Model domains and associated issues

	Domains	Issues
1	Health problem and current use of technology	Target population, target condition, current management of the condition, utilisation, regulatory status.
2	Description and technical characteristics of technology	Features of the technology, investments and tools required to use the technology, training and information needed for utilising the technology.
3	Safety	Patient safety, occupational safety, environmental safety, safety risk management.
4	Clinical effectiveness	Mortality, morbidity, test-treatment chain, change-in-management function, health-related quality of life, quality of life, patient satisfaction, patient safety, test accuracy, benefit-harm balance.
5	Costs and economic evaluation	Resource utilisation, measurement and estimation of outcomes, examination of costs and outcomes, characterising uncertainty, characterising heterogeneity, validity of the model(s).
6	Ethical analysis	Beneficence/non-maleficence, autonomy, respect for persons, justice and equity, legislation, ethical consequences of the HTA.
7	Organisational aspects	Health delivery process, structure of healthcare system, process-related costs, management, culture.
8	Patients and social aspects	Individual, major life areas, information exchange.
9	Legal aspects	Autonomy, privacy, equality in healthcare, authorisation and safety, ownership and liability, regulation of the market.

The assessment elements structure all potential HTA information in a standardised format that facilitates reporting and sharing. These elements can be categorised into two groups: core elements and non-core elements, depending on their significance and transferability across national borders or other contexts. However, this categorisation may involve subjectivity influenced by specific settings, leading HTA organisations or user groups to prioritise differently. In this framework, the domains serve as the focal areas for investigating the value elements of a technology. Each domain and its respective topics (highlighted in bold), as presented in the EUnetHTA framework, are discussed in more detail in the following sections (4.3.1 - 4.3.9).

4.3.1 Health Problem and Current Use of Technology

To assess technologies effectively, it is important to understand their role within the healthcare pathway, including diagnostics and treatment and their relationship to existing technologies. Gathering background information about the health condition, epidemiology, target populations, organisational settings and technology usage is essential. The Health Problem and Current Use of Technology domain, abbreviated as CUR, provides an analysis of the health issue, including its pathophysiology and impact on individuals and society. It also covers current management practices, such as technology usage, policies and regulatory factors, offering the broader context for evaluating the technology.

This domain is critical because it establishes the foundational knowledge needed to interpret findings from other assessment domains, taking into account specific geographic, population, or organisational settings. Clearly defining the health problem and target populations helps determine the most suitable use of the technology. The analysis offers a complete view of the environment in which the technology will be implemented, exploring potential alternative uses, which helps stakeholders understand the wider implications of its adoption. In the case of medical devices, this domain provides the necessary information to understand the technology's role in managing the target condition and its relationship with existing technologies, enabling the evaluation of the technology's value and its potential applications.

The CUR domain covers five key topics addressing 18 specific issues. These topics reflect how healthcare technologies are assessed based on population, disease, existing alternatives, usage trends and regulatory and reimbursement contexts. The topics are briefly described below and a detailed breakdown of these topics and issues can be found in Table 9.1 in Appendix 1.

Target population: The topic addresses the specific population for the technology considering factors such as severity of the condition, timing and risks. This includes understanding the population size and its influence on resource needs and health policy trends, particularly in personalised medicine.

Target condition: The topic focuses on the disease or health condition being addressed by the technology, including risk factors, disease progression, patient perceptions and societal burden. These aspects help evaluate the technology's value and its impact on different stages of disease, ranging from life-threatening conditions to self-limiting illnesses. For instance, technologies designed for life-threatening conditions, like severe coronary artery disease, require different evaluative metrics compared to those targeting self-limiting conditions such as the common cold.

Current management of the condition: The topic examines the landscape of existing alternatives and practices. The focus is on alternative technologies currently in use, diagnostic guidelines and how the new technology fits into existing care practices - whether as an add-on or a replacement.

Utilisation: This topic looks at how the technology is used across various populations, conditions and regions. It includes insights into the current and future utilisation rates, technology adoption phases (experimental, emerging, established, or obsolete) and variations in use across settings.

Regulatory status: The topic points out the technology's marketing authorisation, such as CE marking or FDA/EMA approval and its reimbursement status, which is a key factor influencing adoption in different healthcare systems.

4.3.2 Description and Technical Characteristics of Technology

This Description and Technical Characteristics of Technology domain, abbreviated as TEC, details the technical characteristics of the technology, including its development history, introduction purposes, intended users, conditions of use in healthcare settings and associated material requirements for facilities, equipment and personnel. It also covers specific training and informational needs. Regulatory status, where relevant, is also provided.

Understanding the technical features and clinical scope of a medical device is essential for acquiring the foundational information necessary for the assessment. Furthermore, it is

crucial to describe and consider the premises, pre-installation requirements, civil engineering and construction works necessary for the installation and operation of the technology. For example, imaging devices require robust radiation protection infrastructure. Additionally, the technology may necessitate specific personnel skills, training and clinical education. Lastly, understanding the regulatory status of a technology is critical in determining its level of development and readiness for integration into healthcare practices.

The description and technical characteristics of medical devices provide the groundwork for assessing the technology and identifying its unique aspects compared to comparators. This domain consists of 16 issues organised into five topics. A brief overview is provided below, with a more in-depth analysis available in Table 9.2 in Appendix 1, which offers a description of each issue within the domain topics.

Features of the technology: This topic underlines the importance of comprehensive descriptions of medical technologies and their comparators, emphasising a multi-faceted approach to evaluating new technologies. Key elements include a clear delineation of features, mechanisms of action and claimed benefits, which are essential for assessing efficacy and potential advantages over existing options. Each technology should be detailed alongside its alternatives, highlighting its procedures, intended uses and distinguishing characteristics. The evaluation process focuses on claimed benefits, such as enhanced safety, effectiveness, accuracy and patient compliance, all of which impact clinical outcomes and the organisation of care. Furthermore, technologies are classified by their development phase, such as experimental, emerging, established, or obsolete, which significantly influences their assessment, particularly when considering modifications or new applications. Decision-making regarding technology use involves HCPs, patients and caregivers, with technologies applied across various levels of care (primary, secondary, or tertiary). Finally, reference values or cut-off points are critical for interpreting teachnology evaluation results accurately and consistently.

Regulatory status: This topic emphasises the regulatory status of a technology as crucial for its market authorisation and reimbursement. Clear indications for use, set by regulatory bodies, are essential as they define the specific conditions and purposes for which the

technology can be applied. Similarly, established reimbursement pathways are also vital, as they determine how healthcare providers can receive payment for using the technology. These elements influence both the financial feasibility for providers and patient access to beneficial innovations.

Investments and tools required for technology utilisation: This topic examines how the successful integration of medical technologies relies on specific infrastructure and resource needs. It highlights the need for specialised facilities, such as radiation-protected areas or facilities equipped with essential safety measures. The issues of the topic demonstrate that those different technologies demand various types of installations and equipment, often requiring substantial investments. Furthermore, they emphasise the need to account for disposable items essential for operating these technologies in planning and budgeting. This stresses the importance of considering the broader ecosystem surrounding a technology to ensure that all necessary resources are in place for its effective use.

Training and information needed for technology utilisation: This topic focuses on the critical importance of training and education in the deployment of medical technologies. It highlights that different user groups, such as HCPs, patients and caregivers, require customised training programs to ensure the safe and effective use of these technologies. These programs should range from basic instructions to in-depth, hands-on training sessions, addressing the complexity of the technology involved. Additionally, the necessity for quality assurance processes and ongoing education underlines the dynamic nature of medical technology and the continuous evolution of healthcare practices.

Other considerations: This topic includes information about the technology's manufacturer as an important factor in understanding the technology itself.

4.3.3 Safety

Safety is fundamental to all assessment efforts as it includes any unwanted or harmful effects resulting from the use of a health technology. Safety information, combined with effectiveness data, underpins further evaluations of the technology such as cost and

organisational impact. Safety information is crucial for evaluating the overall diagnostic or therapeutic value of a technology.

The Safety domain, abbreviated as SAF, focuses on gathering essential insights into potential harmful effects on patients, healthcare providers and the environment resulting from the use of a technology or medical device. Assessing safety is particularly critical in cases where the technology poses any risk of serious harm or a high risk of milder harms. It is also crucial when the technology is used by large populations or when the benefit-harm balance is marginal. Safety assessment becomes essential for both individuals and policymakers, providing valuable data for technology assessment, especially when there are no significant differences in effectiveness compared to other options. Additionally, the acceptability of a medical technology can be compromised by issues such as poor tolerability or patient discomfort. SAF domain outlines four topics covering 12 issues, as described below and outlined in the Table 9.3 in Appendix 1.

Patient safety: The topic focuses on the key concerns surrounding the use of medical technology, particularly the need to ensure the safety of devices compared to alternatives. This includes identifying, categorising and reporting risks based on their frequency and severity, with special attention to radiation-based technologies like CT scanners, where even minor dosage changes can impact safety. Variability in safety profiles across different settings and user groups highlights the importance of standardised protocols to maintain consistent safety. Vulnerable populations, such as the elderly, children and immunocompromised individuals, require tailored approaches to minimise risks, as patient-specific factors can affect technology outcomes. Diagnostic accuracy is also crucial for patient safety, as false positives or negatives can lead to significant treatment errors, emphasising the need for reliable diagnostic tools. Additionally, user-dependent risks, influenced by training and expertise, stress the importance of comprehensive training and assessment to prevent human error.

Occupational safety: This topic emphasises the significant concern of occupational hazards in ensuring the safety of HCPs who use medical technology. Regulatory requirements for continuous monitoring of these hazards, such as radiation exposure in imaging systems, highlight the need for protective measures in the workplace.

Environmental safety: This topic examines the significant potential risks that medical technologies pose to the environment. The presence of hazardous materials and radiation requires thorough environmental assessments and strict adherence to safety regulations. Such measures are essential to ensure that healthcare practices do not negatively impact public health, emphasising the importance of protecting both the environment and the communities that depend on these technologies.

Safety risk management: This topic emphasises the importance of effective safety management plans in reducing the risks associated with medical technology. Such plans incorporate training programs, risk minimisation protocols and strict compliance with regulatory guidelines. A significant focus is placed on manufacturers developing dose-reduction algorithms, which represent proactive efforts to enhance safety in technology use. Moreover, systematic data collection and monitoring of both the technology and its alternatives are essential for ongoing safety assessment and improvement.

4.3.4 Clinical Effectiveness

Effectiveness is the core focus in evaluating any healthcare technology. The Clinical Effectiveness domain, abbreviated as EFF, concerns the evaluation of clinical effectiveness in health technology assessments. It focuses on assessing whether a technology provides more benefits than harms in real-world healthcare settings, as opposed to controlled trial conditions. Key aspects include comparing interventions directly, evaluating patient-relevant outcomes like mortality and quality of life.

In healthcare, stakeholders typically prioritise ensuring the safety and effectiveness of a technology before considering its costs. The domain of Safety focuses on the harms. Clinical Effectiveness domain primarily examines the benefits in terms of mortality, morbidity and quality of life. This domain is crucial in health policy because stakeholders, such as insurers, government agencies, healthcare providers and consumers, prioritise understanding the effectiveness and safety of technologies. Evaluating these aspects is essential as cost considerations become relevant only when technologies demonstrate effectiveness.

However, when a technology proves less effective compared to alternatives but is cost-effective, assessing additional aspects becomes pertinent.

The EFF domain outlines 11 topics covering 29 issues. The topics related to this domain are described below and further delineated in the Table 9.4 in Appendix 1.

Mortality: This topic focuses on how medical technology influences overall or disease-specific mortality. It highlights the importance of understanding how a technology may reduce mortality from one cause while potentially increasing it from others.

Morbidity: The topic explores how technology affects the effectiveness of subsequent interventions, symptoms, disease progression and treatment efficacy. This includes understanding how tests like MRIs impact surgeries and how diagnostic accuracy improves patient outcomes.

Function: The topic looks at the technology's effect on patients' body functions, work ability, return to previous living conditions and activities of daily living. This highlights the broader functional impacts on individuals' daily life and overall well-being.

Health-Related Quality of Life (HRQL): The topic considers both generic and disease-specific HRQL, assessing how technology affects physical health, psychological well-being, independence and social relationships, with a focus on patient-specific outcomes.

Quality of Life (QoL): This topic examines how knowledge of test results affects a patient's overall quality of life beyond health-related factors. The impact can be both positive and negative; while the primary health outcome may not change, associated symptoms can significantly influence the patient's experience and perception of their quality of life.

Patient satisfaction: The topic evaluates the patient's perception of a technology, which affects its acceptability and potential for wider use.

Test-treatment chain: The topic examines whether there are effective treatments for conditions detected by the technology. This is crucial, especially when technology can identify risks without offering therapeutic interventions.

Test accuracy: The topic covers the accuracy of medical tests, including sensitivity, specificity and the optimal threshold for diagnosis. It also examines how accuracy varies across different settings and populations and the importance of consistent interpretation of test results.

Patient safety: The topic discusses the potential consequences of false positives, false negatives and incidental findings on patient safety. Ensuring that technologies minimise incorrect results is key to avoiding inappropriate treatments.

Change-in-management: The topic focuses on how technology can modify the need for hospitalisations, influence physicians' management decisions and improve detection and management of other potential health conditions.

Benefit-harm balance: The topic emphasises the need to weigh the overall benefits and harms of a technology, consolidating evidence to find a balance between its risks and rewards.

4.3.5 Costs and Economic Evaluation

Since the start of 21st century, healthcare expenditures have escalated globally, straining national economies and healthcare systems (Deloitte, 2024; World Economic Forum, 2024). Limited healthcare funding globally necessitates a rigorous examination of healthcare costs and investments to optimise value for money (Counte et al., 2019). Economic evaluation aims to achieve an optimal balance between costs and health-related outcomes. The Costs and Economic Evaluation domain, abbreviated as ECO, compares costs and outcomes of healthcare technologies to guide decisions on resource allocation, focusing on economic efficiency. This information is critical as it reflects the cost-effectiveness of health technologies and aids in assessing the opportunity cost of comparative options since, a technology that is clinically effective may not be economically viable or may be more expensive compared to

equally effective alternatives. Several types of economic evaluations are commonly used within HTA:

1. **Cost-Consequence Analysis (CCA)**: Lists costs and all relevant outcomes of different technologies without aggregating them into a single measure.
2. **Cost-Effectiveness Analysis (CEA)**: Measures outcomes in natural units (e.g. life years gained, cases detected) and compares costs across technologies to determine the cost per unit of outcome gained.
3. **Cost-Utility Analysis (CUA)**: Measures outcomes in terms of utility, usually QALYs, providing a common metric to compare the cost-effectiveness of interventions across different diseases and conditions.
4. **Cost-Minimisation Analysis (CMA)**: Assumes equal effectiveness among alternative interventions and focuses solely on comparing costs.
5. **Cost-Benefit Analysis (CBA)**: Measures all costs and outcomes in monetary terms, allowing for a direct comparison of costs and benefits in dollar terms.

The outcomes of economic evaluation in healthcare vary depending on the type of analysis conducted (e.g. CCA, CEA, CUA, CMA, CBA). Common outcomes include tabular presentations of costs and outcomes, $ICER_b$ metrics, incremental cost-effectiveness planes or efficiency frontiers and net monetary benefits or net health benefits. $ICER_b$ metrics are widely used but should be complemented with detailed components, such as costs, LYs and QALYs along with their confidence or credibility intervals. Decision-makers use $ICER_b$ thresholds to assess whether a technology is cost-effective, considering the willingness-to-pay for health outcomes. These thresholds can vary depending on the technology, disease and jurisdiction. The significance of $ICER_b$ outcomes in economic evaluations is shaped by specific healthcare contexts and decision-making processes. A healthcare system, for example, may be more inclined to fund a new cancer treatment, especially if it is seen as a breakthrough or addresses a life-threatening condition, by adjusting the thresholds or demonstrating a greater willingness to pay for additional QALYs.

The ECO domain integrates evidence from areas such as Safety and Clinical Effectiveness to support value-for-money assessments in publicly funded healthcare systems with limited resources. While economic evaluation is crucial for decision-making, it should also consider

societal factors like equity and access. This approach balances economic efficiency with broader societal goals, ensuring transparent reporting and methodological consistency, as per EUnetHTA guidelines. Collaborations with other HTA domains ensure comprehensive assessments, while transparency and validity are essential for guiding resource allocation decisions. Integrating economic evidence with clinical and organisational factors enhances the relevance of HTA outcomes across diverse healthcare settings. ECO domain outlines six topics covering 11 issues. A brief overview of these topics is provided below, with a more detailed breakdown available in Table 9.5 in Appendix 1.

Resource utilisation: The topic addresses the utilisation of resources associated with healthcare technologies. This involves identifying both the types and quantities of resources used, whether for a new technology or its comparators. Resource utilisation not only covers healthcare infrastructure but also considers patient-related costs and societal impacts. Furthermore, the adoption of new technologies can influence the necessity for other interventions, modifying the use of complementary technologies. A major consideration of this topic is the budgetary impact, where decision-makers assess the financial implications of implementing various technologies within healthcare systems.

Measurement and estimation of outcomes: The topic focuses on the identification, measurement and valuation of health outcomes associated with healthcare technologies. Outcomes are often evaluated using clinical effectiveness data and may be represented through metrics like QALYs. This topic stresses the importance of rigorously measuring the outcomes of technologies to ensure that cost evaluations reflect real-world health benefits.

Examination of costs and outcomes: This topic reflects the essence of cost-effectiveness analysis, aiming to determine whether the additional benefits of a technology justify the extra costs involved. The difference in costs and outcomes is often represented by $ICER_b$ or similar metrics.

Characterising uncertainty: The topic highlights the importance of addressing uncertainties that may arise from data limitations, assumptions in models, or the variability of health outcomes. Characterising uncertainty is necessary for transparent reporting and can

significantly impact decision-making processes, as it allows stakeholders to consider the potential range of economic outcomes.

Characterising heterogeneity: This topic emphasises the variability in costs and outcomes across different patient subgroups or treatment contexts. Understanding and documenting these variations are essential for accurate economic evaluations, ensuring that subgroup-specific cost-effectiveness is considered in decision-making.

Validity of models: The topic revolves around the validity of the economic models used in cost evaluations. This topic includes a critical examination of the assumptions underlying these models, such as time horizons, discount rates and the scope of resources included. Transparent reporting of methodological assumptions ensures that the models accurately reflect the real-world implementation of technologies. Additionally, the validation process - whether through internal checks or external review - ensures that the models provide reliable and trustworthy economic estimates.

4.3.6 Ethical analysis

Medical technology aims to enhance human health and quality of life, impacting moral norms and values (Saarni et al., 2008). This influence stems from technology adoption, consequences and the ethical considerations integral to HTA.

The use of technology is intended to promote a good life and alleviate suffering, prompting ethical questions about what constitutes a good life and how to evaluate technologies designed to enhance human well-being (Saarni et al., 2008). Ethical analysis domain, abbreviated as ETH, aims to clarify the normative and value-based considerations that should guide health technology assessments (Assasi et al., 2016). While ethical aspects vary across technologies and regions, their integration into assessments enhances transparency and accountability. Despite its recognised importance, integrating ethical analysis into HTA processes remains a challenge, requiring explicit consideration tailored to each technology's unique context and purpose (Hofmann, 2008; Lehoux & Williams-Jones, 2007). Ethical considerations are particularly pertinent in screening, where issues like overdiagnosis and

moral dilemmas are amplified. Diagnostics, like medical devices, raise unique ethical considerations beyond those common to all technologies, described below:

1. It is essential to clarify the diagnostic purpose, which can range from guiding treatment decisions to protecting public health. Although many procedures, such as echography, pose minimal direct risk, they are often perceived as benign and solely focused on providing information. However, increased testing is associated with increased risks, highlighting the need to assess both direct harms and the broader implications of test outcomes, including false positives (FP), false negatives (FN), true positives (TP) and true negatives (TN). For example, the use of mammography for breast cancer screening goes beyond merely providing information; it also has significant implications for individual and public health that require careful evaluation. This emphasises the importance of clarifying the diagnostic purpose and understanding both the direct and broader risks linked to increased testing.

2. Diagnostic tests can unexpectedly change care pathways and treatment protocols, often requiring additional interventions or care options following a diagnosis or positive triage results. Even when conditions are untreatable, patients and families may value diagnostic information for making personal decisions, which can reshape healthcare system demands and impact both patients and providers. The introduction of a highly accurate genetic test that diagnoses a rare disease long before symptoms appear, or even at birth, for example, could lead to such changes.

3. Diagnostic tests can change disease perceptions by introducing new technologies that, while not entirely replacing existing tests, may lead to more frequent diagnoses of milder cases and shifts in therapeutic approaches, prompting the need for updated effectiveness studies. For example, the introduction of an earlier-stage diagnostic test for Alzheimer's disease calls for new research and updates to treatment protocols to ensure they remain effective for the broader, newly diagnosed patient population.

4. Advanced diagnostic technologies, such as genetic tests and imaging (e.g. non-invasive prenatal testing and ultrasound) for prenatal screening, can affect individual self-

perception and behaviour. These tests provide crucial information about potential genetic conditions, influencing how expectant parents perceive their pregnancies. For instance, a positive result for a genetic abnormality may prompt parents to reconsider their choices, affecting their emotional well-being and future planning. Thus, these technologies shape not only medical decisions, but also personal identities and behaviours related to parenthood.

5. The value of diagnostic test information differs among stakeholders; for instance, a positive HIV test result holds significant implications for patients, who may experience stigma and anxiety, while physicians view it as critical for guiding treatment decisions. Ethical challenges emerge in communicating these results effectively, ensuring that patients receive the necessary support without facing discrimination. Balancing transparency with sensitivity is essential to benefit all stakeholders while minimising harm to individuals' self-esteem and social standing.

The domain addresses ethical considerations in technology use and HTA, including endpoint selection and economic evaluation. It acknowledges that HTA involves not only maximising health benefits but also navigating ethical complexities inherent in healthcare decisions. Ethical analyses closely interact with legal and social evaluations, providing comprehensive decision support for healthcare interventions. It outlines six topics covering 19 issues, rooted in general societal values, healthcare system objectives and technology-specific impacts. The detailed topics and issues related to this domain are outlined below and further delineated in Table 9.6 in Appendix 1.

Benefit-harm balance: The topic focuses on evaluating the benefit-harm balance of health technologies, considering not only clinical effectiveness but also patient perceptions and the overall burden of the disease. Benefits and harms are perceived differently by patients, families, caregivers and society. Unintended consequences, such as overdiagnosis and medicalisation, can impact patients and their support systems. Ethical assessments must account for these broader societal effects, emphasising the need for comprehensive evaluations that consider both direct and indirect impacts on all stakeholders.

Autonomy: Autonomy, especially for vulnerable populations, is another key topic. Using technologies on individuals with limited decision-making capacity raises ethical concerns, as many technologies can impact patient autonomy. It is essential that patients are well-informed about their care and the implications of technology on their daily lives, with adequate support to exercise their autonomy. The potential impact of technology on the patient-physician relationship, including trust and ethical standards, is also a critical issue.

Respect for persons: The topic highlights the ethical duty to honour human dignity, especially for vulnerable individuals. The use of technology can risk dehumanising patients, labeling them, or undermining their value. This topic also covers the impact of technology on patients' moral, religious and cultural beliefs, which may conflict with care, creating ethical dilemmas. Privacy and data management are also key concerns, emphasising the need to protect patients' rights particularly in the digital age.

Justice and equity: This topic focuses on the fair distribution of healthcare resources, particularly as technologies can be costly and may require resource reallocation, impacting certain patient groups more than others. Ensuring equitable access to these technologies is essential, addressing barriers related to geography, gender, ethnicity and other social determinants of health.

Legislation: The topic focuses on the impact of technology on basic human rights, particularly equality and access to healthcare. As existing regulations may not fully address emerging ethical challenges, there is a need for legislative updates to reflect the evolving landscape of health technologies.

Ethical consequences of HTA: The topic highlights key considerations in selecting endpoints and assumptions for economic evaluations. The ethical implications of choosing specific criteria and the timing of assessments are vital to ensuring fair access to new treatments. Potential biases in decision-making and the fairness of addressing patient needs are critical concerns that demand continuous scrutiny.

4.3.7 Organisational aspects

For many years, HTA focused on the clinical aspects and costs of health technologies (Banta, 2003). However, the introduction of technology in healthcare facilities and regional or national health systems affects various organisational aspects, such as infrastructure, medical programs, patient workflows, personnel skills and attitudes, communication practices, work processes and culture. The increasing emphasis on organisational issues in HTA reflects a recognition that resource allocation decisions for technologies are crucial and that organisational aspects influence the behaviour of managers and health professionals (Battista, 2006). The Organisational Aspects domain, abbreviated as ORG, assesses these impacts to capture the broader effects of technology within the organisational space. This is a challenging task, as technology can impact different levels of organisations, including healthcare facilities (e.g. hospitals), regional health systems and national health systems (EUnetHTA Joint Action, 2016; Schnell-Inderst et al., 2015).

The ORG domain focuses on how various resources (materials, human skills and knowledge, money, attitudes, work culture) are mobilised and organised when implementing technology and the subsequent impacts on the organisation and healthcare system. Organisational aspects are considered at three levels:

1. **Intra-organisational**: How information about new technology is provided to patients within an organisation.
2. **Inter-organisational**: How communication occurs between different organisations.
3. **Healthcare system level**: How national objectives are set.

Stakeholders, such as staff, patients, payers, providers and suppliers, each with different aims and expectations, are involved at various levels. Organisational elements include physical structure, social relations, technology and culture, that define task assignments, reporting systems and coordination mechanisms. Different types of organisations (profit centres, matrix, network) exist. The complexity of the respective processes makes the assessment of the aspects a demanding and challenging task. The information needed and the assessment viewpoint is different for a hospital manager in a decision-making process for the introduction

of a technology within a hospital from the one of a policymaker on the national level decision-making. The ORG domain includes five topics with a total of 15 issues, representing significant organisational concerns relevant to specific technologies. The topics are described below, with detailed topics and issues related to this domain provided in Table 9.7 in Appendix 1.

Health delivery process: The topic explores how the introduction of technology in healthcare impacts the delivery process by transforming care pathways, patient flow and the roles of HCPs. While technology can drive efficiencies, it also affects waiting times, care responsibilities and communication among stakeholders, requiring careful management to maintain quality care and patient satisfaction. It may shift care from inpatient to community settings and redistribute responsibilities between patients, caregivers and providers. Additionally, technology demands ongoing staff training, which can influence job satisfaction and organisational dynamics. It also reshapes how healthcare stakeholders collaborate and necessitates updated quality assurance systems to ensure compliance with standards. Overall, technology transforms healthcare delivery, impacting workflows, care coordination and quality monitoring.

Structure of healthcare system: This topic explores how the organisational structure of healthcare systems - whether centralised or decentralised - affects the implementation and accessibility of technology. In centralised systems, advanced technologies are typically concentrated in specialised facilities, limiting broader access. In contrast, decentralisation can promote wider access and improve the quality of care. The adoption and use of new technologies are influenced by various factors, including cultural, economic, social and geographic elements, which affect their acceptance at individual, population and system levels.

Process-related costs: This topic focuses on the financial implications of adopting new technologies. The costs of acquisition, installation and ongoing maintenance can place significant strain on budgets, requiring careful planning for infrastructure investments and operational expenses. Additionally, it is crucial to assess how a new technology may alter the demand for existing resources or require new ones, ensuring effective budgeting and resource management in healthcare environments.

Management: This topic explores the challenges and opportunities technology integration presents for healthcare management. It requires a strategic approach to risk management, resource allocation and operational oversight, along with ongoing staff training and role adaptation. While decisions on technology adoption, influenced by stakeholders like policymakers, HCPs and patients, impact patient outcomes and care equity, transparency and establishing appropriate criteria in decision-making is crucial to consider all relevant factors, such as clinical need and cost-effectiveness.

Culture: This topic explores how the acceptance of new technology in healthcare is influenced by cultural factors, such as staff comfort, organisational readiness and public perception. Early engagement with all stakeholders, including HCPs, patients and regulatory bodies, can facilitate smoother implementation and higher acceptance. Effective collaboration and communication are key to building trust, securing support and driving sustainable improvements in healthcare delivery.

4.3.8 Patient and Social aspects

Patients are integral to the evaluation of health technologies due to their firsthand experience of the disease's impact and treatment implications. They directly perceive and evaluate how technologies affect their health conditions and can provide feedback on practical implications like effectiveness, ease of use and impact on daily life. Beyond being passive recipients of healthcare, patients assume active roles in society, as family members, citizens, employees and consumers, and the introduction of a health technology can create new responsibilities or alter capabilities across these roles, potentially affecting daily routines in both positive and negative ways. Caregivers, including family members and friends, also play a crucial role by witnessing these impacts on patients' lives.

The Patients and Social aspects domain, abbreviated as SOC, focuses on individuals who use health technologies, whether patients or healthy individuals in screening programs. Patients aspects include issues relevant to patients, individuals and caregivers actively involved in healthcare services. The term 'individual' includes both patients and healthy individuals

benefiting from health technologies, while caregivers refer to non-professional support providers within the patient's social network.

Social Aspects in the SOC domain address specific social groups crucial for HTA evaluations, such as older adults, remote communities, people with disabilities, ethnic minorities and immigrants. While these groups may require special consideration due to unique health technology implications or policy guidelines, tailored technologies may vary significantly in their values and needs.

Patients, caregivers and individuals hold diverse perspectives on health, illness and treatment experiences, shaping their attitudes, preferences, values and expectations. Health technologies used in hospitals, primary care, or homes are significant for patients and caregivers and can generate personal meanings like hope or fear and attaching societal values to their outcomes. The assessment within the Patients and Social Aspects domain includes these multifaceted perspectives from patients, individuals, caregivers and relevant social groups.

The importance of the Patients and Social aspects domain in HTA lies in capturing these invaluable perspectives from patients and caregivers who directly experience health technologies' impacts. Their insights inform how technologies influence disease management, daily activities and overall quality of life. Moreover, health technologies' societal impact extends beyond clinical settings, requiring patients to mobilise personal or social resources to integrate these technologies effectively into their lives. This holistic approach views health as human capital, where investments not only enhance population health but also strengthen employability and socioeconomic well-being across diverse societal segments.

The SOC domain includes three topics with a total of eight issues, representing significant organisational concerns relevant to specific technologies. The detailed topics and issues related to this domain are outlined below and further elaborated in Table 9.8 in Appendix 1.

Patients' perspectives: The topic focuses on patients' lived experiences with illness, which often significantly affect daily life, including work, social interactions and self-care.

Psychological challenges, such as stigma, anxiety and fear, along with the financial strain of managing chronic illness, further complicate their well-being. This highlights the need for healthcare systems to adopt a holistic approach, addressing both physical symptoms and emotional/social support. The topic also explores patient and caregiver expectations of healthcare technology, with hopes for better symptom management and improved quality of life. Evaluating how well technology meets these expectations is crucial for patient adherence and satisfaction. Additionally, patients' emotional responses to technology, including self-image and the impact on daily life, are key factors in treatment engagement. The burden on caregivers, often family members, is another critical issue, stressing the need for support systems that help alleviate the emotional and physical toll on those providing care.

Social group aspects: The topic focuses on the inequities in accessing healthcare technologies, particularly for groups such as children, older adults and minorities. These barriers contribute to disparities in care, highlighting the need for inclusive design and implementation of new technologies. Factors such as geography, religion, gender and disease-specific limitations can prevent certain populations from benefiting fully from healthcare advancements. For example, limitations like weight restrictions for MRI scans can disproportionately affect certain groups. Addressing these barriers is essential for promoting equity and inclusivity in healthcare.

Communication aspects: This topic emphasises the importance of clearly conveying treatment options to patients. Providing patients with the necessary information and resources enables them to make informed decisions about their healthcare. Effective communication can reduce fears and anxieties about treatment, leading to better adherence and higher patient satisfaction.

4.3.9 Legal aspects

Understanding legal considerations is essential in decision-making, particularly regarding socio-legal issues. As professional ethics are turned into official laws and the European Union creates more rules for health technology, legal issues in HTA are becoming more important. Policymakers must recognise the legal implications of adopting or rejecting new technologies,

along with the responsibilities of patients, healthcare providers and payers. This perspective covers international, EU and national legislative frameworks, acknowledging national differences that complicate the transfer of legal knowledge across borders.

The Legal aspects domain, abbreviated as LEG, identifies legal barriers to disseminating HTA findings and highlights areas where healthcare legislation requires harmonisation. It offers tools for legislative and policy reforms, addressing potential legal questions that may arise from implementing or not implementing a technology. These questions concern various stakeholders, including patient rights, healthcare professional norms, ethics, payers and society in general. The introduction and use of technology can influence policy-making and legislative reforms, making it crucial to consider legal aspects in the HTA process.

Historically, HTA has not focused extensively on market access or regulatory processes, but these are becoming increasingly relevant as technologies evolve. The LEG domain ensures that legal requirements, such as patient rights, data protection and healthcare personnel duties, are adequately considered, facilitating informed decision-making in HTA. The domain covers seven topics and 18 issues, which are detailed below and further outlined in Table 9.9 in Appendix 1.

Autonomy of the patient: The topic focuses on the importance of informed consent and the proper dissemination of information about technological interventions. Legal frameworks must ensure that patients, including minors and those considered incompetent, receive thorough information on the benefits and risks of proposed technologies. This is especially critical when dealing with high-risk technologies or emergency situations, where patients may need to make quick decisions. Clear guidelines for consent and information sharing are essential to maintaining the balance between patient rights and healthcare providers' responsibilities.

Privacy of the patient: The topic focuses on patient privacy, especially as technology generates vast amounts of data beyond immediate patient care. Protecting the confidentiality of this information is essential for maintaining trust in the patient-provider relationship. Legal frameworks, such as EU regulations on sensitive data, must guide privacy risk assessments.

Additionally, clear protocols are needed for disclosing information to family members, especially in cases where relatives may share health risks. The broader implications for data security and the measures required to prevent breaches bring to light the ongoing challenge of balancing technological advancements with the protection of patient privacy rights.

Equality in health care: The topic emphasises that legal frameworks should guarantee equitable access to healthcare technologies. International conventions and national laws must ensure that disparities in healthcare delivery are addressed. The impact of national reimbursement policies and EU regulations on cross-border healthcare is crucial to provide all patients, regardless of their background, the benefit of technological advancements.

Ethical aspects: The topic focuses on the implications of technology on fundamental human rights, emphasising the need for ongoing ethical consideration as new technologies are introduced, since ethical dilemmas, particularly in diagnostic and treatment processes may not be fully addressed by existing laws. This emphasises the importance of adapting legislation to ensure that technology enhances, rather than undermines, patients' rights. The topic highlights the relationship between ethics and law in guiding the responsible use of technology in healthcare.

Authorisation and safety: The topic focuses on the ongoing evaluation of safety standards that are critical in a rapidly evolving technological landscape. Establishing the necessary certifications and adherence to safety regulations is essential to protect patients. The topic highlights the legal obligations healthcare providers must meet to ensure that technologies are safe for use, reflecting a commitment to high-quality care.

Ownership and liability: The topic covers the legal landscape surrounding intellectual property rights, which can pose significant challenges during technology implementation. Understanding the implications of licensing agreements and guarantees from manufacturers is crucial for healthcare providers to navigate potential legal pitfalls. This topic points to the importance of clarity regarding ownership rights and responsibilities to avoid disputes that could hinder patient care or technology use.

Regulation of the market: The topic focuses on the legal frameworks governing the acquisition, pricing and marketing of healthcare technologies. Understanding price control mechanisms and regulatory guidelines helps ensure that healthcare expenditure remains sustainable. Additionally, this topic highlights the challenges posed by rapidly evolving technologies, where existing laws may not fully address new developments. Potential conflicts of interest in regulatory processes also raise concerns, underscoring the need for transparency and fairness in decision-making.

4.4 Most Economic Advantageous Tender (MEAT) - MedTech framework

The Most Economically Advantageous Tender (MEAT) framework plays a pivotal role in reshaping the procurement of medical technologies, steering the focus from cost-centric decisions to value-driven investments. By incorporating multiple stakeholders, such as medtech companies, healthcare providers, payers and patients - procurement becomes a key component in influencing industry dynamics. However, existing procurement practices often prioritise initial costs over broader, long-term value considerations, leading to solutions that may appear cost-effective but fail to deliver significant benefits, particularly in terms of patient outcomes.

At its core, the MEAT framework defines value as the ratio of outcomes to costs, with the understanding that value is maximised when outcomes improve while costs are reduced. The framework is structured into three layers (MedTech Europe & BCG, 2015; Stanberry et al., 2021). The first layer centres on the core components of value: patient outcomes and associated costs. Outcomes refer to the direct impacts on patients, while costs include the expenses related to the product or service. The second layer expands the evaluation to the benefits for key stakeholders, including patients, HCPs, providers and the broader healthcare system. The third layer examines the wider societal impact of medical technologies, including innovation, sustainability and socioeconomic factors.

The first layer of the MEAT framework addresses the complexity of defining and substantiating patient Outcomes. It encourages stakeholders, ranging from physicians to hospital management, to base their selection of outcomes on available evidence. If this evidence is

inadequate or of low quality, the framework emphasises the responsibility of suppliers to generate, analyse and document reliable data, potentially incorporating risk-sharing mechanisms where pricing is linked to post-treatment outcomes.

Costs are divided into two primary categories: Product Costs and Care Delivery Costs. Product Costs cover the purchase, maintenance, storage and disposal of medical technologies, as well as capital expenditures related to the installation and integration of these technologies into healthcare facilities. Care Delivery Costs include ongoing operational expenses, such as medical personnel time, training, consumables and infrastructure. For example, the energy consumption of diagnostic equipment like MRI or CT scanners can be optimised to reduce costs over time, especially when these machines are in standby mode. The framework also considers the costs of reprocessing reusable devices and the financial impact of product failures, emphasising the importance of managing costs throughout the product lifecycle.

The second layer of the MEAT framework focuses on the benefits for various stakeholders. While these benefits may not always correlate directly with clinical outcomes, they can indirectly influence patient care by improving the overall experience, comfort and convenience. For instance, a wide-bore MRI scanner can alleviate discomfort for claustrophobic patients and a low table height can make transfers easier for elderly or disabled individuals. Technologies that enhance mobility, such as remote patient monitoring, reduce the need for patients to move during diagnostic procedures, thus improving their comfort. Furthermore, innovations like a mammography unit that allows patients to control compression levels can reduce anxiety and increase compliance, while a soothing MRI examination room environment helps patients relax during procedures.

HCPs spend a substantial portion of their time managing medical technologies, so the MEAT framework emphasises the importance of assessing HCPs' benefits in terms of usability, safety, training and ongoing education. The evaluation criteria ensure that technologies are user-friendly, secure and supported by sufficient training and educational resources, enabling HCPs to use them effectively and safely.

For providers, the framework highlights key operational benefits, including the technology's maintainability, warranty provisions, technical support and alignment with reimbursement structures. The MEAT framework encourages an assessment of how well suppliers support operational efficiencies, from the direct use of technology to logistical support. It stresses that technology should not just serve immediate clinical needs but also align with the provider's long-term strategic goals. By considering these operational factors, the MEAT framework broadens the value equation beyond cost and revenue generation, emphasising how technology contributes to overall healthcare system efficiency.

The health system benefits, as outlined in the second layer, focus on the long-term improvements in patient care that can drive broader systemic efficiencies. These benefits include reductions in treatment costs over time, fewer hospital readmissions and an overall reduction in healthcare resource utilisation. By improving patient outcomes, the MEAT framework highlights the importance of technologies that reduce the need for repeated treatments and long-term care.

The third layer extends the MEAT framework's evaluation to the broader societal impact of medical technologies. It assesses how innovations in medical technology contribute to advancing healthcare delivery and improving patient outcomes. Additionally, sustainability is evaluated in terms of the environmental impact of the technology, including energy consumption and waste management. The socioeconomic impact category explores the wider effects of medical technologies on productivity, caregiver burdens and the economic health of the medtech industry. For instance, innovations that reduce caregiver workload or improve workforce productivity are seen as contributing to the overall societal benefit.

The MEAT framework provides a comprehensive method for assessing the value of medical technologies, expanding the evaluation beyond cost-based procurement to incorporate a wider range of factors that impact patients, HCPs, providers and society at large. Table 4.4 outlines the Layers, Categories and Criteria of the MEAT framework, offering a detailed representation of how value is assessed during the procurement process. This table is reproduced directly from the original source by MedTech Europe and Boston Consulting Group (MedTech Europe & BCG, 2017).

Table 4.4: Medtech MEAT framework - Layers, categories and criteria

Layer		Category	Criteria
Layer 1 Outcomes		*Outcomes & Evidence*	Evidence of relevant outcomes improvement
			Existence of high-quality outcomes data
		Outcomes focus	Support in measuring and reporting on outcomes
			Willingness to offer outcomes-dependent risk-sharing
Layer 1 Costs	**Product**	*Purchasing*	Price of purchasing /renting product
			Delivery and Installation
			Conversion: staff training for new product
			Compatibility: upgrades to systems/infrastructure
		Maintenance	Spare parts
			Technical staff time
			Service contract
		Storage	Storage room/infrastructure
			Replacement at end of shelf life
		Disposal	Disposal/decommissioning
	Care delivery	*Operating/healthcare delivery*	Medical staff time using device
			Ongoing staff training
			Cost of consumables
			Unplanned usage: failure rate
			Infrastructure usage
			Power/gas usage
			Reprocessing costs
Layer 2 Other benefits for key stakeholders		*Patients' secondary benefits*	Patient and/or relative comfort and convenience
			Patient flexibility and mobility
			Impact on treatment adherence
		HCP benefits	Secure usage of care providers
			Ease-of-use/handling and functionality
			Training and access to education
		Provider benefits	Maintainability, warranty and technical service support
			Support improving efficiency along patient pathway
			Alignment and support with reimbursement structure
			Support on administration, storage or logistics
			Strategic fit for provider and support of strategy
		Health system benefits	Reduced long-term costs of treatment
			Reduction of rehospitalisation/number of treatments
Layer 3 Broader impact on society		*Innovation*	Development of new and substantially improved technology
			Contribution to development of health care
		Sustainability	Environmental impact
			Socially responsible product value chain
		Socio-economic impact	Impact of people not in the workforce
			Burden carried by non-professional care providers
			Impact on competition in medtech Industry

4.5 AdvaMed - A Framework for comprehensive assessment of medical technologies: Defining value in the new health care ecosystem

The AdvaMed framework for assessing medical technologies presents a comprehensive, multi-dimensional approach that extends beyond traditional cost-based procurement models to incorporate broader healthcare and societal impacts. Launched in 2017, the framework initially identified four value categories: **Clinical Impact**, **Non-clinical Patient Impact**, **Care Delivery Revenue and Cost Impact** and **Public and Population Impact** (AdvaMed & Deloitte, 2017). In 2023, **Environmental Impact** was added as a fifth value category, recognising the increasing importance of sustainability in healthcare technology (AdvaMed & Deloitte, 2023).

While AdvaMed acknowledges the contributions of existing frameworks, such as those from ACC-AHA, ASCO, $ICER_a$ and NCCN, it argues that these models - primarily developed for pharmaceutical drugs - are insufficient for evaluating medical technologies. AdvaMed advocates for a more holistic approach that goes beyond clinical and safety outcomes to consider the broader implications for all healthcare stakeholders, including patients, providers and the public. This approach integrates multiple, weighted contributions rather than offering a singular financial estimate, ensuring a more detailed and comprehensive assessment.

4.5.1 Core principles of the AdvaMed framework

AdvaMed's value assessment is built on several core principles derived from a comprehensive review of existing practices and extensive stakeholder engagement. These principles, described below, guide organisations in designing tailored assessment methodologies that align with evolving healthcare decision-making.

1. **Comprehensiveness:** The framework prioritises patient-centric assessments but acknowledges the importance of considering all relevant stakeholders, such as patients, HCPs, providers and payers. It involves exploring both clinical and non-clinical value sources.
2. **Evidentiary:** Assessments must be based on reliable evidence, including patient-centred and patient-generated data. The type of evidence required depends on the specific

technology or product. In the case of novel technologies with limited existing evidence, alternative methods for data collection may be employed.

3. **Cost:** Both incurred and avoided costs should be considered over time, addressing the perspectives of all healthcare system stakeholders. The evaluation should account for variations in value impact across different patient populations (e.g. children vs. elderly).
4. **Flexibility:** The categories of assessment should accommodate the diverse range of medical technologies, each with its own unique value profile.
5. **Specificity:** Value assessments must capture how value drivers differ across patient populations and evaluate long-term impacts, beyond immediate care.
6. **Engagement:** A collaborative approach is essential, with input from all relevant stakeholders integrated into the assessment process.
7. **Transparency:** The methodologies, decision-making processes and procedures must be transparent to ensure trust and accountability among stakeholders.
8. **Relevancy:** As medical technologies evolve rapidly, there should be mechanisms for regular updates to keep pace with advancements in the field.

4.5.2 Description of AdvaMed value categories

The five value categories of the AdvaMed framework are outlined below, along with their respective value subcategories, which are highlighted in bold for each category and its subcategories.

Clinical Impact

Clinical impact is assessed through three subcategories: **Clinical Efficacy and Effectiveness**, **Patient Safety and Tolerability** and **Quality of Life**. This evaluation focuses on technologies' ability to improve clinical outcomes, such as disease morbidity, mortality, and progression. Clinical Efficacy and Effectiveness uses reliable metrics (e.g. survival rates, reduced hospital stays) as indicators of value. Patient Safety and Tolerability evaluates complications and adverse effects compared to alternative treatments. The importance of data security and privacy is also highlighted due to increasing concerns about safeguarding patient information. Lastly, Quality of Life assessments use metrics like Quality-Adjusted Life Years (QALYs) and Disability-Adjusted Life Years (DALYs) to evaluate patients' overall well-being.

Non-clinical Patient Impact

This category includes **Patient Experience** and **Patient Economics**. The Patient Experience subcategory evaluates care accessibility, predictability of healthcare experiences, and patient reintegration into society. It assesses how innovations that enhance patient comfort and reduce caregiver burdens improve healthcare experiences, adherence to treatment plans and outcomes. The Patient Economics subcategory addresses the financial strain of out-of-pocket expenses on affordability and access to care, as well as the economic benefits of reduced recovery time. Faster recovery enables patients to resume daily activities and work sooner, benefiting both patients and caregivers economically.

Care Delivery Revenue and Cost Impact

This category evaluates the operational and financial implications of medical technologies for healthcare providers and payers. It includes two subcategories: **Quality of Care Economics** and **Care Efficiency**. Quality of Care Economics focuses on the economic impact of performance-based metrics, such as readmissions, hospital-acquired infections and lengths of stay. Care Efficiency evaluates the economic benefits of optimising workflows, reducing resource utilisation and enhancing operational efficiency, including improvements in physician time management and reduced Intensive Care Unit (ICU) stays.

Public and Population Impact

This category evaluates the broader societal effects of medical technologies, specifically focusing on **Population Health** and **Workforce Productivity**. The Population Health subcategory examines the impact of technology on life expectancy, health outcomes and overall healthcare costs. Workforce Productivity evaluates how technology improves employee and caregiver productivity by reducing absenteeism and enhancing presenteeism, leading to a more efficient healthcare system.

Environmental Impact

The addition of Environmental Impact in 2023 reinforces the growing importance of sustainability in healthcare. This category includes two subcategories: **Monetary Impact** and **Perceptions and Differentiation**. Monetary Impact focuses on the cost savings associated with environmentally friendly practices, such as waste reduction, energy savings and recycling.

Perceptions and Differentiation highlight the value of sustainability efforts in improving stakeholder perception and differentiating companies in the market, along with the long-term financial benefits of environmental initiatives.

AdvaMed emphasises that an effective assessment process should provide a clear evaluation of a medical technology's value, using both quantitative and qualitative metrics. This includes economic factors like acquisition costs, staff training and potential savings, along with environmental benefits such as reduced waste. The assessment should consider the relevant timeframes for these impacts, accounting for variations among patient sub-populations. It must be grounded in credible evidence, with different types of evidence used depending on the value category and assessment purpose. Long-term benefits should be considered, especially in value-based care models where outcomes influence provider incentives. Value assessments should quantify impacts without prioritising one category over another and even non-quantifiable effects should be considered. The method of summarising impacts - whether in financial terms or as distinct categories - should align with the technology's unique value profile. Table 9.10 in Appendix 2 displays the AdvaMed value categories and value subcategories.

4.6 The MedtecHTA project

The MedtecHTA project (Methods for Health Technology Assessment of Medical Devices: A European Perspective) was initiated to tackle the distinct challenges of assessing medical devices, which differ from pharmaceuticals. While traditional HTA frameworks have focused on drugs, MedtecHTA aimed to adapt these methodologies to account for the unique characteristics of medical devices, such as device-user interactions, incremental innovations and broader organisational and economic impacts (Tarricone et al., 2017).

One key finding from the project is that medical devices often enter the market with less clinical evidence compared to pharmaceuticals. Pharmaceuticals typically undergo extensive clinical trials, providing a robust evidence base for their safety and efficacy. In contrast, medical devices, especially high-risk Class III devices, often have less clinical trial data available. Class III devices, which include life-sustaining or life-supporting technologies like

pacemakers and heart valves, require stringent evidence for safety and efficacy. However, they can still face regulatory challenges. For example, a device might receive a CE mark in Europe, indicating it meets European safety standards, but be rejected by the FDA in the USA due to differing regulatory requirements. In addition, a survey of 36 non-European HTA agencies revealed that unique aspects of medical devices, such as learning curves and incremental innovations, were frequently overlooked (Ciani et al., 2015). Despite this, 75% of the surveyed agencies had adapted their processes to assess medical devices, although only one had methods tailored specifically to their needs.

An analysis of 45 HTA reports on cardiovascular diseases (18 on drugs and 27 on medical devices) highlighted significant differences between these two categories. Using the EUnetHTA Core Model dimensions, the review found that HTA reports for medical devices were less likely to include evidence from Randomised Clinical Trials (RCTs) but were more inclined to consider organisational factors. Specifically, 44% of device HTA reports covered organisational factors, compared to just 6% for drug HTA reports. These organisational factors primarily involved how the use and effectiveness of medical devices are influenced by the healthcare setting and operator. However, there was a lack of quantitative analysis regarding the impact of these organisational factors on clinical or economic effectiveness (Ciani et al., 2017). Most reports on both drugs and medical devices included considerations of technology-specific issues, such as the technology use and the health problem addressed. Additionally, these HTA reports consistently addressed key domains such as Safety, Effectiveness, and Cost and Economic Evaluation.

MedtecHTA highlighted that the differences in HTA reports between medical devices and pharmaceuticals largely stem from the complexities associated with using medical devices. It proposed that medical devices should be viewed as ‘complex interventions’ due to their interactive nature with users and contexts. Just as interventions often involve various actions, groups (those administering and receiving the intervention) and outcomes, medical devices present unique challenges for assessment due to their specific characteristics. Evaluating a medical device requires considering not only the clinical aspects but also the preferences of HCPs, such as surgeons or radiologists, and those of the patients who use the device. Additionally, the incremental development of the product and the context in which it is used

are crucial interacting components. These factors complicate the assessment of medical devices, necessitating a broader approach that accounts for both clinical effectiveness and professional/organisational factors.

A study conducted within MedtecHTA examined the factors influencing the adoption of cardiovascular devices, including environmental, organisational, individual and technological factors (Hatz et al., 2017). The research found that manufacturer support is crucial for the adoption of new devices, especially when clinical evidence is limited at market entry. Such support, through training and education, helps integrate new technologies into clinical practice and impacts their clinical and economic effectiveness. This support can significantly enhance a device's value, particularly when clinical evidence is sparse.

In contrast, the adoption of older devices was less influenced by manufacturer support. However, as budget pressures increased, the likelihood of adopting older devices also rose, possibly due to physicians' preference for established technologies with predictable reimbursement under financial constraints. In contrast, the adoption of innovative technologies tends to thrive when budget pressures are lower. The healthcare setting, such as the size, type and location of facilities, also influenced device utilisation rates, with larger academic hospitals in urban areas showing higher usage of both new and older devices.

Interestingly, despite the changes in workflows and organisational structures that new devices bring, these factors did not significantly affect clinicians' adoption behaviours. Organisational factors, such as hospital management decisions and group decision-making processes, were found to be more influential in determining adoption outcomes than individual motivations.

The MedtecHTA project demonstrated that assessing medical devices requires a detailed understanding of their complexity and interactive nature. While devices often face less stringent clinical evidence requirements compared to pharmaceuticals, safety and effectiveness remain essential. The iterative assessment process must involve all stakeholders - including physicians and patients - and address uncertainties due to limited initial evidence. Manufacturer support plays a pivotal role in facilitating device adoption, directly influencing clinical and economic effectiveness. However, economic value remains a complex aspect,

particularly in organisational contexts where factors like budget constraints, workflow changes and resource needs significantly affect the evaluation and adoption of medical devices. Based on these findings, Table 4.5 outlines key value elements that should be considered in the assessment of medical devices within a value framework.

Table 4.5: MedtecHTA project's main value elements

Key value elements	Description
Safety	Essential for patient safety and regulatory compliance, especially with varying levels of evidence.
Clinical effectiveness	As with pharmaceuticals, clinical effectiveness is crucial for demonstrating a device's benefits, despite often having less clinical evidence.
Costs and economic evaluation	Understanding the device's economic value is crucial for budgetary decisions. Economic assessment is complex and requires further exploration, considering budget constraints, workflow changes and resource needs in evaluating and adopting medical devices.
Organisational aspects	Assessment of the device's integration into existing systems and its implications for healthcare delivery and efficiency.
Incremental innovation	The device's contribution to technological progress and enhancement over current standards.
Manufacturer support	Essential for the successful implementation and utilisation of new technologies, particularly when clinical evidence is limited.
User preferences (Healthcare Professionals)	Ensures the device meets user needs and integrates effectively into clinical practice. Medical devices should be seen as 'complex interventions' due to their interactive nature with users and contexts.
Healthcare setting	The size, type and location of healthcare facilities influence device utilisation rates. Larger, urban, academic hospitals show higher utilisation of both new and old devices.
Regulatory and market access	Highlights the importance of regulatory compliance and potential barriers to market entry.
Learning curve and training needs	Highlights the importance of training and support to ensure effective use and minimise implementation challenges
Patient preferences	Medical devices are 'complex interventions' requiring evaluation of patient preferences and context.

4.7 The AdHopHTA project

Hospital-based Health Technology Assessment (HB-HTA) has played a critical role in clinical practice over the past 15 years, driven by the need for hospitals to evaluate innovative technologies and support managerial decision-making (Cicchetti et al., 2018). Unlike national or regional HTA frameworks, HB-HTA is specifically tailored to the hospital setting, emphasising the value of technologies within tight timelines (Sampietro-Colom et al., 2015). These assessments are typically conducted internally by hospital professionals, following various organisational models, such as independent informal groups, integrated essential HB-HTA, stand-alone HB-HTA and integrated-specialised HB-HTA (Cicchetti et al., 2018).

The European-funded AdHopHTA project (Adopting Hospital Based Health Technology Assessment) sought to enhance HB-HTA by developing tools and resources, involving over 385 participants across 20 countries. As a result, the project produced a Handbook for HB-HTA, a Toolkit for managing HB-HTA units and a database of HB-HTA reports (Halmesmäki et al., 2016). In addition to developing these resources, the AdHopHTA project assessed the informational needs of hospital and clinical managers regarding technology adoption and disinvestment. A comprehensive literature review, interviews with hospital professionals and a large-scale web survey identified five of the nine EUnetHTA Core Model domains as particularly relevant: Health Problem and Current Use, Clinical Effectiveness, Safety, Costs and Economic Evaluation and Organisational Aspects.

However, the EUnetHTA Core Model lacked a domain addressing political and strategic issues - factors hospital managers identified as crucial. To address this gap, the AdHopHTA project introduced a new domain: Political and Strategic Aspects. This domain assesses how technology investments align with a hospital's values, strategic objectives, competitive positioning and political factors. For instance, a hospital might prioritise a 3 Tesla MRI system over a 1.5 Tesla model to maintain competitiveness, reflecting strategic and political factors beyond clinical needs. The Political and Strategic Aspects domain includes:

- **Strategic Issues:** Alignment with research strategies, local values, prestige and competition.

- **Political Issues:** Alignment with the local political climate and decisions from municipal or county authorities.

Additionally, the AdHopHTA project refined two existing domains:

- **Clinical Effectiveness:** Divided into Clinical Outcome/Effect Size and Quality of Evidence.
- **Costs and Economic Evaluation:** Split into Societal and Hospital Perspectives.

These refinements offer a more detailed understanding of clinical and economic data, addressing both broader societal impacts and specific hospital concerns. This sophisticated approach stresses the importance of detailed domain segmentation to address the specific needs of hospital decision-makers.

While the EUnetHTA Core Model provides a strong foundation, the AdHopHTA project emphasises the need to incorporate political and strategic considerations, as well as to differentiate between broader societal and hospital-specific economic impacts. The survey results confirmed that hospital decision-makers prioritise information on health problem, clinical effectiveness, economic impact (from a hospital perspective), safety and organisational aspects. Strategic considerations have emerged as a key area of interest, while social, legal and ethical aspects are generally deemed less critical. Table 4.6 summarises these findings, highlighting the importance of incorporating political and strategic factors - absent in the EUnetHTA Core Model - in aligning technology investments with strategic goals and competitive positioning.

Table 4.6: AdHopHTA value domains with respect to EUnetHTA Core Model and level of significance for hospital decision makers

EUnetHTA - HTA Core Model	**AdHopHTA HB-HTA Core Model (new and modified domains (D)** are **highlighted in italics)**	**Importance for Hospital Decision-Makers**
Health problem and current use	D1: Health problem	**most important**
Description and technical characteristics	D2: Technology characteristics	relevant
Safety aspects	D3: Safety	**most important**
Clinical effectiveness	*D4.1 Clinical outcome/effect size*	**most important**
	D4.2 Quality of evidence	
Costs and economic evaluation	*D5.1 Societal point of view*	relevant
	D5.2 Hospital point of view	**most important**
Ethical aspects	D6: Ethical	relevant
Organisational aspects	D7: Organisational aspects	**most important**
Social aspects	D8: Social	relevant
Legal aspects	D9: Legal	relevant
	D10.1: Strategic	**most important**
	D10.2: Political	relevant

4.8 The INTEGRATE-HTA project

The INTEGRATE-HTA project (Integrated Assessments of Complex Health Technologies) aimed to develop concepts and methods for a comprehensive evaluation of health technologies, addressing their inherent complexity and the fragmented nature of traditional HTAs (Gerhardus et al., 2017).

MedtecHTA researchers argue that medical devices should be regarded as complex interventions. According to the UK Medical Research Council (MRC), complex interventions are defined by several factors: multiple interacting components, varied and challenging behaviours required from users, involvement of multiple groups or organisational levels, diverse outcomes and the flexibility allowed in the intervention's application (Craig et al., 2008; Lysdahl et al., 2017; Rehfuess & Gerhardus, 2017). This complexity arises from the context, the patients and their caregivers and the non-linear relationship between the intervention and its outcomes, all of which must be considered in HTA (Petticrew, 2011).

The INTEGRATE-HTA project introduced a comprehensive model for conducting integrated HTAs, incorporating various dimensions alongside contextual factors, patient characteristics and implementation issues (Rehfuess and Gerhardus 2017; Lysdahl et al. 2017). This model

includes four key dimensions: (a) the assessment aspects, (b) modifying factors that may influence these aspects, including context, implementation and patient characteristics, (c) the associated uncertainties and (d) the values, preferences and experiences of HTA researchers and relevant stakeholders (Wahlster et al., 2017).

The INTEGRATE-HTA Model adopts a systematic methodology to assess the effectiveness, economic, ethical, social-cultural and legal, aspects of complex health technologies. By incorporating patient preferences, contextual factors, healthcare settings and implementation considerations, this approach ensures a comprehensive, patient-centred evaluation. The model employs a stepwise approach (Gerhardus, 2016; Rehfuess & Gerhardus, 2017; Wahlster et al., 2017):

- Definition of the technology and HTA objectives, involving stakeholders (Step 1).
- Development of a logic model that includes all HTA issues and dimensions, including contextual factors and graphically representing both the technology and the systemic environment, outcomes and mechanisms (Step 2).
- Collection, synthesising and assessing evidence on effectiveness, economic, ethical, legal and socio-cultural aspects (Step 3).
- Integrating the evidence and data from the previous steps into the logic model to create a visual representation of interrelationships (Step 4).
- Facilitating decision-making through decision support tools (Step 5).

The INTEGRATE-HTA Model has issued guidance addressing those aspects with focus on the assessment of complex health technologies taking into consideration their intertwined nature. The aspects are briefly described in the sections 4.8.1-4.8.5 below.

4.8.1 Assessing effectiveness

Assessing effectiveness in complex health technologies, including medical devices, can present challenges due to difficulties in defining review questions and interpreting results. For example, a health technology might impact different patient populations or conditions in varying ways. Therefore, it is crucial to accurately scope the assessment by thoroughly understanding the technology and its complexities and by selecting methods and evidence

that address its diverse aspects. The guidance for the assessment of effectiveness emphasises two main areas: employing suitable methods for handling heterogeneous study designs in effectiveness reviews and synthesising evidence effectively.

4.8.2 Economic assessment

The guidance for assessing economic aspects advocates for a systems approach to economic evaluation, which moves beyond traditional models focused solely on outcomes like Quality of Life (QoL) or population health. This approach views health technologies in the broader context of healthcare systems, where multiple entities interact and outcomes are dynamic.

This approach moves away from static economic analyses, which assume equilibrium, to embrace the evolving nature of interventions and settings. Additionally, it emphasises the importance of evaluating non-health outcomes, such as well-being, participation, self-respect and dignity, as part of a broader quality of life assessment. This systems approach integrates seamlessly with other aspects of the model.

4.8.3 Ethical considerations

The ethical evaluation of complex health technologies is complicated by the variety of ethical frameworks available, such as principlism, casuistry and social shaping of technology (Assasi et al., 2014; Hofmann et al., 2015). Given the diverse perspectives on ethical issues, the INTEGRATE-HTA project provides a structured framework for selecting the appropriate ethical approach based on the complexity of the technology. This approach takes into account the ethical profile of the technology, which include factors such as multiple and changing perspectives, indeterminate phenomena, uncertain causality, unpredictable outcomes and ethical complexity (Lysdahl et al., 2016). Addressing these aspects requires a flexible, adaptive and inclusive approach to fully capture the ethical dimensions embedded in the technology and its impact on various stakeholders.

4.8.4 Socio-Cultural aspects

Assessing socio-cultural aspects is a critical component of HTA because these aspects can significantly impact how health technologies are utilised. Technologies or medical devices may be perceived and accepted differently by various patient or professional groups depending on their socio-cultural contexts. For example, the adoption of remote diagnostics or

telemonitoring can evoke a range of responses influenced by cultural attitudes. The guidance provides a socio-cultural framework designed to assess these aspects comprehensively. The INTEGRATE-HTA Model outlines three key socio-cultural categories essential for HTA: **Social construction/understanding of health Issue**, **Social image/understanding of technology and use** and **Socio-cultural aspects of technology implementation and organisation of use**. These categories are summarised below and further elaborated in Table 9.11 in Appendix 3.

Social construction/Understanding of health issues focuses on how health issues are defined and understood within different socio-cultural contexts. Since perceptions of health technologies are shaped by cultural factors, it is important for designers to consider these nuances to ensure broader acceptance and effective use.

Social image/Understanding of the technology and use explores how stakeholders, such as HCPs, patients, families and policymakers, perceive the benefits and safety of a technology. As knowledge of health technologies is socially constructed and legitimised, cultural perspectives can heavily shape these perceptions. Addressing misconceptions through targeted education and communication is crucial for enhancing technology acceptance.

Socio-Cultural aspects of technology implementation and organisation of use explores how factors like age, gender, ethnicity and social networks affect the adoption of technologies. It also considers how social inequality and access disparities may impact different cultural groups, potentially leading to stigma or discrimination. The relationship between patients and HCPs, shaped by cultural context, plays a key role in how technology is perceived and used. Additionally, professional dynamics, such as social power, cooperation styles and team structures, can influence the effectiveness of technology implementation within healthcare teams.

These categories provide a comprehensive framework for assessing the socio-cultural implications of health technologies, ensuring their integration and acceptance within diverse societal contexts. While such evaluations are often overlooked, the INTEGRATE-HTA Model offers a structured approach for addressing these dimensions in any HTA.

4.8.5 Legal aspects

Assessing legal aspects in health technologies is challenging due to the complex legal education required and the diverse legal rules across national systems. These rules vary significantly, such as those governing the safety of an X-ray machine versus data consent and ownership. Additionally, the importance of legal aspects can differ among stakeholders and decision-making levels. The INTEGRATE-HTA guidance offers a framework for identifying key legal aspects relevant to HTA, addressing nine core issues. While it does not replace detailed legal expertise, it helps HTA practitioners without legal training to pinpoint and integrate crucial legal considerations into their assessments, ensuring a focus on relevant issues and avoiding unnecessary evaluations (Lysdahl et al., 2017). The legal aspects are described below and outlined in Table 9.12 in Appendix 3.

Autonomy of the Patient I: Informed consent

Patients must agree to any therapeutic action that affects their physical or mental integrity, with complete information provided about the intervention.

Autonomy of the Patient II: Alternative forms of consent

Not all patients can provide informed consent due to factors like age, cognitive impairment, or emergency situations. This necessitates alternative consent methods to ensure inclusivity and protect vulnerable populations, highlighting the need for flexible approaches to consent in these contexts.

Autonomy of the Patient III: Privacy and data protection

The integration of technology in healthcare often involves the collection and processing of sensitive patient data. Legal frameworks governing privacy and data protection are essential to ensure that informed consent extends beyond formality, serving as a genuine safeguard for patient autonomy, confidentiality and the ethical handling of personal information.

Market Authorisation I: Medical devices

Market authorisation is a critical process that ensures the safety and efficacy of medical devices. In Europe, obtaining a CE mark is mandatory for medical devices to comply with safety and quality standards, allowing them to be marketed and used.

Market Authorisation II: Medicinal products

Medicinal products must be authorised before they can be introduced to the market. This process ensures that drugs meet safety, efficacy and quality standards necessary for patient use.

Clinical trials

The legal governance of clinical trials is vital to protect patient rights and safety. When HTA involve clinical trials, understanding their legal implications ensures that participant protection is prioritised and that trials are conducted ethically and transparently.

Intellectual property

Intellectual property laws protect technologies and patents, fostering innovation in healthcare. However, they also raise concerns about access to and affordability of new technologies for patients and healthcare systems, balancing the need for innovation with the ethical imperative of equitable access.

Reimbursement in public healthcare systems

Reimbursement decisions based on HTA, considering clinical, economic and safety evaluations, are crucial for ensuring patient access to new treatments. Clear guidelines on reimbursement criteria can help streamline the adoption of innovative technologies and reduce potential barriers to access within public healthcare systems.

Special medical fields

Technologies used in specialised areas, such as organ transplantation or prenatal screening, require careful examination of legal and ethical considerations. Tailored legal frameworks are essential to address the unique challenges these fields present and to ensure that patient rights and safety are upheld.

4.8.6 The role of Context and Implementation

The INTEGRATE-HTA Model reveals some overlaps between domains, such as ethical and socio-cultural aspects, reflecting their interrelated nature and the need for integrated assessment. Although the INTEGRATE-HTA Model does not separately address the Organisational, Patient and Social, or Safety domains, elements of these are incorporated within its five core guidances. Instead, a unique feature of the INTEGRATE-HTA Model is the inclusion of two critical dimensions - **Context** and **Implementation** - which act as modifiers in the evaluation process (Pfadenhauer et al., 2016). These modifiers assess factors influencing technology uptake and inform the evaluation of effectiveness, economic, ethical, legal and socio-cultural aspects. Separating an intervention from its implementation and context can be challenging, as the outcomes of a technology or intervention can vary depending on how it is implemented and the context in which it is applied.

4.8.6.1 Context dimension

The Context dimension includes eight factors surrounding and interacting with the technology or intervention, with relevant domains identified: **Setting, Geographical, Epidemiological, Socio-economic, Socio-cultural, Political, Legal and Ethical**. The domains are briefly described below and further outlines in Table 9.13 in Appendix 3.

Setting: This domain covers the geographic location and type of healthcare facility, such as hospitals or primary care settings, along with factors like the number of study sites, physical characteristics and the work environment. It also considers how location affects stakeholders and healthcare delivery over time.

Geographical: This domain examines geographic factors, including climate, infrastructure, land use and healthcare access and how they impact service delivery, particularly in isolated areas or those undergoing significant change.

Epidemiological: This domain considers demographic factors, such as population density, disease prevalence and mortality rates, along with the spatial distribution of diseases and trends over time, including epidemics.

Socio-economic: This domain looks at economic and social factors, including financial conditions, occupation, living standards, disease burden and access to healthcare. It also

considers how broader economic changes like inflation or crises affect healthcare access and provision.

Socio-cultural: Socio-cultural factors explore how health is understood and managed across different communities, considering language, cultural practices, health beliefs, lifestyle behaviours, social capital and the influence of power dynamics, discrimination and biases.

Political: The political domain addresses the political environment in which healthcare technologies are deployed, including power distribution, political stability, government effectiveness and regulatory frameworks that influence healthcare policies and decision-making.

Legal: This domain focuses on healthcare regulations, the rights and duties of healthcare personnel and legal frameworks guiding care delivery and patient rights. It ensures that healthcare technologies comply with relevant laws and regulations.

Ethical: The ethical domain examines moral principles related to healthcare, such as autonomy, privacy, informed consent and the resolution of conflicts of interest. It also considers shifts in ethical standards over time and their impact on decision-making and patient care.

4.8.6.2 Implementation domain

The Implementation domain addresses the efforts by various stakeholders to apply and use the technology in practice. The domains consist of **Provider, Organisation and Structure, Funding and Policy**, as detailed below and summarised in Table 9.14 in Appendix 3.

Provider: This domain covers the personal characteristics of healthcare providers, including traits like openness and curiosity, along with their skills, knowledge and emotional factors such as memory and attention. It also includes their attitudes toward technologies, motivation, goals and behavioural regulation, as well as their social or professional roles and identities.

Organisation and Structure: This category examines organisational factors, such as staffing, team coordination, external collaborations and the overall structure of the healthcare setting. Key elements include organisational culture, leadership, communication, training and knowledge transfer. It also addresses the readiness for change, team dynamics, policies and the implementation climate within the organisation.

Funding: This domain focuses on financial aspects, including funding and reimbursement models, purchaser-provider contracts and financial incentives. It covers the availability of resources, changes in provider income, pay-for-performance programs and how financial support aligns with federal and state policies. It also includes the flexibility and sustainability of funding sources.

Policy: This category looks at the political and policy environment affecting implementation, including donor policies, political stability and the prioritisation of healthcare agendas. It also considers external mandates, legislation, public reporting and incentives, as well as how policymakers use evidence-based practices and advocate for health interventions.

The INTEGRATE-HTA project advances the integration of complex health technologies into HTAs by developing a comprehensive framework that addresses the multifaceted nature of such interventions. This framework advocates for a holistic approach, recommending the use of five distinct dimensions - Effectiveness, Economic Impact, Ethical, Socio-cultural and Legal considerations - while introducing two additional dimensions, Context and Implementation, as critical modifiers. Key findings highlight that integrating contextual and implementation factors is crucial for accurate evaluation, as these dimensions can significantly affect the outcomes and real-world impact of health technologies. This integrated approach not only improves the relevance and applicability of HTA findings but also enhances the decision-making process, ensuring that complex health technologies are evaluated in a way that reflects their full real-world impact.

4.9 The NICE Technology Appraisal

The National Institute for Health and Care Excellence (NICE) provides the National Health Service (NHS) in the United Kingdom with guidance and advice on the use of both new and established health technologies, including pharmaceuticals, medical devices and interventions (NICE, 2018; Rawlins et al., 2010). The NICE independent advisory committees base their judgments and decisions on an evidence-based approach, considering the clinical and cost-effectiveness of health technologies (De Folter et al., 2018; Rawlins et al., 2010). This approach relies on reviewing clinical and economic evidence to demonstrate health benefits in terms of

quality of life (QoL) and value for money. Clinical evaluation is supported by experimental and observational studies, while the $ICER_b$ is used to assess whether the benefits justify the costs.

However, Rawlins *et al.* (2010) highlight that scientific evidence alone may not always suffice for decision-making (Rawlins et al., 2010). NICE advisory boards often need to apply their experience and judgment, especially given frequent quality issues with systematic reviews, the absence of direct comparisons, study time scales, endpoints used and the generalisability of available data. Furthermore, decisions on cost-effectiveness and the use of a rigid $ICER_b$ threshold are influenced by social criteria. Rawlins *et al.* (2010) identify six criteria that impact NICE judgments: illness severity, end-of-life treatments, stakeholder persuasion, significant innovation, disadvantaged populations and children (Rawlins et al., 2010). These factors, although not easily quantifiable or their combined impact clearly defined, introduce social value judgments into the decision-making process. For example, an innovative product may be favoured despite unproven QALY contributions and technologies for severe or end-of-life conditions may be accepted even if $ICER_b$ thresholds are exceeded. Stakeholder input, particularly from patients and advocates, can also shift perspectives beyond what is captured in clinical trials. Disadvantaged populations and children, as vulnerable groups, require special and flexible consideration.

De Folter *et al.* (2018) used automated text analysis on 243 NICE technology appraisals to uncover the key decision factors in their advisory boards' decision-making process (De Folter et al., 2018). Their findings confirmed that while clinical and cost-effectiveness are principal domains, decision factors extend to eight domains: **Condition, Current Practice, Clinical Need, New Treatment, Studies, Clinical Effectiveness, Cost Effectiveness and Other Factors**. These main domains are further divided into 125 sub-factors with varying frequencies, though the frequency does not indicate the relative weight of each factor. Treatment effectiveness, $ICER_b$ and comparator treatments were frequently used in appraisals, whereas clinical need appeared less frequently, likely due to textual analysis algorithm limitations. De Folter *et al.* (2018) also proposed that social values are considered during evaluations, favouring a flexible rather than purely mathematical appraisal process. The eight top-level domains and 125

decision factors used in NICE technology appraisals are detailed below and summarised in 9.15 in Appendix 4.

The **Condition** domain emphasises the impact of medical treatments on various stakeholders, including patients, their families and caregivers. Emerging criteria within this domain focus on quality of life (QoL) as a crucial measure of treatment success. Psychological aspects also play a vital role, as mental health considerations can significantly influence treatment adherence and overall satisfaction. This domain reflects the necessity for patient-centred approaches that address the holistic impact of conditions on individuals and their support systems.

The **Current Practice** domain sheds light on existing treatment landscapes. It includes aspects such as currently available treatments, the current treatment pathway and the success rates of these interventions. Variations in current practice suggest inconsistencies in treatment effectiveness, with implications for clinical management. This domain also addresses the stigma associated with seeking expert treatment, which can deter patients from pursuing optimal care. Overall, this domain highlights the necessity of aligning new treatments with established practices to enhance patient outcomes.

The **Clinical Need** domain focuses on the pressing demand for improved treatments and practices. It highlights the necessity for better monitoring, optimised dosing and the identification of specific patient subgroups requiring tailored interventions. This domain indicates a critical need for advancements in treatment strategies to address gaps in current healthcare delivery and meet the evolving needs of patients.

The **New Treatment** domain examines the introduction of novel interventions with key considerations including treatment safety, adverse events and long-term treatment effects. The validity of comparator treatments and the effectiveness of new patient access schemes are also critical. This domain reveals the importance of ensuring that new treatments not only demonstrate efficacy but also maintain an acceptable safety profile, particularly when compared to existing options.

Within the **Studies** domain, factors such as study relevance, methodology and quality emerge as significant in influencing the credibility of research findings. The generalisability of study results to current practice is crucial for making informed decisions about the adoption of new technologies. This domain emphasises the importance of rigorous study designs that can reliably inform clinical practice and decision-making.

The **Clinical Effectiveness** domain is central to assessing the overall impact of treatments. Key considerations include treatment effectiveness, relative effectiveness/comparisons and the relevance of evidence to clinical practice. This domain highlights the need for robust evidence supporting the effectiveness of interventions across different patient populations, particularly concerning subgroup comparisons and patient-reported outcomes.

Cost considerations are integral to the **Cost Effectiveness** domain, where cost-effectiveness analysis and the estimation of $ICER_b$ metrics are paramount. The validity of economic models and their implications for treatment length and application in practice are critical components of this analysis. The domain also addresses the importance of establishing appropriate comparative frameworks for assessing new technologies. Considerations such as the representation of current treatment scenarios and the limitations of existing models are essential for understanding the context in which new interventions will be implemented. The domain emphasises the necessity of aligning clinical benefits with economic feasibility to ensure sustainable healthcare practices and highlights the complexity of comparing different treatment options and the need for transparency in the appraisal process.

Finally, the **Other Factors** domain introduces aspects related to innovation, equity and the impact of treatments on vulnerable populations. Considerations such as rare conditions, treatment for children and the need for recent advancements in treatment options are critical. Additionally, issues related to stigma, family impact and uncaptured benefits illustrate the broader social and ethical implications of technology appraisals. This domain stresses the importance of recognising and addressing the unique challenges faced by specific patient groups and ensuring equitable access to innovative therapies.

4.10 Findings from Phase 1: Key value criteria for assessing medical devices in value frameworks

Medical devices differ fundamentally from pharmaceuticals and understanding these differences is crucial for identifying the appropriate value criteria. The assessment of medical devices is guided by a range of value frameworks designed to address the unique complexities specific to these technologies. These frameworks, which are applied at various levels, from centralised HTA to local hospital-based approaches and procurement guidelines, draw on the expertise of multiple institutions and stakeholders, ensuring a broad diversity of perspectives. These frameworks are tailored to address their unique characteristics, offering targeted insights that support effective evaluation. The following key aspects distinguish medical devices from pharmaceuticals and shape their assessment:

Mechanism of action: Unlike pharmaceuticals, which work chemically, metabolically, or immunologically, medical devices operate through mechanical, electromagnetic, radiation, or thermal means. This difference requires distinct safety and regulatory considerations (Pecchia & Craven, 2013).

Lifecycle: Medical devices generally have shorter lifecycles and often undergo iterative updates. Unlike pharmaceuticals, which tend to have specific compounds, the rapid evolution of medical devices necessitates continuous reassessment of their effectiveness, safety and costs over time (Pecchia & Craven, 2013; Polisena et al., 2018).

Pre-market evidence: The development of medical devices is often faster and less reliant on extensive pre-market evidence. This lack of robust randomised controlled trials (RCTs) can present challenges when evaluating their safety and effectiveness (Taylor & Iglesias, 2009).

Learning curve: Medical devices require specialised training for their proper use, leading to a longer learning curve compared to pharmaceuticals. The skill and experience of the operator can significantly influence the performance and outcomes of the device, introducing variability that is less common in pharmaceutical interventions.

Context and organisational impact: Unlike pharmaceuticals, which are typically consumed in a straightforward manner, medical devices often require specific infrastructure, installation and maintenance. Their effectiveness can be influenced by organisational factors, such as resource availability, staff training and integration with existing systems.

Diagnostic and therapeutic roles: Medical devices serve a variety of roles such as diagnostic, therapeutic, invasive or non-invasive. Their benefits may not always be immediate and can only be fully realised after subsequent interventions, requiring careful assessment of their long-term impact on patient care.

Cost considerations: The total cost of medical devices extends beyond their initial acquisition. Ongoing costs, such as installation, maintenance, upgrades, training and eventual disposal must be factored into their economic evaluation, making their cost assessment more complex than that of pharmaceuticals.

The thematic analysis of various value frameworks highlights key value criteria for assessing medical devices. While the core assessment criteria for medical devices include clinical effectiveness, safety, quality and cost-effectiveness, the technological aspects of medical devices can significantly influence these factors. The rapid evolution of technology can alter its effectiveness and value. Furthermore, medical devices impact organisations at various levels, including healthcare facilities and broader health care systems. They affect resource requirements, necessitate user training and can alter patient workflows and pathways. Medical devices can influence revenue streams, differentiate healthcare services, attract skilled professionals and impact the profitability of healthcare units. Medical devices affect patients by determining diagnosis or treatment outcomes, comfort, adherence and overall effectiveness. They also provide new capabilities to HCPs, enhancing their skills and prestige. Beyond individual stakeholders, medical devices influence both healthcare system and society by defining healthcare quality, ensuring equitable access and raising ethical concerns regarding availability, usage and patient access. Ethical considerations also play a role in shaping the development and distribution of medical devices, which must comply with regulatory rules and legal frameworks. Medical devices are complex technological achievements resulting from advances in various scientific fields and iterative development.

They are continuously evolving, serving both their immediate clinical purpose and contributing to ongoing research and development. As such, they offer hope and options for patients and drive scientific progress. An ecosystem of medical devices includes the environment and its sustainability. Medical devices may only exist and operate in an environmentally sustainable and responsible manner.

Thematic analysis reveals that a comprehensive evaluation must include not only traditional clinical and economic criteria but also factors such as technological complexity, organisational impact, patient outcomes and ethical considerations. The thematic groups, organised in Table 4.7, offer a structured approach to the assessment of medical devices, including clinical, technological, operational, safety, regulatory, legal, strategy, patient, healthcare professionals, societal, health system, environmental, ethical, future perspectives and economic value criteria. The following sections provide a more detailed discussion of each value criterion, focusing on how they influence the medical device assessment. Key elements, as identified in the analysis, that make up each main value criterion are highlighted in bold. These expanded criteria ensure that medical devices are evaluated holistically, considering both their immediate and long-term contributions to healthcare systems and society.

Clinical Value criterion focuses on the device's intended purpose and its impact on patient health outcomes. At its core, clinical value is determined by the device's ability to achieve a defined **clinical outcome**, which directly addresses a specific healthcare need. This primary purpose is central to the device's role in patient care, ensuring that it contributes meaningfully to health improvements. Clinical value is further evaluated through a balance between **benefits and harms**, where the positive effects of the device are weighed against potential risks or adverse outcomes. The **effectiveness** of the device is also assessed, examining how effectively it delivers tangible health benefits, such as symptom improvement, better diagnoses, or therapeutic gains. Additionally, the device's influence on **quality of life** is considered, highlighting its impact on the patient's overall well-being, comfort and daily functioning. A comprehensive evaluation of clinical value also requires a strong foundation in **evidence-based** analysis. This means that clinical outcomes, effectiveness and the benefit/harm balance must be supported by high-quality, well-documented evidence, such as

clinical trials or real-world data. This ensures that the claims about the device's clinical benefits are reliable and substantiated by empirical research.

Technology & Quality criterion includes the device's type of technology, mechanism of action and manufacturing quality, all of which influence its clinical effectiveness, safety and overall value. A device's identity is shaped by its **technical characteristics**, such as power, energy, speed, ionising radiation and heat, which define its function and differentiate it from other devices in the same category. These characteristics define the **mechanism of action**, explaining how the device interacts with the human body to achieve its therapeutic or diagnostic effect. In addition, the **features of technology**, including aspects like user interface, automation and portability, further enhance its performance and usability in clinical settings. **Differentiators**, such as innovation, functionality, or cost-effectiveness, set the device apart from others, providing distinguishing advantages for healthcare providers and patients. The **claimed benefits** of a device, which describe its intended clinical outcomes, must be clearly defined and supported by evidence to justify its value. Furthermore, **manufacturing quality** plays a critical role in ensuring the device's safety and reliability, including high-quality materials, rigorous production processes and strong quality control measures.

Operational Needs & Impact criterion emphasises the device's influence on healthcare delivery processes and its integration into the broader organisational context. Central to this evaluation are **patient pathways**, which reflect how the device shapes the clinical program, from diagnosis through treatment and follow-up care. The introduction of new technology often requires changes in **processes**, particularly in terms of **change management**, as devices can alter workflows, enhance productivity and impact team dynamics within healthcare settings. For instance, a device might streamline patient care workflows, improve collaboration across disciplines, or require new methods for task allocation among healthcare teams. Moreover, the **learning curve** associated with medical devices necessitates effective **education and training** to ensure HCPs are proficient in device operation and can integrate it into their practice. Alongside this, medical devices demand **resources**, including medical staff time, infrastructure, consumables, maintenance and spare parts, all of which contribute to both operational costs and efficiency. The successful adoption of a device also depends on the

culture of the healthcare organisation, as attitudes toward innovation, technology and teamwork influence how well the device is received and integrated into daily operations.

Safety criterion ensures that both patients and HCPs are protected from potential harm. Medical devices must adhere to stringent safety standards, which are typically enforced through regulatory frameworks during the approval and licensing process. However, the **safety profiles** of devices can vary significantly depending on their design and application. For instance, an X-ray machine may offer different radiation settings to minimise patient exposure, while devices like MRI scanners may present risks related to operator ergonomics or noise levels, affecting the safety of the users. Beyond immediate risks, safety also includes **long-term effects**, such as complications or adverse outcomes that may not be evident at the point of use but emerge after prolonged or repeated exposure. These longer-term risks could include issues such as device-induced tissue damage or chronic health effects. **User-dependent harms** are another important consideration, as the safety of many devices is contingent upon the skill and knowledge of the operator. Inadequate training or improper use can significantly increase the risk of harm, making it essential for operators to be well-trained and for devices to have user-friendly interfaces that minimise the likelihood of misuse. Additionally, **occupational harms** must be factored into safety assessments. HCPs who interact with medical devices daily may be exposed to risks such as physical strain, repetitive motion injuries, or occupational hazards like radiation exposure. A comprehensive safety evaluation thus involves not only considering risks to patients but also safeguarding the health and well-being of healthcare workers.

Regulatory & Legal Frame criterion addresses the complex legal and regulatory environment that governs the development, approval and use of medical devices. Central to this frame are the **licensing and authorisation** processes, which ensure that medical devices meet safety, efficacy and quality standards before being made available on the market. Regulatory bodies across different countries assess devices to guarantee they comply with national and international standards, safeguarding both patient safety and the legal protection of healthcare providers. This compliance is not only vital for patient care but also for the credibility of the healthcare institutions adopting these technologies. Another critical consideration is **liability**, which involves the legal responsibilities tied to the use of medical

devices. Manufacturers, healthcare providers and users must be aware of the potential legal consequences should a device malfunction or cause harm. This includes product warranties, the risk of legal claims and the broader implications of device failure, which can influence decisions regarding technology adoption and deployment. Ensuring clear understanding of these liabilities helps mitigate risks to all stakeholders involved in patient care. Additionally, **autonomy** is a significant consideration, particularly in ensuring that medical devices respect patient's rights. Devices must facilitate informed consent, allowing patients to make autonomous decisions about their treatment based on transparent, accessible information about potential risks, benefits and alternatives. Respecting patient autonomy is fundamental to ethical healthcare practice. Finally, **privacy**, both for patients and their data, is increasingly important as medical devices become more digital and interconnected. Ensuring compliance with data protection laws, such as General Data Protection Regulation (GDPR), is crucial in maintaining patient trust and safeguarding sensitive health information. Medical devices must be designed with robust data security measures to protect patient privacy throughout their use.

Market - Strategy criterion focuses on the strategic and economic factors that influence adoption and success of medical devices within healthcare organisations. The introduction of new devices can significantly impact a healthcare facility's business model, enabling access to new patient groups and expanding service offerings. For example, acquiring technologies like MRI scanners or mammography units can open new diagnostic or therapeutic pathways, enhancing service scope and targeting specific populations. Central to the market strategy is the **competitive landscape**, where the presence of rival technologies and their relative advantages can shape the device's market penetration and adoption. **Reimbursement schemes** and **state policies** also play a pivotal role, as these determine the financial viability of adopting medical technologies. High equipment costs, combined with insufficient reimbursement or weak business cases, may discourage investment. Furthermore, economic factors such as budget constraints, resource availability and infrastructure limitations can affect the decision-making process within healthcare organisations. Another crucial element is **efficiency in clinical pathways**. Devices that optimise workflows and reduce inefficiencies offer a compelling value proposition, improving patient outcomes while lowering operational costs. The **economic climate** and **resource availability** further influence the market dynamics,

as healthcare budgets and resource allocations fluctuate, impacting the demand for certain technologies. Finally, **profitability** is integral for both manufacturers and healthcare providers. For manufacturers, profitability ensures sustainability in the market, while healthcare providers must weigh the cost-effectiveness of a device against its potential clinical and operational benefits.

Patient criterion includes factors that directly influence patient outcomes, satisfaction and overall treatment effectiveness. Central to this criterion is the **comfort and experience** a device provides, which must minimise discomfort and be easy to use to promote patient cooperation and adherence. The **productivity** of a device is also important, as it evaluates how efficiently the device supports care, whether by reducing procedure times or facilitating faster recovery, ultimately improving the patient's overall experience. **Adherence and tolerability** are important aspects, as devices that are painful, difficult to use, or require complicated maintenance may reduce patient adherence, leading to suboptimal health outcomes. **Mobility and flexibility** further enhance patient experience, as devices that are portable or adaptable to different care settings provide greater freedom for patients, whether in hospitals, outpatient settings, or at home. The **perception of technology** plays a significant role as well, as patients' trust in the device's safety, usability and effectiveness influences their willingness to engage with it, affecting both compliance and clinical outcomes. In addition to these factors, the financial burden on patients and their families - while often considered in other categories - also affects how patients perceive a device's value.

Healthcare Professionals (HCPs) are pivotal stakeholders in the evaluation of medical devices, as their engagement, perceptions and expertise directly influence the adoption and success of these technologies in clinical practice. Central to this criterion are several key elements that shape how HCPs interact with medical devices. **Ease of use, functionality and convenience** are critical factors, as devices that integrate seamlessly into existing workflows and reduce cognitive or physical burdens are more likely to be embraced by HCPs. These attributes directly enhance clinical efficiency and provider satisfaction. Additionally, **training and education** are essential considerations, as effective device use requires adequate preparation. HCPs value devices that come with comprehensive training and ongoing support, ensuring they can use the technology to its fullest potential and stay current with new techniques or

updates. **Perception of technology** also plays a significant role, as HCPs are more likely to adopt devices they perceive as innovative, reliable and effective. Positive perceptions can drive broader acceptance and integration within medical practice. Another important factor is the **symbolic value** linked to technology adoption, where devices that elevate clinical capabilities or enhance professional prestige can influence an HCP's willingness to adopt and advocate for their use. The influence of **early adopters** or key opinion leaders also contributes to the initial uptake of new technologies, with these professionals setting trends that can drive wider adoption.

Society criterion focuses on the broader societal impact and ethical considerations that go beyond individual patient care to include public health and community well-being. Central to this criterion is **population health**, which examines how a device contributes to improving health outcomes at the population level, particularly in addressing public health priorities and reducing disease burden. Equally important is **access to healthcare**, which evaluates whether the device improves equitable access to medical services, especially in underserved or marginalised populations. Medical technologies that bridge gaps in care can significantly enhance healthcare delivery in areas where resources are scarce, improving overall health equity. The impact of medical devices on **caregivers and family quality of life (QoL)** is another critical consideration. Devices that improve patient outcomes can alleviate the burden on caregivers, enhancing their well-being and reducing absenteeism, which in turn improves family dynamics and reduces social costs. In this context, **equality, justice and transparency** are key considerations, ensuring that medical devices contribute to fair access and do not exacerbate health disparities. The ethical principles of fairness and social justice require that medical technologies are used to reduce inequities in healthcare, ensuring that their benefits reach all segments of society. Furthermore, **social responsibility** is integral to the evaluation process. Medical devices should support socially accepted values, such as protecting vulnerable populations and promoting public health. The adoption of certain technologies can be influenced by societal perceptions - what is seen as acceptable or beneficial within a particular cultural context. For instance, the adoption of routine screening technologies, like mammography, may be influenced by cultural attitudes and these perceptions can evolve as more evidence emerges about the technology's benefits. Lastly, the **perception of technology** by the public is a significant factor in its acceptance and widespread use. Positive public

perception, based on trust in the technology's safety, effectiveness and ethical considerations, fosters higher adoption rates. In contrast, negative perceptions can hinder a technology's integration into the healthcare system.

Health system criterion focuses on assessing its overall effectiveness, efficiency and sustainability in delivering quality healthcare. This criterion is underpinned by several key factors that define a high-functioning system: **reduced cost of treatment**, **fewer hospitalisations**, **improved system throughput**, **efficient resource and staff utilisation** and **optimal public/private spending**. Medical devices play a crucial role in achieving these objectives by enhancing the productivity and efficiency of healthcare delivery. For example, advanced diagnostic tools and automated laboratory devices can reduce the need for manual labour, expedite processes like sample analysis and ultimately lower treatment costs. These innovations also help reduce hospitalisations by enabling earlier diagnosis and treatment in outpatient settings, thus alleviating pressure on hospital resources. Additionally, AI-driven algorithms optimise patient flow by prioritising cases based on urgency, which enhances system throughput and reduces waiting times. The broader context of this value criterion emphasises not only meeting the healthcare needs of a population but also optimising the use of limited resources and minimising waste. Achieving cost-effectiveness involves providing high-quality care while avoiding excessive financial burdens on individuals or governments. Effective **resource and staff utilisation** ensure that both human and physical capital, such as healthcare personnel and medical infrastructure, are deployed efficiently, meeting demand without overuse or inefficiencies. Furthermore, the criterion highlights the importance of **public/private spending** collaboration, ensuring that investments are directed to areas that maximise patient outcomes and system sustainability.

Environment criterion is centred on minimising the ecological impact of medical devices while ensuring that healthcare delivery is both effective and responsible. This criterion is composed of two essential considerations: **disposal** and **sustainability**, each contributing to the overall environmental value. **Disposal** refers to the proper handling and management of medical waste, which can include hazardous materials like pharmaceuticals, medical devices and radioactive sources such as those used in nuclear medicine. Given the potentially harmful effects of improper waste disposal on soil, water and air quality, it is critical that healthcare

facilities adhere to strict environmental regulations and standards to mitigate risks and protect public health. The safe and environmentally responsible disposal of medical waste associated with medical device use is a fundamental aspect of this process. **Sustainability** extends the environmental focus to the broader operational practices of healthcare systems. It involves reducing the long-term ecological footprint of healthcare delivery by minimising energy consumption, optimising resource use and adopting renewable energy sources and environmentally friendly technologies. Sustainability also encloses a broader commitment to integrating eco-conscious policies into the entire lifecycle of medical devices and healthcare operations, from production and use to disposal. This includes promoting the use of materials and devices that are designed to have minimal environmental impact.

Ethics criterion focuses on ensuring that medical practices and policies align with moral principles that uphold individual rights, fairness and dignity. Healthcare decisions, particularly those involving medical devices, raise complex ethical concerns, as they can significantly impact human life and well-being. These concerns often involve justice, equity, privacy and cultural integrity, as well as the potential for stigmatisation or the need to avoid it. Medical devices, for example, can provoke moral questions about their influence on personal identity, moral beliefs and privacy, challenging healthcare providers to navigate these issues with sensitivity and respect for patients' diverse backgrounds. At the core of the **ethics** criterion are several interrelated elements: **autonomy**, **respect**, **equity**, **justice**, **stigmatisation** and **accessibility**. **Autonomy** emphasises individuals' right to make informed healthcare decisions without coercion, while **respect** affirms the importance of recognising patients' inherent dignity and honouring their values and beliefs. **Equity** and **justice** focus on the fair distribution of healthcare resources, ensuring that all individuals, regardless of socio-economic status or background, have equal access to quality care. These principles also address disparities in healthcare access and outcomes, promoting social justice. **Stigmatisation** stresses the ethical obligation to avoid marginalising individuals based on health conditions or personal characteristics, as such stigmatisation can perpetuate inequities and harm well-being. Lastly, **accessibility** ensures that healthcare services are available to all, particularly to marginalised or vulnerable populations, by overcoming barriers related to both physical access and financial constraints.

Perspectives criterion focuses on the broader, multifaceted impacts that health interventions, policies and innovations have on individuals and society. This criterion is composed of several key elements: **innovation**, **research spillovers**, **hope**, **options**, **end-of-life considerations**, **value of reducing uncertainty** and **insurance value**, each of which contributes to a more comprehensive understanding of the value healthcare can provide. **Innovation** refers to the development and integration of new technologies, treatments, or approaches that enhance the effectiveness and efficiency of healthcare, driving improvements in patient outcomes. Closely tied to this is the concept of **research spillovers**, which highlights the broader societal benefits that arise from scientific and medical research, such as the advancement of knowledge, the development of new therapies and the generation of economic opportunities, that extend beyond the immediate scope of a particular study or intervention. **Hope** emphasises the psychological and emotional value that healthcare can provide, particularly when new treatments or interventions offer patients and their families a sense of optimism and possibility. **Options**, on the other hand, reflect the value of providing patients with choices in their care, enabling them to make decisions that align with their personal values and preferences. **End-of-life considerations** introduce an ethical and compassionate dimension to healthcare, ensuring that decisions regarding care at the end of life are made with dignity, respect and sensitivity to the wishes of the patient and their family. The **value of reducing uncertainty** focuses on the importance of providing clear, evidence-based information that helps patients navigate their healthcare decisions, reducing the anxiety that comes from ambiguity or lack of knowledge. Finally, **insurance value** recognises the role of health insurance in providing financial security and access to care, ensuring that individuals are protected from unmanageable health costs and can access necessary treatments without undue financial strain.

Financial aspects criterion focuses on evaluating the economic implications of healthcare interventions, particularly in terms of their costs and the broader financial impact on healthcare budgets. Costs and economic evaluation and budget impact comprise the main considerations within this criterion. **Costs and economic evaluation** involve a detailed assessment of the financial outlay required for medical devices and interventions, which includes direct costs, such as purchase, maintenance, consumables and personnel, as well as indirect costs like long-term healthcare needs, operational expenses and potential savings.

Economic evaluations, such as cost-effectiveness or cost-utility analyses, provide a framework for comparing the financial burden of different healthcare options relative to their health outcomes, helping policymakers prioritise interventions that deliver the best value for money. **Budget impact** examines the broader financial implications of adopting a particular medical device or intervention across a healthcare system or population. It considers both the immediate and long-term costs that may influence overall healthcare expenditure, such as increased demand for services, the need for infrastructure investment and potential strain on existing resources. Budget impact analysis is essential in determining whether the costs of new treatments or technologies can be sustained within the available financial resources, ensuring that the introduction of innovations does not lead to unsustainable cost increases.

Table 4.7 details the value criteria and their elements, as previously described, along with the primary reference sources or relevant criteria within the frameworks examined in this chapter. While the reference sources listed in Table 4.7 are not exhaustive, they represent a significant connection between the value criteria and the existing frameworks. Figure 4.2, presented as a Value Criteria Map, visually depicts these value criteria. This map was shown to the interviewees and serves as the foundation for the subsequent phases of the research.

Table 4.7: The main criteria and elements for the value assessment of medical devices

Criteria	Elements	ICER$_a$	EUnetHTA	MEAT	AdvaMed	MedtecHTA	AdHopHTA	INTEGRATE-HTA	NICE
Clinical Value	• Intended purpose • Clinical outcome • Effectiveness - benefit/harm balance • Quality of Life • Evidence-based	Comparative clinical effectiveness	Clinical effectiveness	Outcomes & Evidence Outcomes focus	Clinical impact	Clinical effectiveness	Clinical effectiveness Clinical outcome/ effect size Quality of evidence	Effectiveness	Clinical need Clinical effectiveness
Technology & Quality	• Type of technology • Mechanism of action • Features of technology • Differentiators • Claimed benefits • Quality of manufacturing	Mechanism of action	Health problem and current use of technology Description and technical characteristics of technology	Existence of high-quality outcomes data	Clinical efficacy and effectiveness	Incremental Innovation	Health problem Technology characteristics	Effectiveness Implementation domain	Condition Current practice New treatment
Operational Needs & Impact	• Patient pathways - Medical program • Processes - Change management (Efficiencies & Productivity, Teamwork efficiency, Workflow optimisation) • Education-Training • Resources - Personnel (i.e. medical staff		Health problem and current use of technology Description and technical characteristics of technology Organisational aspects Cost and economic evaluation	Product Training and access to education Support improving efficiency along patient pathway Maintainability, warranty and technical service support	Care efficiency	Organisational aspects Manufacturer support Healthcare setting Learning Curve and Training Needs	Organisational aspects	Implementation domain	Current practice New treatment

Criteria	Elements	ICER$_a$	EUnetHTA	MEAT	AdvaMed	MedtecHTA	AdHopHTA	INTEGRATE-HTA	NICE
	time, infrastructure usage, consumables, maintenance & spare parts, investments) • Culture								
Safety	• Safety profile of the technology (Risks for the patients, users, environment) • Long treatment effects • User-dependent harms • Occupational harms		Safety Clinical effectiveness Ethical analysis	Secure usage of care providers	Patient safety and tolerability	Safety	Safety	Effectiveness	New treatment
Regulatory & Legal frame	• Licensing & authorisations • Liabilities • Autonomy • Privacy (patients & data)		Health problem and current use of technology Description and technical characteristics of technology Legal aspects	Alignment and support with reimbursement structure	Reduction in regulatory, legal and activist shareholder interventions	Regulatory and market access	Legal aspects	Legal aspects	Clinical effectiveness
Market-Strategy	• Competition • Reimburse-ment/payment models - state policies • Efficiency in clinical pathways • Economic climate and			Strategic fit for provider and support of strategy	More preferable site of access (ease of access)		Political and strategic aspects	Context domain Implementation domain	

Criteria	Elements	ICER$_a$	EUnetHTA	MEAT	AdvaMed	MedtecHTA	AdHopHTA	INTEGRATE-HTA	NICE
	resources availability • Profitability								
Patient	• Comfort & Experience • Productivity • Adherence & Tolerability • Mobility & Flexibility • Perception of technology	Complexity of regimen	Patients and social aspects Clinical effectiveness Ethical analysis	Patients' secondary benefits	Patient experience Patient economics Improvement in compliance with plan of care Improved patient safety and tolerability vs alternative treatments	Patient preferences		Socio-cultural aspects	Condition Clinical effectiveness New treatment
Healthcare Professionals (HCPs)	• Ease of use, Functionality, Convenience Access to education/inno-vation • Perception of technology • Relationships between HCPs (prestige) – Symbolic value and early adopters' pressure		Organisational aspects	HCP benefits	Economic impact of improved adoption due to easier/more effective training/educati on	User preferences (Healthcare Professionals)	Cost and economic evaluation Hospital point of view	Socio-cultural aspects Implementation domain	Other factors

Criteria	Elements	ICER$_a$	EUnetHTA	MEAT	AdvaMed	MedtecHTA	AdHopHTA	INTEGRATE-HTA	NICE
Society	• Population health • Access to health • Caregivers & Family Quality of Life (QoL) • Equality, Justice, Transparency • Social responsibility • Technology perception	Disadva-ntaged or undeserved communities Caregiver and Family Impacts Return to Work and/or Productivity)	Patients and social aspects	Socio-economic impact Innovation	Improved population health (burden of illness/disease) Workforce productivity Reduced time to return to activities of daily living	Incremental Innovation Patient Preferences	Social aspects Ethical aspects	Socio-cultural aspects	Condition Other factors
Health System	• Reduced cost of treatment • Less hospitalisations • System throughput • Resource and staff utilisation • Efficient public/private spending	Incremental Cost-effectiveness	Clinical effectiveness Cost and economic evaluation Organisational aspects	Health system benefits Innovation	Patient economics Quality of care economics Impact to overall private and public spending More efficient private and public spending Workforce productivity		Political and strategic aspects	Context domain	Clinical effectiveness
Environment	• Disposal • Sustainability		Environmental safety (Safety)	Broader impact on society Disposal/decom-missioning Sustainability	Environmental impact			Context domain	

Criteria	Elements	ICER$_a$	EUnetHTA	MEAT	AdvaMed	MedtecHTA	AdHopHTA	INTEGRATE-HTA	NICE
Ethics	• Autonomy • Respect, • Equity, Justice, Stigmatisation, Accessibility	Disadva-ntaged or Undeserved Communities	Ethical analysis			Ethical analysis	Ethical aspects	Ethical considerations Legal aspects	Other factors
Perspectives	• Innovation • Research Spillovers • Hope • Options • End of Life considerations Value of Reducing Uncertainty • Insurance Value	Balance or Timing of Risks and Benefits (Value of Hope) Absolute QALY shortfall Proportional QALY shortfall		Broader impact on society Innovation				Socio-cultural aspects Ethical considerations Context domain Implementation domain	Other factors
Financial aspects	• Costs and economic evaluation • Budget impact		Costs and economic evaluation	Purchasing Cost of consumables	Monetary impact	Costs and economic evaluation	Costs and economic evaluation Societal and Hospital point of view	Economic assessment Legal aspects Context domains	Cost effectiveness

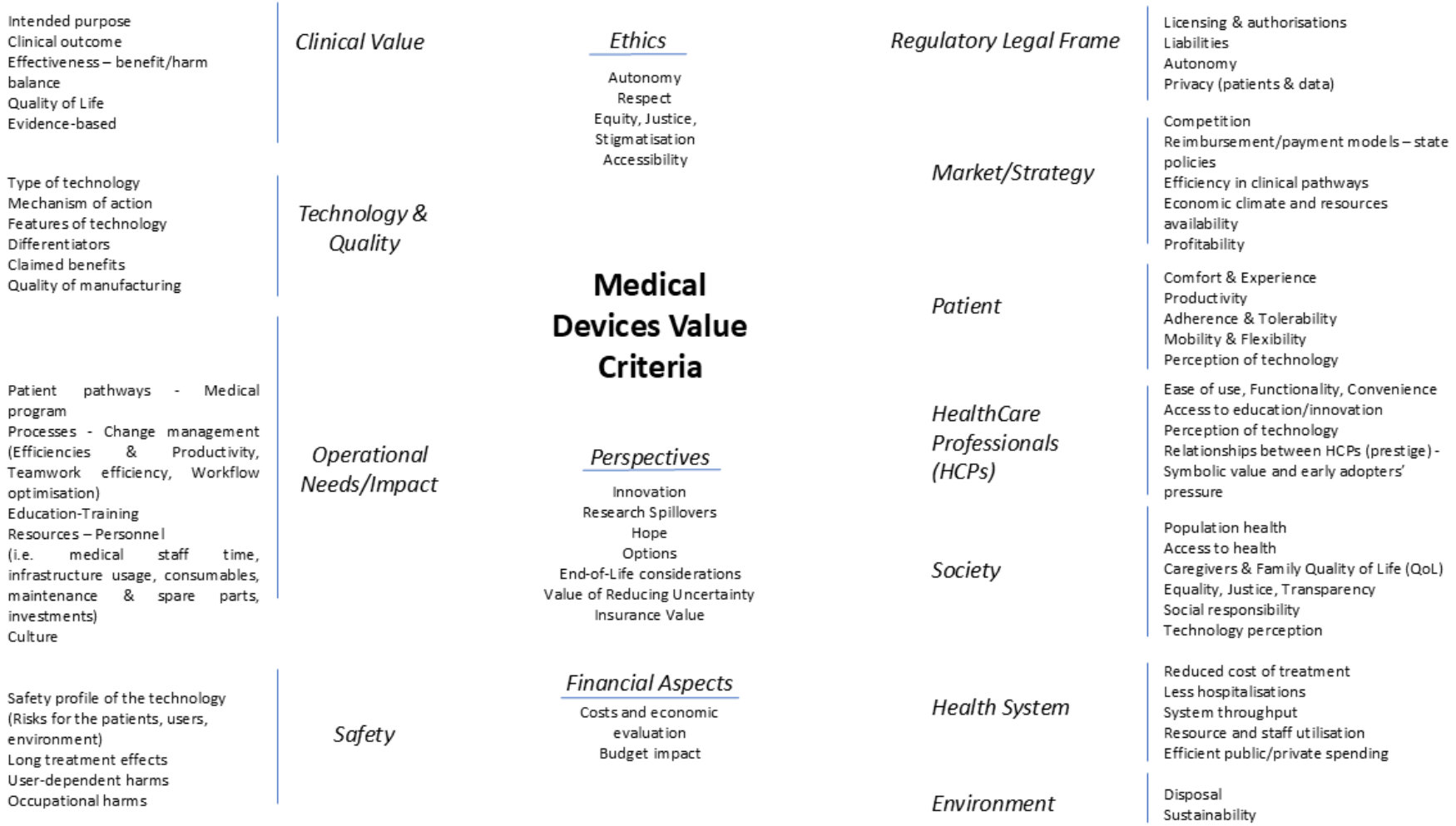

Figure 4.2: Medical Devices Value Criteria map.

5. Findings from Phases 2 and 3: Perceived value drivers in transforming medical devices into medtech solutions

5.1 Introduction

This chapter presents and analyses the findings from Phases 2 and 3 of the research, with a specific focus on the key value drivers that transform a medical device offering into a medtech solution offering, as perceived by both HCPs and medtech professionals.

The chapter begins by examining the key value elements of an imaging medical device offering from the perspective of HCPs. These value elements, as identified through the interviews and subsequent analysis, reflect how HCPs assess the value of a stand-alone medical device. The analysis provides a detailed description of these value elements, supplemented by indicative quotes from interviewees to illustrate the source of each value element and the rationale behind its perceived importance.

The discussion then explores the critical value elements associated with a medtech solution offering, as perceived by HCPs. In this section the distinctions between the value elements of medtech solutions and those of traditional medical devices are discussed. The primary data source comprises interviews, which provide insights into HCPs' perceptions of the added value inherent in medtech solutions. Representative quotes from the interviews are included to substantiate and further clarify these value elements, providing a deeper understanding of their significance.

Next, the chapter integrates insights from medtech professionals to provide an additional layer of understanding about the value elements in medtech solutions. These contributions enrich the perspectives of HCPs by illustrating how medtech professionals conceptualise value in terms of integrated solutions rather than individual devices. The inclusion of these insights facilitates a more comprehensive understanding of the dynamics involved in the transformation from traditional medical devices to medtech solutions.

The chapter concludes by defining the key value drivers, as derived from the previous analysis, that differentiate a medtech solution offering from a traditional medical device offering, directly addressing the research sub-question: 'What key value drivers transform a medical device offering into a medtech solution, as perceived by healthcare professionals (HCPs) and medtech professionals?'. To visually illustrate this transformation, Figure 5.1 is presented, mapping the value elements associated with both types of offerings and highlighting the value drivers responsible for the shift from medical device to medtech solution.

5.2 Key value elements of imaging medical devices for HCPs: insights from interviews

One of the initial questions posed in the discussions was, 'What does value mean in the context of a medical device, particularly an imaging system?' This question prompted participants to reflect on and articulate their perceptions of value. Throughout the interviews, references to the value criteria identified in Phase 1, which are integrated into value or procurement frameworks, facilitated a deeper exploration of the value elements as they pertain to an imaging device. This approach enabled a deeper discussion, providing further insights into how interviewees perceive the composition of value.

The responses primarily focused on elements related to the medical device itself, including dimensions such as safety, quality and clinical value (i.e. the intended purpose of the medical device). However, the discussion also extended to consider the beneficiaries, including both the user, such as clinicians within the healthcare provider and the patient, who is the recipient of the services. Patient satisfaction and clinical outcomes emerged as key value elements associated with the patient experience. Additionally, interviewees identified broader access to care, expansion of scope and increased specialisation (e.g. managing and treating advanced clinical cases) as significant value elements, thereby emphasising the social impact of the medical device.

The key value elements identified from the interviews are summarised below, presented in Table 5.1 and further detailed in sections 5.2.1 to 5.2.9, accompanied by representative quotes from the research participants:

- Technical specifications and features
- Clinical requirements and outcomes (clinical value)
- Service availability, coverage and quality (serviceability)
- Safety
- Regulatory framework (compliance)
- Clinician experience (medical doctors and operators)
- Patient satisfaction (outcome and comfort)
- Societal impact (local)
- Cost and budget

Table 5.1: The medtech device offering value elements

Medtech Imaging Device Offering								
Technical specs and features	Clinical require-ments and outcomes	Service availability, coverage and quality (serviceability)	Safety	Regulatory framework (compliance)	Clinician expe-rience	Patient satisfaction	Societal impact (local)	Cost & Budget

5.2.1 Technical specifications and features

The technical specifications and features of the imaging medical device play a pivotal role in its value assessment, especially from the perspective of healthcare providers. These attributes such as power, scanning speed, resolution, field of view and the size of the gantry or table, are fundamental to the daily use of the device by HCPs. They serve as the basis for evaluating the device's utility and performance. As one clinician/radiologist noted, 'In a device, we set certain specifications. We want the medical devices to be fast…with modern software…Clinically right…' (hcpintw#1). This sentiment is expressed by other professionals, including a CEO/COO

who emphasised, ‘Good product… we do not evaluate many value criteria in every procurement if we do not have a good product first’ (hcpintw#2).

However, while these technical specifications are essential, they are often seen as a means for assessing attributes such as reliability, clinical excellence, precision and overall quality. For instance, a technologist/radiographer highlighted the importance of ‘Fast clinical result(s) to save time for more exams…’ and the need for an ‘optimal (radiation) dose for the needed result’ (hcpintw#8). This shows the broader implications of the device’s technical capabilities in real-world clinical settings.

Medical physicists and biomedical engineers also stressed the significance of advanced technological capabilities, with one medical physicist stating the need ‘to provide to the patient, the maximum, to have the highest technological capabilities, state-of-the-art…’ (hcpintw#11). Similarly, a CTO/biomedical engineer pointed out that a medical device ‘shall fulfil the end-users’ needs’, adding that from an engineering perspective, they also consider ‘what’s behind the ‘box’, the device - its technology and features’ (hcpintw#13).

While subject-matter experts in medical technology, such as biomedical engineers, medical physicists and radiographers, often linked their value judgments directly to these technical specifications, medical doctors and managerial executives tended to associate these specifications with broader attributes like reliability and consistency. Despite this difference in focus, both groups consistently emphasised the importance of the product-specific attributes in their overall assessment of value. As one clinician/radiologist aptly summarised, the ‘technical capabilities…deliver the expected result’ (hcpintw#5), highlighting the intrinsic link between technical features and perceived value. Table 5.2 summarises the quotes from participants related to the value element of technical specifications and features.

Table 5.2*:* Representative quotes highlighting technical specifications and features

Source/Quote
Clinician/Radiologist (hcpintw#1): 'In a device, we set certain specifications. We want the medical devices to be fast…with modern software…Clinically right…'.
CEO/COO (hcpintw#2): 'Good product' … 'we do not evaluate many value criteria in every procurement if we do not have a good product first'.
Clinician/Radiologist (hcpintw#5): '…technical capabilities…deliver the expected result'**.**
Technologist/Radiographer (hcpintw#8): 'Fast clinical result to save time for more exams…'. 'Radiation dose should be optimal for the needed result'.
Medical Physicist (hcpintw#11): '…to provide to the patient, the maximum, to have the highest technological capabilities, state-of the art …'.
CTO/Biomedical Engineer (hcpintw#13): '(A medical device) shall fulfil the end-users' needs. From our perspective, as engineers and subject matter experts, beyond this fulfilment, we also look at what's behind the 'box', the device - its technology and features'.

5.2.2 Clinical requirements and outcomes (clinical value)

A medical device's primary function is to address a specific clinical need, that defines its core purpose. For healthcare providers and patients, this involves ensuring that the device is equipped with the necessary capabilities to meet its intended clinical function effectively. There is a strong consensus among respondents that a medical device must fulfil its intended purpose and perform its clinical function reliably. As one technologist/radiographer emphasised, the 'first priority is the clinical need. How much the clinical need is met' (hcpintw#10). This highlights the critical role of the device in providing precise diagnoses and treatments, ultimately aiding patients in restoring function and relieving symptoms (Ettinger, 1998). Thus, meeting clinical needs and achieving clinical excellence are considered fundamental to the value of medical technology.

The notion of clinical value is a recurring consideration in the perspectives of various respondents. A CEO/COO simply stated, 'Clinical value…Technology & quality' (hcpintw#3), highlighting the importance of clinical effectiveness alongside technological advancement. A CTO/biomedical engineer reiterated this by noting, 'Clinical value is very important. I respond very spontaneously…Technology and quality are significant too' (hcpintw#9), further

emphasising the close relationship between clinical outcomes and the technical aspects of the device.

The alignment between fulfilling clinical needs and achieving functional value is evident in the broader context of value assessment. According to Park *et al.* (1986), functional needs drive the pursuit of products that can solve consumption-related problems, such as addressing current issues or preventing potential ones. This concept is directly applicable to medical devices, where successfully meeting clinical requirements generates what Smith *et al.* (2007) refer to as functional or instrumental value (Smith & Colgate, 2007). As a medical physicist pointed out, 'Clinical outcome, (this is my opinion) as a medical physicist' (hcpintw#11), the clinical outcome is a crucial criterion in evaluating the device's overall value. Consequently, the functional dimension of value, particularly in terms of clinical requirements and outcomes, has emerged as a critical aspect of the value assessment as perceived by HCPs. Table 5.3 provides a summary of key quotes from the interviewees.

Table 5.3: Representative quotes on clinical requirements and outcomes

Source/Quote
CEO/COO (hcpintw#3): 'Clinical Value…Technology & Quality'.
CTO/Biomedical Engineer (hcpintw#4): 'Clinical Value - 2nd priority'.
CTO/Biomedical Engineer (hcpintw#9): 'Clinical value is very important. I respond very spontaneously…Technology and Quality are significant too'.
Technologist/Radiographer (hcpintw#10): 'First priority is the clinical need. How much the clinical need is met'.
Medical Physicist (hcpintw#11): 'Clinical outcome, (this is my opinion) as a medical physicist'.

5.2.3 Service availability, coverage and quality (serviceability)

The interview responses reveal that HCPs place significant emphasis not only on a medical device's clinical performance but also on its serviceability and ongoing operational reliability. Serviceability, including aspects such as uptime, maintenance and ease of service, has emerged as a critical component of a device's overall value. Respondents consistently emphasised the importance of a medical device that not only delivers optimal clinical services but also does so in a consistent and uninterrupted manner. This indicates that the reliability

of a device, including its maintenance, ease of service and sustained functionality, is integral to its overall value assessment.

HCPs recognise that even the most advanced medical technology is only as valuable as its ability to remain operational and effective, underlining the need for robust support systems that ensure the device is always ready to perform its intended clinical functions. As articulated by the CEO/COO, 'At the end of the day, what you are looking for is the best technical support, increased output and maximum power for the worth of money, or a combination of these elements' (hcpintw#2). This statement reflects a high-level perspective on the value of technical support and operational efficiency. The emphasis on 'best technical support' and 'increased output' suggests that the effectiveness of a medical device is not solely determined by its clinical capabilities but also by the quality and efficiency of the support services that ensure its optimal performance. The mention of 'maximum power for the worth of money' indicates that cost-effectiveness, in combination with high-quality support, is a crucial factor in assessing value. A technologist/radiographer added, 'Easy service and easy update…Remote service' (hcpintw#8). This quote emphasises the importance of straightforward service processes and the benefits of remote service capabilities.

Efficient maintenance procedures and the ability to perform updates remotely are crucial for minimising downtime and operational disruptions, thereby enhancing device reliability and overall efficiency. Similarly, the medical physicist's comment, 'Service should give me the opportunity not to be down for several days without a good reason' (hcpintw#7), highlights the critical need to minimise device downtime. This statement reflects a concern for maintaining continuous device availability and functionality, which is essential for uninterrupted clinical operations.

The interview responses illustrate that service availability, coverage and quality are fundamental to the value of medical devices. The participants' emphasis on serviceability highlights that the value of a device extends beyond its clinical capabilities to include the effectiveness of support systems that ensure its consistent and reliable operation. Table 5.4 provides a summary of key quotes from the interviewees.

Table 5.4: Representative quotes on service availability, coverage and quality (serviceability)

Source/Quote
CEO/COO (hcpintw#2) 'At the end of the day, what you are looking for is the best technical support, increased output and maximum power for the worth of money, or a combination of these elements'.
Technologist/Radiographer (hcpintw#8) 'Easy service and easy update…Remote service'.
Medical Physicist (hcpintw#7) 'Service should give me the opportunity not to be down for several days without a good reason'.

5.2.4 Safety

Safety emerged as a critical component of value for respondents across various roles within healthcare organisations, including clinicians, medical physicists, radiographers and administrators. This focus on safety is particularly noteworthy because, in today's medical equipment market, safety is generally viewed as a baseline requirement for the distribution and use of any medical device. However, the respondents emphasised the importance of safety in ways that go beyond standard regulatory compliance, linking it directly to long-term treatment outcomes, hospitalisation needs and occupational safety.

The quotes from the interviewees provide a deeper understanding of how safety is perceived and prioritised in the context of medical device use. For example, a technologist/radiographer explicitly stated, 'Safety is my second priority' (hcpintw#10), indicating that while safety is not the top priority, it is still of significant importance in their professional practice. This suggests that safety is considered alongside other crucial factors, such as clinical effectiveness and efficiency, but remains a key determinant in the overall value assessment.

A medical physicist further elaborated on the multifaceted nature of safety, noting that it includes the 'safety profile of the technology, which is related to long-term treatment effects, user-dependent harms and occupational harms' (hcpintw#11). This statement highlights the broad scope of safety concerns, containing not only the immediate risks associated with device operation but also the potential long-term impacts on both patients and HCPs. The inclusion of user-dependent harms also points to the variability in safety outcomes based on

how the technology is employed, emphasising the need for robust training and user-friendly design.

From a leadership perspective, a CEO/COO simply stated emphatically 'Safety' (hcpintw#3), stressing its foundational role in decision-making processes at the executive level. This concise emphasis suggests that safety is a non-negotiable criterion in the selection and use of medical devices, reinforcing its status as a core value element across all levels of healthcare operations.

Finally, a radiologist connected safety directly to patient care, stating, 'the patient shall have the best service provision, feeling safe, high clinical value and less hospitalisation' (hcpintw#1). This quote reflects the intrinsic link between safety and patient satisfaction, where a safe medical device not only minimises risks but also enhances the overall quality of care, reducing the need for extended hospital stays and ensuring a positive patient experience.

The interview responses reveal that safety is a multifaceted and essential attribute in the value assessment of medical devices. It is not merely about meeting regulatory standards; it also includes long-term treatment outcomes, the prevention of user and occupational harms and the enhancement of patient care. The participants' emphasis on safety indicates that it is a critical consideration for HCPs across various roles, shaping their perceptions of value and influencing decision-making processes related to medical technology adoption and use. Table 5.5 summarises sample quotes from the interviewees regarding safety.

Table 5.5: Representative quotes on safety

Source/Quote
Technologist/Radiographer (hcpintw#10): 'Safety is my second priority'.
Medical Physicist (hcpintw#11): 'Safety profile of the technology which is related with the long-term treatment effects, user-dependent harms and occupational harms'.
CEO/COO (hcpintw#3): 'Safety'.
Radiologist (hcpintw#1): 'Patient shall have the best service provision, feeling safe, high clinical value and less hospitalisation'.

5.2.5 Regulatory framework (Compliance)

The compliance to the regulatory frameworks and legislation was also raised in the interviews, primarily from the administrative participants such as management executives within healthcare organisations. These executives are sensitive about the liabilities linked with the use of a medical device. In the case of the imaging devices of the study, the patient awareness about radiation dose and the related long-term and cumulative effects have made the healthcare executives very vigilant on compliance. However, it was also sensed that in today's competitive and abruptly globalised medical devices market, the pursuit of low-price by an ever-growing number of medtech companies, may set at risk the regulatory requirements.

A CEO/COO's remark, 'Compliance to Regulatory framework' (hcpintw#5), indicates the fundamental expectation that medical devices must adhere to established regulatory standards. This statement reflects a basic requirement for all medical technologies, positioning regulatory compliance as a foundational aspect of device evaluation and deployment. Similarly, another CEO/COO stated, 'A technology shall fit with the legislation or expectation' (hcpintw#2). This quote reinforces the concept that compliance is not merely a procedural formality but a critical element ensuring that medical technologies meet legal and ethical standards. It suggests that adherence to regulatory frameworks is viewed as an integral component of a device's legitimacy and operational acceptability.

The interview responses indicate that while compliance with regulatory frameworks is considered a fundamental requirement, there is also an underlying concern about the potential for legal risks and liabilities. The recognition of compliance as a baseline expectation stresses the importance of adhering to regulatory standards, while the discussion also reveals a cautious awareness of the challenges posed by market pressures and the need for stringent regulatory processes. Table 5.6 summarises sample quotes from the interviewees regarding compliance to regulatory frameworks.

Table 5.6: Representative quotes on compliance to regulatory frameworks

Source/Quote
CEO/COO (hcpintw#5): 'Compliance to regulatory framework'.
CEO/COO (hcpintvw#2): 'A technology shall fit with the legislation or (regulatory) expectation'.

5.2.6 Clinician experience

The interviewees' responses indicate that clinicians, including radiologists and radiographers, view medical technology as an essential part of their daily practice, integral to both diagnosing and treating diseases. These HCPs are not only the primary users of these technologies but also act as crucial intermediaries in delivering value to patients. Their experiences with medical devices significantly influence the perceived value of these technologies, extending beyond mere adherence to product specifications to cover overall functionality and usability. The data highlights that the experience of clinicians with a medical device is a pivotal aspect of its value. This experience is deeply connected to the device's final functionality and operational ease, rather than just its technical specifications (Tukker & Tischner, 2006). Usability and convenience were recurring aspects in the interviews.

For instance, usability contains more than the physical handling of the device; it also includes aspects such as setup and operational configuration. It is essential for imaging systems like CT or MRI systems to feature diagnostic workstations that are not only well-installed but also equipped with remote access capabilities. These systems should include user-friendly applications that enhance diagnostic confidence and reliability. As one clinician noted, 'If you purchase a device which you won't be able to work with, then you will have a poor performance and this will affect the quality of life' (hcpintw#12). This quote underlines the importance of a medical device in facilitating a more efficient workflow and, consequently, increasing job satisfaction among clinical personnel. Another perspective is provided by a CEO/COO, who highlighted that 'Easiness to use the device, how to evaluate an exam (workstation tools), remote accessibility, service (technical)' (hcpintw#6), are critical factors. This quote reflects the comprehensive importance of ease of use, which includes the user interface, remote capabilities and technical support. Similarly, a radiologist stressed the importance of simplicity, noting that the device should be 'easy to use' (hcpintw#5). A

technologist/radiographer further emphasised that ease of use is crucial even if a feature does not provide additional clinical benefits, stating, ‘Ease of use. For instance, when a feature, despite it does not give any additional clinical benefit, still makes my work easier, I would like that’ (hcpintw#10).

Additionally, satisfaction derived from a device’s functionality often extends to a more experiential aspect. A technologist/radiographer remarked, ‘Beyond the patient and the hospital manager, the personnel must like and love the device. To excite them’ (hcpintw#8). This statement highlights that clinician satisfaction with a medical device can significantly influence their engagement and enthusiasm. Unlike consumer markets, where satisfaction is often evaluated post-purchase, clinicians need to ensure that the device enhances their daily work experience. This satisfaction can affect their professional choices and retention within healthcare organisations. For example, a CEO/COO pointed out that improving clinical value, ease of use and specialisation could help ‘enlarge the circle of the retention of radiologists’ (hcpintw#3).

Clinician experience with medical technology is critical in determining its overall value. Factors such as ease of use and user satisfaction are essential components that influence how medical devices are perceived and utilised in clinical settings. These factors affect day-to-day workflow and clinician engagement, highlighting the importance of designing technologies that cater to both functional and experiential needs. Table 5.7 provides indicative quotes from the interviewees specifically regarding the clinician experience related to ease of use.

Table 5.7: Representative quotes on clinician experience

Value element sub-category	Source/Quote
Empowerment	**Medical Physicist (hcpintw#7):** 'Collaborate into developing pilot new protocols. The info shall come from the vendors quite ready so that it can be integrated in the clinical routine. Keep-informed continuously'.
	Technologist/Radiographer (hcpintw#8): 'Beyond the patient and the hospital manager, the personnel must like and love the device. To excite them'.
Ease of use	**Clinician/Medical Doctor (hcpintw#12):** 'If you purchase a device which you won't be able to work with, then you will have a poor performance, and this will affect the quality of life'.
	CEO/COO (hcpintw#6): 'Easiness to use the device, how to evaluate an exam (workstation tools), remote accessibility, service (technical)'.
	Radiologist (hcpintw#5): 'Easy to use'.
	Technologist/Radiographer (hcpintw#10): 'Ease of use. For instance, when a feature, despite it does not give any additional clinical benefit, still makes my work easier, I would like that'.
Engagement	**CEO/COO (hcpintw#3):** 'Enlarge the circle of the retention of radiologists thanks to clinical value, ease of use, specialisation (i.e. cardiac examinations)'.

5.2.7 Patient satisfaction

The value of medical technology, as defined by the respondents, is predominantly centred around the patient, who is considered the ultimate recipient of healthcare services. This focus places the patient at the core of value assessment across all healthcare professional roles. The interviews revealed two primary dimensions of patient satisfaction that are integral to defining value. First, there is an emphasis on the patient's entitlement to achieve the best possible clinical outcome. A medical device must meet the expectations for high-quality clinical service, aligning with the patient's needs and perceptions of efficacy. Second, patient experience enfolds several aspects related to the procedure, including comfort, ease of use and the overall friendliness of the technology. This also involves considerations of hospitalisation times and evaluation durations. The recurrent value element across the

interviews was the importance of patient comfort, highlighting its critical role in the overall assessment of value.

The first sub-category of the value element involves the patient's right to achieve the best possible clinical outcome. As articulated by a radiologist, 'Patient shall have the best service provision, feeling safe, high clinical value and less hospitalisation' (hcpintw#1). This perspective affirms that a medical device should not only meet high standards of clinical service but also align with patient expectations for safety and efficacy. Similarly, a CEO/COO noted the importance of optimising outcomes, stating, 'Better outcome, less dose, shorter evaluation time' (hcpintw#2). The focus here is on delivering high-quality clinical results while minimising radiation exposure and reducing the time required for evaluations. A clinician added, 'How can we quantify the quality of life in relation with a medical device? The quality of life is mostly related with the quality of the intervention' (hcpintw#12). This brings to the forefront the belief that superior clinical interventions directly enhance patient quality of life.

The second sub-category of the value element concerns patient comfort, which includes the overall experience of the patient during and after the medical procedure. This includes the comfort of the procedure itself, the ease of use of the technology and the efficiency of the process. A CEO/COO highlighted this aspect by stating, 'Patient value generation, for instance the ability to have access to a multiparameter prostate MRI scan, so they (patients) do not commute, or a fast system so they don't wait' (hcpintw#3). This quote reflects the value of convenience in reducing patient wait times and minimising the need for multiple visits. A technologist/radiographer emphasised safety and comfort by noting, 'Safe (device) towards the patient (dose)… Patient comfort. Adherence & tolerability relate to patient comfort' (hcpintw#8). This statement reflects the importance of ensuring that the device minimises discomfort and adheres to safety standards, which in turn affects patient adherence to recommended treatments. A CTO/biomedical engineer also noted the significance of ease of use and friendliness in patient interactions with the technology, stating, 'Easiness, friendliness' (hcpintw#9). Moreover, another technologist/radiographer remarked on the importance of 'Patient-friendliness' (hcpintw#10), reinforcing the aspect of patient-friendly design.

The interpretation of patient comfort varies among different roles within healthcare providers. Administrative executives may view patient satisfaction as a metric for customer loyalty, leading to repeat services and a loyal clientele. Clinicians might see it as crucial for ensuring that patients adhere to follow-up care and treatments, thereby contributing to better long-term outcomes. Operators often focus on the procedural convenience and how the device facilitates a smoother experience for the patient. Biomedical engineers may prioritise the reliability of the technology, ensuring that it operates without malfunctions, thus avoiding unexpected disruptions.

In all cases, patient comfort has been consistently recognised as a critical value contributor. The broad consensus is that enhancing patient satisfaction through both clinical efficacy and comfort is fundamental to assessing the overall value of medical technology. Table 5.8 presents sample quotes from the interviewees regarding patient satisfaction.

Table 5.8: Representative quotes on patient satisfaction

Value element sub-categories	**Source/Quote**
Quality of service/clinical outcome	**Radiologist (hcpintw#1):** 'Patient shall have the best service provision, feeling safe, high clinical value and less hospitalisation'.
	CEO/COO (hcpintw#2): 'Better outcome, less dose, shorter evaluation time'.
	Clinician/Medical Doctor (hcpintw#12): 'How can we quantify the quality of life in relation with a medical device? The quality of life is mostly related with the quality of the intervention'.
Patient comfort	**CEO/COO (hcpintw#3):** 'Patient value generation (i.e. multiparameter prostate MR, so they do not commute, or a fast system so they don't wait'.
	Technologist/Radiographer (hcpintw#8): 'Safe (device) towards the patient (dose)…'. 'Patient comfort. Adherence & tolerability relate to patient comfort'.
	CTO/Biomedical Engineer (hcpintw#9): 'Easiness, friendliness'.
	Technologist/Radiographer (hcpintw#10): 'Patient-friendliness'.

5.2.8 Local societal impact

The societal impact of medical technology emerged as a significant consideration in the interviews, even though the sample did not include payors or policymakers. This focus on societal impact highlights how HCPs are influenced by and contribute to societal norms and values, reflecting the assertion that individuals are shaped by their social contexts (Giddens, 1984). Although the societal impact was explicitly discussed in four interviews, the backgrounds and roles of the HCPs varied widely. Clinicians, technologists and medical physicists all agreed that society should benefit from the evaluated medical technology. These benefits can be summarised as follows: a) quality in service delivery b) augmented clinical capabilities, c) access and equity and d) appropriateness to the local needs.

Quality of service delivery: The quality of services, frequently highlighted in the interviews, is directly associated with a positive societal impact. HCPs view the level of quality a medical device delivers as a crucial element of value, reflecting how well the device enhances healthcare services and benefits society. For instance, a radiologist emphasised, 'The return to society has to do with the quality of the exam and not the volume. The return to society happens with the high quality of the diagnosis, with emphasis on the return and impact to the local society' (hcpintw#1). This statement points out that quality is perceived as a return on the community's investment in healthcare.

Augmented clinical capabilities: The expansion of clinical capabilities was also highlighted as a valuable societal impact. A medical physicist noted, 'We need to inform society of the capabilities that technology can achieve. For instance, in the local society, it was not known that a mammography unit with stereotaxis was available in a public facility' (hcpintw#7). This quote reflects that a medical device is considered more valuable when it enhances or broadens the range of clinical options available to society.

Access and Equity: Accessibility to medical services, such as those provided by imaging devices, was highlighted as a significant value component. A technologist/radiographer noted that accessibility must cover both the broad availability of services and their financial feasibility, stating, 'Accessible to as many people as possible (needs to be financially

accessible)' and emphasising that 'Accessibility is also the major (and maybe perhaps the only) ethics element relevant to medical devices' (hcpintw#8). This perspective emphasises that accessibility extends beyond simply having clinical services available; it also involves ensuring that the technology is affordable and sustainable. HCPs have mentioned the connection between reimbursement policies, financial accessibility and the societal value of medical devices.

Appropriateness to local needs: The interviews revealed a clear emphasis on the local impact of medical technologies. Respondents viewed the societal return on investment primarily in terms of immediate benefits at the local level, such as within specific healthcare facilities or community settings, rather than broad societal gains. A clinician observed, 'Assessment versus the local needs' (hcpintw#12). HCPs expressed a preference for observing tangible benefits that are both practical and achievable within realistic timeframes.

The interviews reveal that HCPs interpret the societal impact of medical technology primarily at a local level. They expect tangible benefits that address immediate needs in their specific healthcare settings, rather than abstract or generalised societal gains. For instance, in areas with high rates of cardiac diseases, there is an expectation for dedicated imaging systems and applications that cater specifically to those needs. Table 5.9 summarises the relevant quotes from the interviewees.

Table 5.9: Representative quotes on societal impact

Value element sub-categories	Source/Quote
Quality in service delivery	**Radiologist (hcpintw#1):** 'The return to society has to do with the quality of the exam and not the volume. The return to society happens with the high quality of the diagnosis, with emphasis on the return and impact to the local society'.
Augmented clinical capabilities	**Medical Physicist (hcpintw#7):** 'We need to inform society of the capabilities that technology can achieve. For instance, in the local society, it was not known that a mammography unit with stereotaxis was available in a public facility'.

Value element sub-categories	Source/Quote
Access and Equity	**Technologist/Radiographer (hcpintw#8):** 'Accessible to as many people as possible (needs to be financially accessible)'. 'Accessibility is also the major (and perhaps the only) ethics element relevant to medical devices'.
Appropriateness to local needs	**Clinician/Medical Doctor (hcpintw#12):** 'Assessment versus the local needs'.

5.2.9 Cost & Budget

Cost, budget affordability and price were anticipated to emerge as key value elements in participants' responses regarding value perception. This aligns with the understanding that, like most consumers, HCPs often act as rational economic agents who make decisions based on utility and financial constraints (Chahal & Kumari, 2012; Sanchez-Fernandez & Iniesta-Bonillo, 2007). It is a common phenomenon, both in literature and practice, for consumers to balance benefits against sacrifices.

In this study, the significance of cost emerged as a prominent factor in the value perception by respondents. Participants, coming from diverse backgrounds and roles within healthcare providers' organisations, highlighted cost as a critical dimension in evaluating imaging systems. For some, the importance of cost was an absolute measure, with statements such as 'Cost is a priority' frequently appearing in the interviews, underscoring its self-explanatory and definitive role. Other respondents, however, approached the cost factor in a more relativistic way, emphasising budget affordability over sheer cost. A dominant sentiment expressed was, 'What or how much value can we buy with our budget?'.

Budget affordability was closely linked to the accessibility of technology, which, by extension, affects patient access to advanced medical technologies. It is particularly noteworthy how respondents connected budget constraints not only to their organisation's opportunities but also to broader patient benefits. As one technologist/radiographer succinctly stated, 'Technology should not be very expensive so as to be accessible. Budget is a determinant factor' (hcpintw#10).

Moreover, the concept of return on investment (ROI) was also tied to cost and affordability. Rather than merely viewing the cost of medical devices as a sacrifice to be weighed against benefits or budget, some respondents emphasised ROI. They noted that reimbursements from payors often depend on the specific medical devices used, such as low-dose or cardiac CT scanners. These insights are further supported by various quotes from the interviews, as summarised in Table 5.10, illustrating the multifaceted role of cost and budget considerations in the decision-making process.

Table 5.10: Representative quotes on cost & budget

Value-element sub-categories	Source/Quote
Cost as Business/Operations determinant	**CEO/COO (hcpintw#2):** 'Priority no.1'.
	Medical Physicist (hcpintw#7): 'This is a priority'.
	Radiologist (hcpintw#1): 'Can the hospital respond to the cost based on the number of exams it performs? Or the solution will be a Ferrari in the hands of a driver who cannot speed more than 70km/hr?'.
	CTO/Biomedical Engineer (hcpintw#9): 'For me, it is important also the relation between cost and effectiveness and the utility of the device or technology'.
Cost/Budget determines accessibility to technology	**Technologist/Radiographer (hcpintw#8):** 'Technology shall not be very expensive so as to be accessible - Budget is a determinant factor'.
	Technologist/Radiographer (hcpintw#10): 'Cost'. 'All must enter in a budget mentality'. 'Cost must come last because the primary objective for a healthcare system shall be the patient. I cannot tell an overweight patient that he cannot have a CT scan because my system has a small gantry and he cannot fit in it'.
	Radiologist (hcpintw#5): 'When we work with a device, cost is very important. You would like at the budget available to find a device, modern to the extent possible, to deliver the expected result'.
Cost vs ROI	**CTO/Biomedical Engineer (hcpintw#4):** Middle priority…Financials not at the top but in the middle because in my view what we are aiming with Value Based Healthcare (VBH) is the higher patient experience or satisfaction. We need to make sure that the cost anatomy control is not on the supplier side but also at the payor side'.

Value-element sub-categories	Source/Quote
	'If you ask the clinical team, there will be always a clinical reason to be always at the top of the technology, but you cannot allow this. You have to take into account the financials, you have a budget impact. You cannot build your assets to the highest, premium level. You must take into consideration the healthcare system you are working in'.

5.3 Value elements in the perception of medtech solutions for HCPs: insights from interviews

To understand the value drivers behind a medtech solution offering, as perceived by HCPs, the interview began by discussing what the term 'solution' means to the participants. This initial conversation set the stage for a deeper exploration of how value is perceived within the context of a solution. Then specific questions were posed to the participants to uncover the key value elements associated with a solution-based offering, as opposed to a stand-alone medical device:

- How do you perceive the value derived from a solution?
- What value elements would you like to see added to a solution offering compared to a medical device alone?
- Which value elements are most relevant or important for a solution-based offering?

These questions aimed at drawing out the participants' perceptions and priorities regarding what constitutes value in a medtech solution. As in the examination of value elements for imaging systems, the value criteria map, generated in Phase 1 of the study, was utilised. This map served as a tool to facilitate the discussion, helping participants compare and contrast the value of a single medical device with that of a comprehensive solution offering. The value elements identified in these discussions are summarised below and presented in Table 5.11, highlighting the key factors HCPs consider when evaluating the value of a medtech solution. In sections 5.3.1 through 5.3.8, each value element is explored in detail, with representative quotes from participants included to illustrate their perspectives.

- Business impact
- Ongoing education and skill enhancement for healthcare personnel
- Enhanced service delivery
- Turnkey approach and workflow optimisation
- Connectivity and interoperability
- Professional networking and second opinions
- Impact to the healthcare system
- Patient experience

Table 5.11: The medtech solution value elements

Medtech Imaging Solution							
Business impact	Education Upskilling	Enhanced service delivery	Turnkey approach Workflow optimisation	Connectivity Inter-operability	Profes-sional network Second opinion	Healthcare system	Patient experience

5.3.1 Business impact: How can medtech solutions drive business growth?

The potential for a medtech solution to drive business growth and revenue emerged as a key value element in the research, particularly emphasised by the administrative executives of healthcare provider organisations. While a medical device is primarily viewed as a clinical asset designed to meet patient needs, it is simultaneously regarded as a crucial business asset. This dual perspective emphasises the importance of viewing medical devices not just as tools for healthcare but also as contributors to the financial and operational success of healthcare organisations.

The respondents highlighted that the business value of a medtech solution extends beyond mere cost or price considerations. Instead, it incorporates a broad range of key performance indicators (KPIs) that reflect the entire lifecycle and operational context of a high-tech asset like an imaging device. These KPIs include productivity, efficiency, profitability, cost reduction

and increased revenues. A CEO/COO (hcpintw#2) articulated this perspective, stressing the importance of obtaining the 'best worth for money', which includes profitability, uptime, cost per patient and revenue per patient. This approach reflects a comprehensive view of how a medical device contributes to the overall business value.

Similarly, the ability to achieve market differentiation through the introduction of new services enabled by medical devices holds significant importance in private markets. Imaging systems, for instance, can serve as a key differentiator and provide a strong competitive edge. Healthcare providers also face the risk of commoditisation in the delivery of their services. Medical devices, aside from fulfilling their clinical purposes, can help healthcare providers distinguish themselves in the marketplace. The specific area of differentiation may vary depending on local competition and the commercial and strategic needs of the healthcare providers. For example, a CEO/COO (hcpintw#3) noted that private centres often invest in state-of-the-art equipment to offer unique scans and stand out from the competition. In public hospitals, the focus shifts slightly, with efficiency becoming the primary value element. Fast scanning capabilities, which can allow for additional exams per day, were cited as essential for maintaining a competitive edge in this setting.

This differentiation is not limited to administrative viewpoints. A medical physicist (hcpintw#7) also stressed the necessity of staying competitive within both public and private sectors, stating, 'We need to see how we do in comparison with others. We do not live in isolation. Even within a public hospital, there is competition with another public hospital or a private hospital'. This comment reflects the broader understanding that even in a public healthcare setting, there is an inherent competition that drives the need for clinical and operational excellence.

These insights collectively highlight that technology is not just a clinical tool but also a strategic asset that can promote business growth. By enabling new services, improving operational efficiency and differentiating a healthcare provider in a competitive market, medtech solutions are seen as integral to the financial and strategic success of healthcare providers. The appropriateness of the technology in aligning with the organisation's strategic goals - whether through enhancing clinical excellence or driving business performance - is thus a

critical value contributor. Table 5.12 presents representative quotes related to the business impact.

Table 5.12: Representative quotes on business aspect

Value-element sub-categories	Source/Quote
KPIs - driven	**CEO/COO (hcpintw#2):** 'Not necessarily the best price but the best worth for money'… 'Profitability, uptime, cost per patient, revenue per patient, to give you power for the worth of money'.
Appropriateness and competitive distinction	**Medical Physicist (hcpintw#7):** 'We need to see how we do in comparison with others. We do not live in isolation. Even within a public hospital, there is competition with another public hospital or a private hospital'.
	CEO/COO (hcpintw#3): 'Depends on centre profile. In private centres we go for state-of-the-art equipment so that we have different scans and we differentiate from competition'. 'In public hospitals, where efficiency becomes your value, we are looking for fast scanning, to generate 2-3 more exams per day'.

5.3.2 Ongoing education and skills enhancement for healthcare personnel

Respondents were unequivocal in emphasising the importance of education within a medtech solution offering. The performance of a medical device is intricately linked to the level of training and knowledge of its users. However, the interviews revealed that participants expect more than just a basic training session; they seek comprehensive, ongoing education throughout the entire lifecycle of the device. This sentiment was clearly expressed by a clinician (hcpintw#12) who stated, 'Education throughout the lifecycle of a device', highlighting the need for continuous learning. Similarly, a technologist/radiographer (hcpintw#10) pointed out the necessity of being 'taken by the hand, educated and brought up to the level of the technology', especially when transitioning to advanced devices from older models.

The complexity of imaging devices, which require extensive training, was a recurring consideration in the discussions. Participants view a medtech solution as a commitment to a lasting relationship that includes ongoing educational support. A radiologist (hcpintw#1)

highlighted a common issue: ‘The vendors, after the sale of a device, forget the buyer (user), who may ‘abuse’ the device’. This comment underlines the need for vendors to remain engaged with users to ensure the device is used optimally, preventing misuse or underperformance due to inadequate training.

Education as a critical factor for the optimal use of medical devices was further reinforced by a CEO/COO (hcpintw#2), who recognised the value of educating both clinicians and technicians: ‘My customers are the clinicians and my partners are the hospitals… Training of the doctors, training of the technicians, also brings me value’. This perspective highlights the broader impact of education on the entire healthcare ecosystem, from patient outcomes to the efficiency of healthcare providers.

In addition to initial training, the respondents stressed the importance of ongoing education, tailored to the evolving needs of both the technology and the users. A CEO/COO (hcpintw#3) suggested that technology should be ‘combined with education when needed’, indicating that training should be adaptable and responsive to the specific demands of the situation. The expectation for continuous education is not just about acquiring skills but also about ensuring that HCPs are equipped to handle the latest technological advancements. As the technologist/radiographer (hcpintw#10) described, ‘If we are given a latest technology CT, this will be operated by personnel that was familiar with lower-level technologies. We need to be educated… this shall happen within the daily routine’. This quote encapsulates the necessity for education to be integrated seamlessly into daily practice, ensuring that the technology is used to its full potential. Table 5.13 presents interviewees’ quotes relevant to the value element of ongoing education and skill enhancement for healthcare personnel.

Table 5.13: Representative quotes on the ongoing education and skill enhancement for healthcare personnel

Value-element sub-categories	Source/Quote
Upskilling	**Radiologist (hcpintw#1):** 'I trust the people I work with. When things go wrong, it is the people to blame and not the machines. Do the personnel have the necessary and adequate background and skills to respond to the offered solution?'. 'The vendors, after the sale of a device, forget the buyer (user), who may 'abuse' the device'.
Education	**CEO/COO (hcpintw#2):** 'My customers are the clinicians and my partners are the hospitals…Training of the doctors, training of the technicians, also brings me value'.
	CEO/COO (hcpintw#3): 'Combine with education when needed'.
	Clinician/Medical Doctor (hcpintw#12): 'Education throughout the lifecycle of a device'.
	Technologist/Radiographer (hcpintw#10): 'Education…If we are given a latest technology CT, this will be operated by personnel that was familiar with lower-level technologies. We need to be taken by the hand, educated and brought up at the level of the technology. This shall happen within the daily routine'.

5.3.3 Enhanced service delivery

The study participants highlighted the critical importance of maintenance and corrective services as fundamental components of medtech offerings. When considering a solution-based approach, this aspect remained central but with an expanded focus on outcomes and a more comprehensive understanding of service delivery. The emphasis was not just on fixing problems but ensuring the system's continuous availability and performance.

Uptime emerged as a dominant subject among the respondents, representing more than just the operational status of the device - it symbolised the supplier's commitment to meeting the business needs of healthcare providers. For instance, a CTO/biomedical engineer (hcpintw#04) articulated this well: 'Uptime is the no. 1 priority', emphasising that maintaining uptime requires a robust infrastructure, meticulous processes and a proactive approach to service delivery. He further elaborated, 'As a medtech supplier, to give high uptime, you have

to do thousands of things in the background. It is not a simple thing... Uptime describes all these things', underscoring the complexity and importance of this commitment. The importance of uptime was echoed by a medical physicist (hcpintw#07), who noted, 'Uptime gives me the ability not to be down without real reason'. This perspective highlights the critical role that uninterrupted service plays in maintaining operational efficiency and ensuring that patient care is not compromised.

In the context of a solution offering, uptime is not only a technical metric but also a Key Performance Indicator (KPI) that symbolises a supplier's dedication to providing prompt, high-quality and thoughtful service. The need for reliable service was further emphasised by a technologist/radiographer (hcpintw#10), who stated, 'Minimise downtime, have credibility in service and operation. If this is not ensured, it also causes stress to the personnel'. This statement reflects the broader impact of service reliability on the entire healthcare team, beyond just the technical aspects.

Moreover, participants expressed a desire for a service model where risk is transferred to the solution provider, allowing healthcare providers to focus on delivering care without the burden of managing unpredictable costs or bureaucratic hurdles. A clinician (hcpintw#12) advocated for 'full risk contracts to avoid downtime and bureaucracy in approving small budgets for repairing a system', recognising that even minor issues can lead to significant operational disruptions if not addressed swiftly. Table 5.14 summarises interviewees' quotes regarding enhanced service coverage.

Table 5.14: Representative quotes on enhanced service coverage

Value-element sub-categories	Source/Quote
Outcomes	**CEO/COO (hcpintw#3):** '…during warranty and after warranty - monitor the quality of the services. Find ways to improve service outcomes'.
Uptime	**CTO/Biomedical Engineer (hcpintw#4):** 'Uptime is the no. 1 priority…As a medtech supplier, in order to give high uptime, you have to do thousands of things in the background. It is not a simple thing. It is not that you have an FE on site. Human resources are one thing. Spare parts availability is another thing. Logistics and then experience, knowledge must be set-up for this one and then the total process how you manage the incoming service calls. It is quite complicated, but Uptime describes all these things'.
	Medical Physicist (hcpintw#7): 'The service contracts are a big frustration. I would like to be able to predict when a detector will be broken to inform the management and make a budget forecast'. 'Uptime gives me the ability not to be 'down' with not real reason'.
	CTO/Biomedical Engineer (hcpintw#9): 'If there was a service to address a device failure immediately so as at that moment there would not be a critical problem with the patient treatment, this would be very useful'.
	Technologist/Radiographer (hcpintw#10): 'Minimise downtime, have credibility in service and operation. If this is not ensured, it also causes a stress to the personnel'.
Risk transfer	**Clinician/Medical Doctor (hcpintw#12):** 'Full risk contracts to avoid downtime and bureaucracy in approving small budgets for repairing a system. A small problem can cause downtime which is attributed to bureaucratic procedures to get the budget approved'.

5.3.4 Turnkey approach and workflow optimisation

The concept of a solution offering in the medtech space prompted respondents to adopt a more holistic view that extends beyond solely the provision of an imaging device. This broader perspective contains everything from site construction and preparation to ambience design and workflow optimisation. Participants highlighted the importance of a turnkey approach, where the responsibility for delivering a fully functional and ready-to-use system lies with the vendor. This approach was vividly illustrated by a radiologist (hcpintw#1) who mentioned the

expectation of ‘installation in a room that the vendor will build for us’, highlighting the desire for a seamless integration of the medical device into the healthcare environment.

The significance of site preparation and the overall environment was further expressed by a CEO/COO (hcpintw#3), who noted the importance of finding the best site and preparing it adequately: ‘Help into finding the best site and preparation of the site… Ambience. In the past, healthcare areas were ‘cold’ places. Today comfort becomes an important parameter of preference’. This reflects a shift in the industry towards creating more patient-friendly and comfortable spaces, recognising that the environment plays a crucial role in patient care and experience.

In addition to the physical aspects of installation, the concept of workflow optimisation emerged as a key component of the solution offering. A clinician (hcpintw#12) expressed particular interest in this area, noting, ‘What is really interesting is the workflow optimisation’. This indicates a strong demand for solutions that not only integrate well into existing practices but also enhance efficiency, streamline operations and ultimately improve patient outcomes.

The participants’ views suggest that an imaging system should be seen within its broader context, as part of a complete system that includes the installation site, operating conditions and optimised workflows. A solution offering, therefore, is perceived as a turnkey project where the vendor assumes the responsibility and risk to deliver a fully functional outcome that meets the specific needs and expectations of healthcare providers. Table 5.15 summarises sample quotes from the interviews about turnkey solutions and workflow optimisation.

Table 5.15: Representative quotes on turnkey approach and workflow optimisation

Value-element sub-categories	Source/Quote
Turnkey solutions	**Radiologist (hcpintw#1):** 'Installation in a room that the vendor will build for us'.
	CEO/COO (hcpintw#3): 'Help into finding best site and preparation of the site…Ambience. In the past, healthcare areas were 'cold' places. Today comfort becomes an important parameter of preference'.
Workflow optimisation	**Clinician/Medical Doctor (hcpintw#12):** 'What it is really interesting is the workflow optimisation'.

5.3.5 Connectivity and interoperability

The significance of connectivity and interoperability in medical imaging systems was strongly emphasised by the study participants, who recognised these features as critical to enhancing clinical diagnosis across multiple medical specialties. The ability to connect systems and share information seamlessly was viewed as essential for improving collaboration among HCPs. As a clinician (hcpintw#12) explained, 'A specialist may do the diagnosis, i.e. on a CT scan, but the entire team shall be able to look at it and make their own measurements and judgment'. This statement highlights the importance of integrated information and the ability for multiple experts to interact with the data.

Participants, regardless of their specific roles within healthcare provider organisations, consistently identified access to information and its collective evaluation as key components of a solution offering. The notion of connectivity was frequently mentioned in the interviews, not only in terms of linking systems together but also in connecting specialists and facilitating communication. A radiographer (hcpintw#8) clearly articulated this by stating, 'This is a solution. Remove the headache of making systems work together. The integration is a solution element. The ability of a machine to communicate with other machines seamlessly'. This sentiment points out the need for interoperability between different manufacturers' systems, allowing for a smooth flow of information. Moreover, the participants recognised that an integrated technological approach is not just about connecting devices; it is about enabling better clinical capabilities and fostering improved communication and collaboration between

different clinical specialties. This, in turn, contributes to better clinical outcomes. A medical physicist (hcpintw#11) noted, 'Connectivity is the key in achieving an integrated solution proposal', emphasising the importance of a unified approach to medical technology.

Interviewees highlight how the integration of connectivity and interoperability into a medtech solution is seen as essential for enabling seamless communication, enhancing clinical capabilities and ultimately improving patient outcomes. Table 5.16 summarises the respective interviewees' quotes.

Table 5.16: Representative quotes on connectivity and interoperability

Source/Quote
Radiographer (hcpintw#1): 'Connect a system with more systems in the hospital in order to maximise the clinical capabilities, such as Fusion Imaging'.
Clinician/Medical Doctor (hcpintw#12): 'What I would like to see out of the synergies is the transparency. I would like to be able to see an exam in my own screen, to have access to all exams. A specialist may do the diagnosis, i.e. on a CT scan, but the entire team shall be able to look at it and make my own measurements and judgement'. 'Access to info …Info sharing'**.**
Medical Physicist (hcpintw#7): 'Facilitate the interaction between medical doctor, technologist and medical physicist'.
Technologist/Radiographer (hcpintw#8): 'This is a solution. Remove the headache of making systems working together. The integration is a solution element. The ability of a machine to communicate with other machines seamlessly'.
Medical Physicist (hcpintw#11): 'Connectivity is the key in achieving an integrated solution proposal'. 'Interoperability is major today. Between different manufacturers, products, departments'.

5.3.6 Professional networking and second opinions

Participants emphasised that information sharing and diagnostic support are key characteristics of a comprehensive solution. Unlike the integration of information that enhances system connectivity, this aspect is focused on boosting diagnostic confidence. As a radiologist (hcpintw#1) noted, 'Networking with professionals who use similar technology or have access to a second opinion to diagnosis so as to enhance diagnostic confidence'.

Several respondents viewed a solution offering as an opportunity to join a network of experts, gaining access to shared knowledge, experience, best practices and clinical support. This service could also be facilitated by digital tools or AI applications. The participants indicated that this expectation is ongoing, similar to a membership in a society dedicated to technological expertise and assistance. A technologist/radiographer (hcpintw#8) succinctly described it as, 'Second opinion, aiding diagnosis, use of AI… Clinical assistance diagnosis… Early diagnosis through technology and diagnosis-assisted services'.

The integration of professional networks and second opinions into solution offerings is seen as invaluable for enhancing diagnostic accuracy and efficiency. By connecting HCPs to broader expert networks, the solution not only aids in individual cases but also encourages continuous learning and application of best practices, which are critical for improving patient outcomes. Table 5.17 presents sample quotes from interviewees regarding professional networking and second opinions.

Table 5.17: Representative quotes on professional networking and second opinions

Source/Quote
Radiologist (hcpintw#1): 'Networking with professionals who use similar technology or have access to a second opinion to diagnosis so as to enhance diagnostic confidence'.
CEO/COO (hcpintw#3): 'Accessibility…Sharing info'.
Radiologist (hcpintw#5): 'Every radiologist approaches an exam based on own experience, depending on how many similar images he/she has seen before. In case, there is no previous experience, one shall look for it and this is time-consuming. Innovative techniques that can direct and support the doctor would be a huge help'.
Medical Physicist (hcpintw#7): 'I would like that you will keep me informed about similar devices, elsewhere, though published articles, if it can do more. To interconnect me with this hospital and help me to understand how this is done, instead of letting me re-invent the wheel'.
Technologist/Radiographer (hcpintw#8): 'Second opinion, Aiding diagnosis, use of AI… Clinical assistance diagnosis…Early diagnosis through technology and diagnosis assisted services'. 'Incorporated Clinical Guidelines which can help with the justification of an exam according to the guidelines before this exam is carried out'.
CTO/Biomedical Engineer (hcpintw#9): 'If a service relates with the technology, if there is an AI which assists the clinician to make a diagnosis'.

5.3.7 Impact to the healthcare system

The healthcare system is the ecosystem in which HCPs operate, offering their expertise and services while exercising their creativity and professionalism. Participants in the study recognised that decisions regarding medical technology, such as the selection of an imaging system, significantly impact the healthcare system. This was evident in how respondents discussed the value elements of a solution offering. A technologist/radiographer (hcpintw#10) emphasised this by stating, 'Third priority in my evaluation is the healthcare system', indicating its high importance in their decision-making hierarchy. Three major aspects emerged from the interviews regarding the impact on the healthcare system: innovation, cost-containment and treatment/hospitalisation (Table 5.18).

Innovation was frequently linked to its benefits for patients and the broader healthcare system within a solutions offering context. However, innovation was not necessarily defined as disruptive technology. Instead, it often referred to significant, localised changes in healthcare delivery enabled by a medical technology solution. As a biomedical engineer (hcpintw#9) clarified, 'I do not mean a global innovation, but an innovation at the local level'. This kind of innovation, triggered by a solution offering, aligns with considerations for inclusion, clinician empowerment and addressing ethical issues related to patient care.

Cost containment is a pervasive challenge for healthcare systems worldwide and it is a primary consideration in decision-making processes for healthcare investments. Rising healthcare costs are often associated with the high expense of advanced medical devices like imaging systems. Healthcare providers, working within this cost-conscious environment, expect solution offerings to contribute to cost reduction and financial efficiency. They see solution offerings as a way to achieve total delivery cost improvements through cost-effective technologies. Discussions with HCPs revealed insights on how this could be achieved, such as by expanding services, enhancing productivity, or shifting service delivery from secondary to primary healthcare. A solution offering that includes medical imaging systems is viewed as a crucial safeguard against the escalating costs of healthcare in both the public and private sectors.

Improving the quality of treatment through reduced hospitalisation was another recurring topic among respondents. While closely related to cost reduction, the emphasis on reduced hospitalisation was also seen as an indicator of improved treatment quality. HCPs expressed that fewer hospitalisations benefit both the patient and the healthcare system, as shorter stays often correlate with better outcomes. They expect medical devices, such as imaging systems, to deliver measurable, data-driven improvements in healthcare provision while reducing associated hospitalisations.

Healthcare systems are a focal point for policymakers and political initiatives worldwide and HCPs and their organisations are deeply affected by and benefit from these systems. Consequently, they view solution offerings as enablers of sustainable growth that ensures quality care and embraces innovation. A medical physicist (hcpintw#11) explicitly captured this sentiment, stating, 'Financial impact to the healthcare system, meaning reduced cost of treatment, efficient public/private spending, a system may be of the latest technology but very expensive'. Table 5.18 summarises sample quotes from interviewees regarding the impact of medtech solutions on the healthcare system.

Table 5.18: Representative quotes on the impact to the healthcare system

Value-element sub-categories	**Source/Quote**
Innovation	**CTO/Biomedical Engineer (hcpintw#9):** 'I would be impressed by innovation. What is the new a technology brings to the healthcare system?'. 'I do not mean a global innovation, but an innovation at local level. For instance, in a small clinical centre, a telemedicine system would provide a lot of abilities and solve a lot of problems. This would impress me. Some things may look trivial but in certain conditions, some technologies provide clinical capabilities and provide solutions'.
	Medical Physicist (hcpintw#11): 'Financial impact to the healthcare system, meaning: reduced cost of treatment, efficient public/private spending, a system may be of latest technology but very expensive'.
Cost containment	**CEO/COO (hcpintw#2):** 'Minimise cost…'.

Value-element sub-categories	Source/Quote
	CTO/Biomedical Engineer (hcpintw#4): 'Decrease cost of healthcare system through prevention, being proactive'.
Treatment /Hospitalisation	**Technologist/Radiographer (hcpintw#8):** 'Reduced cost of treatment' 'Less hospitalisations'.
	Radiologist (hcpintw#1): 'Less hospitalisation'.
	Technologist/Radiographer (hcpintw#10): 'Third priority in my evaluation is the healthcare system'.

5.3.8 Patient experience

How does a solution offering approach impact the patient compared to a traditional medical device offering? For the respondents, the patient occupies a central and vital role in all healthcare scenarios. It is the patient who must ultimately receive the greatest benefit from the services provided by HCPs. Throughout the interviews, patient outcomes frequently emerged as a key concern, reflecting the strong patient-centric mindset among the HCPs.

Interestingly, many respondents - whether clinicians, technologists, or managers - highlighted the consumeristic aspect of the patient, viewing the patient not just as a recipient of healthcare but as a client with specific expectations. This perspective became even more pronounced when discussing the solution offering approach. Participants emphasised that, beyond clinical outcomes, it is crucial for patients to feel safe, comfortable, well-cared for and treated with respect. In the context of a solution offering, HCPs expect greater efforts and tangible results in enhancing patient satisfaction.

One respondent attributed this shift in patient expectations to the recent generations, who are better informed and more technologically literate. As a CEO/COO (hcpintw#3) noted, 'Patients (millennials, generation Z) are more careful about comfort, independence. Medtech shall provide products to comply with their expectations'. This sentiment was commonly shared by the respondents, who identified this trend as a broader change in patient attitudes.

In addition to comfort and satisfaction, the predictability and reliability of services were also seen as crucial to patient experience. A CTO/biomedical engineer (hcpintw#4) remarked, 'If we can do spare parts replacement out of working hours or during preventive maintenance, then it helps us to be more predictable, avoiding (patient) frustrations'. Focusing on minimising disruptions and ensuring seamless, uninterrupted care to prevent patient frustration is a crucial expectation in a solution-based model.

Moreover, respondents highlighted the importance of the best technology in delivering optimal patient outcomes. A radiologist (hcpintw#5) emphasised, 'The best technology relates with the final outcome and this is important for the patient', stressing the direct link between advanced medical technology and improved patient experience and care. This focus on technology also extends to improving patient access to necessary exams, as another radiologist (hcpintw#5) pointed out, referencing tools like the availability of dedicated breast coils in MRI examinations.

Ultimately, the overarching consideration among HCPs was that the patient experience must be at the forefront of healthcare service delivery. A technologist/radiographer (hcpintw#10) succinctly summed up this perspective by stating, 'Patient must feel comfortable, safe', capturing the essence of what HCPs strive to achieve through a solution offering approach. Table 5.19 presents sample quotes from interviewees regarding patient experience.

Table 5.19: Representative quotes on patient experience

Source/Quote
CEO/COO (hcpintw#3): 'Patients (millennials, generation Z) are more careful about comfort, independence. Medtech shall provide products to comply with their expectations'.
CTO/Biomedical Engineer (hcpintw#4): 'Predictability in service'. 'If we can do spare parts replacement out of working hours or during preventive maintenance, then it helps us to be more predictable, avoiding (patient) frustrations'.
Radiologist (hcpintw#5): 'The best technology relates with the final outcome and this is important for the patient'. 'Better access for the patient to exams (i.e. (availability of) breast coil (in MRI examinations)'.
Technologist/Radiographer (hcpintw#10): 'Patient must feel comfortable, safe'.

5.4 Medtech professionals' contributions to solution offering value elements: insights from Phase 3 interviews

Phase 3 of the research involved presenting the perceived value elements of a servitised solution to medtech industry experts and gathering their feedback. The primary objective was to evaluate whether these identified value elements align with the professionals' perceptions, solution designs and Go-to-Market strategies within the medtech industry.

Discussions with medtech professionals were both engaging and productive, providing critical insights into how solution offerings are designed, assessed and valued across the industry. These conversations not only supported the existing understanding but also introduced new perspectives and knowledge specific to the medtech domain, strenghtening the overall analysis.

The key findings from these discussions, along with the major value elements that emerged, are listed below and explored in detail in sections 5.4.1 - 5.5.2.

- Business growth as a driver for solution offerings
- Enhancing personnel competence
- Expanding service capabilities though collaborative services, technology management and digitalisation
- Process improvement through connectivity, interoperability and clinical pathway integration
- Redefining patient-centredness in medtech solutions beyond patient experience
- Enhancing healthcare system sustainability through innovation and cost reduction
- Artificial intelligence to enhance diagnostic capabilities and boost productivity
- Clinician satisfaction

These insights are instrumental in refining the understanding of solution value elements and improving their alignment with industry standards and expectations.

5.4.1 Business growth as a driver for solution offerings

The interviews with medtech professionals confirmed the essential role of solution offerings in supporting business growth and innovation for healthcare providers. The insights reflect a strong understanding of the need for flexible, scalable solutions that not only address immediate needs but also support long-term growth and adaptability.

Medtech professionals emphasise the critical role of solution offerings in enabling healthcare providers to expand and enhance their clinical services. A modality manager (medintw#3) articulated this perspective, stating, 'Customers must be viewed as growing businesses. Initially, they may require basic solutions to generate revenue, but as their business evolves, they need upgrades to improve workflows, system ergonomics and commercial outcomes'. This strategic approach, as highlighted by medtech professionals, is essential for ensuring that HCPs are well-equipped to accommodate future growth and technological advancements.

Solutions also function as a strategic asset for healthcare providers to enhance their market position. As noted by a modality manager (medintw#1), 'Large private chains are eager to acquire cutting-edge technology to attract specific customer segments within their regions'. By providing advanced technologies, medtech companies enable their clients to differentiate themselves and effectively target key market segments.

Medtech professionals view medical imaging technology as an enabler for innovation and advocate for a solution offering model that fosters continuous business development. A clinical education manager (medintw#9) highlighted the benefits of a 'continuum' approach, wherein clients receive extensive support, including training and system updates, over a period of up to ten years. This model ensures that HCPs remain up to date with technological advancements and can consistently enhance their operations.

The need for future-oriented planning is a recurring subject emphasised by various modality managers. They emphasise that HCPs must account for potential future upgrades and expansions when investing in equipment. As expressed by one modality manager (medintw#1), 'It's essential to consider the future capabilities of the equipment and how it

will address needs in the coming years'. This forward-thinking approach enables HCPs to remain competitive and adapt to evolving industry demands.

Table 5.20 provides key quotes from the interviewees regarding business growth and innovation. These insights highlight the perspective of medtech professionals on how solution offerings are crucial for driving business growth, enhancing market positioning and sustaining ongoing innovation and adaptability within the healthcare sector.

Table 5.20: Representative quotes on business growth

Source/Quote
Modality Manager (medintw#2): 'Non obsolescence offered to the customer...And this is something which allows customer to stay on top of the technology development for particular equipment, not knowing what exactly will happen in two or three, four years from now'.
Modality Manager (medintw#1): 'What you are planning to do with the system, what you are trying to achieve with your business, where you would like to be with your business, what kind of patients you would like to attract? Because nobody is discussing during the sales moment about the future upgrades that might appear'. **Modality Manager (medintw#1):** '…you need to take a look where they would like to be in the next couple of years because for example, after five years, six years since they bought the system, they reached the maximum capacity of the system'. 'So, you definitely need to think when you buy an equipment for the next ten years, what could be your outcome also in the next ten years'. **Modality Manager (medintw#1):** '… It's also the solution that you are offering because we know that there are big private chains, that they would like to have the best technology on the market just to market some specific customers in their regions'.
Modality Manager (medintw#3): '... So, you have the solution for the customers because we have to look at the customers like growing business. So, some of them, they are starting the business and they need just the basic solution that makes the cash generator for them. But then they have to be ready also to extend, expand their business. So, we are ready then to upgrade their systems to improve the workflows, improve the ergonomics of the system, improve from the commercial way'.

5.4.2 Enhancing personnel competence

Enhancing the competencies of HCPs is a critical aspect of transitioning to a solution-based offering in the medtech industry. This was strongly confirmed by the medtech interviewees,

who emphasised the importance of a) education and b) the sharing of best practices as essential components of this transition.

Education, both clinical and business-oriented, was highlighted as a crucial factor in supporting a servitised approach. The aim is to enhance the skills and competencies of personnel, enabling them to navigate the complexities of modern medical technology more effectively. As a modality manager (medintw#1) noted, 'We are able to offer solutions starting from the education, which I think is the most important factor in diagnostic imaging. Business education in our region is one of the key factors and we need to make our customers realise how important it is for them to have a good education solution'.

This focus on education extends beyond initial training to include continuous learning, ensuring that HCPs remain proficient as technology evolves. Another modality manager (medintw#2) described this as an ongoing process: 'We incorporate in this solution trainings that are always a given to the customer, allowing them to operate at the best level possible, not just after installation but also one or two years down the line. These trainings help them achieve the next level of excellence'.

Moreover, the integration of advanced technologies like AI into medical devices further emphasises the need for enhanced skills and knowledge. A commercial finance manager (medintw#7) expressed concerns about the readiness of HCPs to adapt: 'With AI becoming more embedded in our products, this requires more skills, knowledge and testing from the users. This is one of the most important pillars, but I'm not sure if our offering is meeting their needs or if they even recognise that they have these needs'.

The medtech professionals also recognised the role of education in addressing broader business challenges, such as personnel retention. A clinical education leader (medintw#9) pointed out that comprehensive education offerings can be an attractive benefit for HCPs, particularly in markets where there is a shortage of radiologists and radiographers: 'Education is part of their program for addressing attrition challenges. They try to attract staff by offering comprehensive education, of which our medtech education is a key part'.

This holistic approach to education not only improves the immediate competencies of HCPs but also supports the long-term sustainability of healthcare institutions by enhancing their ability to adapt to new technologies and retain skilled personnel. Table 5.21 highlights key quotes from medtech interviewees on the role of education as a critical element.

Table 5.21: Representative quotes on education

Source/Quote
Modality Manager (medintw#1): 'So, we are able to offer solutions starting from the education, which I think is the most important factor in in diagnostic imaging. Business education in our region is one of the key factors and we need to make our customers realise how important is for them to have a good education solution'.
Modality Manager (medintw#2): '… we also incorporate in this solution trainings which could be, well not could be, they are always a given to the customer and allows customer to be operational on the best level possible for the equipment, not only just after installation, but also during the, maybe not life cycle of the equipment because it would be too long, let's say, but in one, two years from installation. We have these trainings for customers which allow them to go to the next level of excellence as they continue with the system'.
Commercial Finance (medintw#7): '…but what I have seen in general by discussing with different doctors, they have the tendency to think that they already know everything. Bringing a new equipment in the market with a lot of research and development, with AI becoming more and more embedded in our products, I think this, requires more and more skills, knowledge and testing from the users. In my opinion, this is one of the most important pillars, but I don't know if our offering is meeting their needs or if they really have the ability to admit that they have these needs'.
Service Manager (medintw#6): 'In certain products, we have seen this working in an excellent way. Our application specialists work a lot with our customers ensuring they are truly experts on the technology in use'.
Top accounts Director of Service (medintw#12): 'Continuous education. Yes. You cannot say that the most important is the system's reliability and the proper service because it is only going to give you uptime. But without having a person at the other side of the console that is going to be able to properly operate and then, you know, properly describe the scan to the patient. It is not going to be like a full picture, a full puzzle'.
Clinical Education Leader (medintw#9): '…we tend to forget that customers who are buying equipment, especially in the public market, I mean the decision makers who are professors or head of the department, they have no clue about the equipment. So, their focus is how to use the equipment optimally. They believe us that the equipment has what we promised, but they need to know how to use it in the way which, firstly allows to optimally use the equipment, but secondly, use in that way as they are expected to do by the organisation or research or whatever'. 'Education is part of their program for attrition challenge. So especially now when you have shortages in the radiologists and the radiographers' market, they try to attract them by offering them comprehensive education offering which our (medtech) education is only part of'.

In addition to formal education, the sharing of best practices and networking among HCPs were identified as vital for improving competencies. This exchange of knowledge can act as both an educational tool and a form of consultative support, particularly when dealing with complex medical technologies. A modality manager (medintw#1) highlighted the importance of this collaborative approach: 'It's really important for key customers to offer them research capabilities, training opportunities and experiences with other sites in other regions to provide second opinions'.

The concept of networking was further elaborated by a director of project management (medintw#12), who described it as a means of elevating customer relationships: 'How we can share this kind of knowledge among customers and help each other, like bringing networking to the next level'. This approach not only enhances individual competencies but also fosters a community of practice where HCPs can learn from each other's experiences. Table 5.22 presents selected quotes from medtech interviewees regarding the importance of networking and sharing best practices.

Table 5.22: Representative quotes on networking and sharing of best practices

Source/Quote
Modality Manager (medintw#2): '…to offer them experience with other sites in other regions that they are doing similar things or different things in order to give some second opinion'.
Modality Manager (medintw#1): 'So, it's really important for some, for the key customers, to offer them research capabilities, training opportunities, to offer them experience with other sites in other regions that they are doing similar things or different things in order to give some second opinion'.
Director of Project Management (medintw#12): 'One of the things just came into my mind, like the very first thing, that how we are showing other customers, like client B to client A, when client B is really good, right? And how we can share this kind of knowledge among customers. And help each other. Like bringing the networking on the next level'.
Education Manager (medintw#9): 'In Eastern European region, we have seen the second opinion or networking support for customers from us as a vendor. I think that at least I have heard about this case, but in Western countries… which is maybe in front of us and we can, we need to consider this, but this is something that is new'.

The medtech interviewees stressed that enhancing personnel competence through education and networking is essential for the successful implementation of a solution-based approach.

These efforts help HCPs optimise the use of technology, stay current with innovations and ultimately contribute to better patient outcomes and business growth.

5.4.3 Expanding service capabilities through collaborative services, technology management and digitalisation

Medtech professionals have confirmed the significance of advanced service capabilities in delivering value to healthcare providers. While traditional services, such as preventive and corrective maintenance remain fundamental, there is a growing emphasis on enhancing service provision to better meet the specific needs of HCPs. This evolution in service offerings not only adds value but also serves as a crucial differentiator in a competitive market.

Professionals in the field highlight that high-quality service is now considered a standard expectation rather than a negotiable component. For instance, service experiences and reputations are increasingly recognised as critical elements of the overall value proposition, with many viewing superior service as essential for maintaining competitiveness.

The shift towards elevated service provision includes more tailored solutions, integrating aspects such as customer education and skill enhancement. One participant connected effective service delivery with thorough training for in-house maintenance, suggesting that well-trained engineers or embedded medtech engineers supported by remote services could offer a more effective solution (service manager - medintw#6). Similarly, an Executive Account Manager highlighted the shift towards fleet solutions instead of traditional equipment and service models, noting that this approach represents a more comprehensive strategy for managing technology. As he explained, ‘what we are trying to do right now, which is going to be a differentiator, is that we are starting to propose a fleet solution, not purely equipment and service, which is just break and fix’ (medintw#12).

Additionally, the integration of digital technologies, such as Artificial Intelligence (AI) and Deep Learning (DL), is transforming service delivery. These advancements enable a predictive maintenance approach rather than relying solely on traditional preventive methods, facilitating more efficient data management and analysis. This digital shift is anticipated to

redefine service delivery, optimising the use and management of medical devices and enhancing the overall support provided to HCPs.

The evolution of service capabilities, including the incorporation of advanced digital tools, is reshaping the landscape of medtech solutions. These developments ensure that HCPs have access to the resources and support needed to provide optimal care. Table 5.23 presents representative quotes from medtech interviews regarding the expansion of service capabilities.

Table 5.23: Representative quotes on expanding service capabilities

Source/Quote
Education Leader (medintw#9): '…service experience, the service reputation. I would say from my experience, it is a sales tool more than a solution. … service is a natural part of this offering. …I expect this now as a standard. Nobody wants to discuss that…. And now I think there is no step back for any organisation to compromise on the service quality'.
Service Manager (medintw#6): 'Customers demand a quick fix or pursue to have a device which will never break! However, why shouldn't they demand a thorough education of their own engineers for an in-house maintenance service? A well-trained engineer, or alternatively, an embedded medtech engineer with the support of remote services, might provide a better solution. Is the customer ready to pay for this though?'
Executive Account Manager (medintw#12): '…what we are trying to do right now, which is going to be a differentiator as well, is that we are starting to propose a fleet solution, not purely equipment and service, which is just break and fix…'.
Commercial Service Leader (medintw#8): '…We are taking our first steps in the digital world, the digital services. This does not mean that we are at a very good level, but we have entered this approach in a quite dynamic way which shows that this will be the new approach…'.

5.4.4 Process improvement through connectivity, interoperability and clinical pathway integration

Medtech professionals view connectivity, interoperability, workflow optimisation and a turnkey approach as essential strategies for process improvement within healthcare environments. These enhancements can manifest in various forms, such as the optimisation of clinical pathways or workflows (e.g. patient scheduling) or the seamless integration and upgrading of technology (technology continuum). This servitised approach, offering comprehensive services like Information Technology (IT) integration and device connectivity,

ensures smooth operations and efficiencies, ultimately delivering turnkey solutions that address healthcare providers' needs.

Medtech interviewees emphasised that a servitised business model is particularly well-suited for HCPs seeking process improvements at clinical, operational, or business levels. These improvements are often linked to cost reduction or revenue growth, contributing to better patient outcomes. A clinical education leader (medintw#10) provided a compelling example of clinical process improvement through an innovative CT application that enhances diagnostic capabilities. This technology integrates morphological and functional assessments, which were previously distinct, into a single, streamlined process. The leader illustrated this with the case of kidney stone diagnosis, where the new application eliminates several diagnostic steps, reducing costs and accelerating treatment planning: 'Now with this application, for example, you can do an axial scan, determine the type of stone and immediately decide on the treatment. Essentially, you skip the intermediate stages that previously required multiple tests and procedures'.

Another example comes from a clinical education manager (medintw#9), who discussed how analysing workflows around medical devices, such as imaging systems, can result in substantial operational improvements across a department. By refining protocols and addressing inefficiencies like appointment cancellations, these solutions can enhance departmental efficiency. Additionally, a commercial finance manager (medintw#7) described how medtech companies assist HCPs in optimising specialised departments, such as nuclear medicine, by advising on the optimal number of injection rooms and the timing of radiopharmaceutical deliveries. This guidance helps achieve greater overall efficiency.

The alignment between medtech professionals and HCPs is evident in their shared emphasis on the value of seamless connectivity and process improvements in healthcare delivery. Medtech professionals view the turnkey approach more broadly than its traditional association with construction or infrastructure, regarding it as a comprehensive solution that addresses practical problems and ensures smooth integration and operational efficiency for HCPs. This comprehensive turnkey approach, facilitated through servitised offerings, can establish enduring collaborative partnerships that include streamlined technology integration

and long-term operational support. For instance, a commercial finance manager (medintw#7) described a long-term partnership model where medtech companies oversee the entire lifecycle of imaging technology, including maintenance, replacement and financing. This model guarantees that healthcare providers receive continuous access to up-to-date technology and operational support throughout the duration of the contract. Table 5.24 presents detailed examples from the interviews with medtech professionals, illustrating how the concepts of process improvement through connectivity, interoperability and the turnkey approach are applied.

Table 5.24: Representative quotes on process improvement through connectivity, interoperability, workflow and clinical pathway integration

Source/Quote
Clinical Education Leader (medintw#10): 'In imaging, in general there are two different roads. There is the morphological assessment and also the functional assessment. In the morphological one, so far, we have been talking about the radiological ones, the CT, the Mammography and in the functional (assessment) we went much further to the Nuclear Medicine, to Magnetic Resonance. So, there were these two ways, these two roads. Now the (commercial name of the application) tool is a device that came to marry these two ways, to give to the already existing anatomical information that you obtained with the CT, the functional information. So, this extra information, gives to the doctor the diagnostic information which helps a lot going forward. First of all, in treatment planning, it reduces the cost of health care because every doctor with a CT, applying the new application, will be able to provide the information needed for further treatment planning. The easiest example I can give with (commercial name of the application) this application, is the one of kidney stones. Well, until now, through a CT scan, you could see that your patient has a kidney stone, then you had to do another kind of test. If you do an ultrasound, you should do a biopsy to see what kind of stone it is so that the doctor can then, in the third phase, determine whether to go for lithotripsy. Whether he will have to remove it or if he will treat it pharmacologically. That means, this patient had to go through 3-4 stages. Now with the (commercial name of the application), for example, you can do an axial scanning and see what kind of stone it is and then you can determine which one the treatment will be. Essentially, the intermediate stage of that extra of the characterisation - let's say - that will characterise what kind of stone it is, you skip it'.
Clinical Education Manager (medintw#9): '…The protocol optimisation, but also analysis of the workflow in the departments. Improvements we can offer not only in the equipment part but also in the organisational area…' '…For example, improving efficiency of the department itself from a registration point up to - what is the most important efficiency of the system - eliminating cancelled slots, for example. So, kind of solution is to analyse the reasons of the cancellation and then turning this analysis into some recommendations which can improve… and making a few iterations of this kind of analysis to improve to the maximum level the outcome of the department'.
Commercial Finance Manager (medintw#7): 'Working with the customer to optimise, for example, their operational activity, for example, in case of a PET/CT, how many injection rooms they should have, what time they should bring the radiopharmaceutical, in accordance with the number of patients? How should they group these patients in order to have a better efficiency at the end of the day? I think these are things that we can support them'.

Source/Quote
Modality Manager (medintw#2): '…And of course as a turnkey solution, we are working also with some construction companies and construction providers to secure for customer turnkey projects. So, it's like doing all the designing stage, installation, construction, whatever is needed and implementation'.
Commercial Finance Manager (medintw#7): 'But I would say that a seven, eight-year solution under which we get a contract and we replace the equipment, so at least we have a seven year contract in which we know that we, they make some tenders and we, whatever medtech vendor (they choose), we participate and we take all the burdens from their shoulders. …and we take all the responsibility for replacing these equipments, keeping them in a certain uptime for the entire period, offering them financing, taking, replacing the existing equipment, taking these equipments back at the end of the term and so on…'.

5.4.5 Redefining patient-centredness in medtech solutions beyond patient experience

In discussions with medtech industry professionals, the role of the patient as the ultimate recipient of healthcare services has been emphasised, yet there is concern that current solutions may fall short of truly embodying patient-centredness. While technology and financial factors often dominate, there is a growing recognition of the need to align technological solutions with patient care strategies and available resources.

A clinical leader (medintw#10) pointed out that the emphasis is often placed on technology and financial value rather than how equipment supports the overall patient care strategy. This highlights a significant gap in aligning technological solutions with the needs of patients and healthcare providers. A modality manager (medintw#4) reinforced the idea that patient-centredness should be the foundation of all healthcare solutions. According to this perspective, evaluating the benefits for patients should be the primary focus, with considerations for clinicians, administrative staff and investors following in sequence. This approach ensures that patient-centredness drives technological innovation and aligns with the broader healthcare ecosystem.

Additionally, medtech professionals stress that patient-centredness must be integrated into clinical pathways for specific diseases or conditions. A modality manager (medintw#2) emphasised the need for solutions that support patients throughout their healthcare journey, tailored to specific diseases such as oncology or cardiology. This approach ensures that

technologies are not stand-alone tools but integral to the patient's treatment process. A commercial service manager (medintw#8) supported this view by highlighting the importance of maintaining patient focus from admission to discharge, ensuring that healthcare technologies contribute to a cohesive treatment process.

Finally, patient-centredness is recognised as an evolving concept that guides value creation through technology. As a marketing manager (medintw#5) noted, there is ongoing potential to better leverage patient-centredness within the healthcare ecosystem.

Achieving true patient-centredness in medtech requires designing and evaluating technologies based on their integration into patient care pathways and ensuring that patient benefits are central to the value proposition. Table 5.25 presents detailed examples and quotes from medtech interviewees regarding a patient-centric approach.

Table 5.25: Representative quotes on patient-centredness

Source/Quote
Clinical Leader (medintw#10): 'I only see it in one point and I don't know how important this point is in relation to all the rest, patient-centredness, i.e. everything, everything as I see focuses on technology, focuses on financial value. But really what I would expect if I were like a healthcare provider and I had to discuss the value that a piece of technological equipment should give me is how this equipment will be able to align with the strategy and the resources I have to offer the specific services to my patient - that is to put my patient at the centre...'.
Modality Manager (medintw#4): 'Patient shall be always at the centre. It is the foundation of every solution. We shall answer to the question: what is the benefit for the patient? Then we shall go upwards and explore the benefit for the clinicians, then the administrative professionals and then the investors and entrepreneurs. We can start from there and go towards the clinicians'.
Modality Manager (medintw#2): '...we need to develop an approach which will give the healthcare provider the ability to work with medtech on every step of the patient journey through the system... But then it goes to the solutions which are tailored for oncology, cardiology. You are not talking about equipment this moment, but you are talking about the type of disease you want to treat. And then everything which is in the pathway of the patient'.
Commercial Service Manager (medintw#8): 'The medtech companies shall focus on the patients. The HCPs shall do the same. Patient shall be the centre of interest from the moment of admission in a healthcare unit until their dismissal from it'.
Marketing Manager (medintw#5): 'And I think the healthcare ecosystem, that's patient-centredness. This is also something that we have potential to better leverage'.

5.4.6 Enhancing healthcare system sustainability through innovation and cost reduction

Discussions with medtech industry professionals reveal a consensus on the importance of sustaining the healthcare ecosystem through innovation, eco-friendly practices and cost management. Sustainability in healthcare is not just about controlling expenses but also about leveraging innovative solutions to improve diagnostic accuracy and reduce overall costs. As one modality manager (medintw#2) noted, the goal is to use innovation to lower costs by enhancing diagnostic precision, which minimises unnecessary tests and treatments and ultimately reduces system-wide expenses.

The integration of innovation with cost reduction also involves pioneering advancements that optimise resource use while addressing medical conditions effectively. For instance, advancements in diagnostic technologies, such as those for chronic diseases like epilepsy, are essential. A modality manager (medintw#1) highlighted the need for integrating various diagnostic tools, such as PET scans, EEGs and functional MRI, to address the root causes of diseases rather than merely managing symptoms. This integrated approach improves treatment efficacy and cost-efficiency.

Furthermore, sustainability in healthcare incorporates eco-friendly practices in both the manufacturing and operation of medical technologies. A modality manager (medintw#2) pointed out the growing emphasis on designing systems to be more environmentally friendly. This includes reducing helium use in MRI systems, optimising electricity consumption and minimising space requirements. These considerations reflect a broader shift towards incorporating environmental impacts into the design and operation of medical devices.

Promoting sustainability in the healthcare system requires a comprehensive strategy that combines innovation to drive cost reduction, the integration of advanced diagnostic solutions and a commitment to eco-friendly practices. This multi-faceted approach supports not only the financial and operational sustainability of healthcare systems but also their environmental stewardship. Table 5.26 presents sample quotes and examples from the medtech interviewees.

Table 5.26: Representative quotes on healthcare system sustainability

Source/Quote
Modality Manager (medintw#2): 'I think of the healthcare system… first of all, about the innovation. But the innovation which is targeted to the reduction of the cost in the very broad meaning; because what does it mean the reduction of the cost? If your diagnosis is more precise, this is a cost reduction for the healthcare system because then you do not diagnose unnecessarily further the patient and you treat the patient in the most effective way. So, this is cost reduction for the health system'.
Modality Manager (medintw#1): 'So, the big fighting between the companies in this moment, different companies, is who is coming faster, who can do more patients and so on. But I think in this moment, we need to go to the next level. Next level means try different tracers, try different solutions, because in this moment, if we look, for example, in PET area, we have one investigation. For example, for epilepsy, there is a dedicated protocol that normally together with some other investigations like EEG and the special functional MRI, you can combine all of them and try to define the cause of that disease and treat the cause, not the effect'.
Modality Manager (medintw#2): 'Of course, the natural cost reduction will be like designing the systems (to be) eco-friendly. So, helium cost for MRI, electricity cost, even cost of installation, the sense of space needed for the equipment and all of this. This is also, I think, happening and we see more and more pressure on this where honestly... the space requirement was never the highest priority historically. Let's say now it is changing and we see it more and more coming…'.

5.5 Identifying missing value elements: Insights from medtech professionals

Interviews with medtech professionals revealed critical value elements that are often overlooked in HCPs' assessments of value. These insights emphasise aspects that could significantly improve the solution offering model in the medtech industry, including the integration of AI and the enhancement of clinician satisfaction.

5.5.1 The role of Artificial Intelligence

One of the most notable discrepancies identified is the underemphasis on AI within HCPs' value perceptions. While HCPs often focus on digital applications and the broader digitalisation of healthcare, AI has not been prominently featured in their considerations. This could be partly due to concerns among radiologists and imaging professionals about AI potentially replacing their roles (Gallix & Chong, 2019; Jungmann et al., 2021; Murugesan et al., 2023). The debate around AI's impact on the medical imaging field is ongoing, with polarised opinions about its potential to transform the domain. However, medtech professionals, who are more familiar with AI technologies, recognise its transformative

potential and are advocating for its clear inclusion in solution offerings. They see AI as contributing to healthcare in two primary ways:

a. **Enhancing diagnostic capabilities**: AI has the potential to greatly enhance diagnostic accuracy and confidence. A modality manager (medintw#1) provided a pertinent example in the context of epilepsy care, stating, 'Currently, we are addressing only the effects of epilepsy, not the underlying causes. By integrating AI software designed for brain imaging, we can offer more comprehensive solutions beyond those available for oncology'.

b. **Boosting productivity without compromising quality**: AI is also seen as a tool for increasing productivity while maintaining high standards of care. Another modality manager (medintw#2) explained, 'While medtech companies cannot produce doctors, they can develop AI systems that significantly aid them. I anticipate that AI will reduce doctors' workloads, allowing them to perform more exams and write more prescriptions each day - potentially increasing from 30 or 40 to 60 or 80 - without sacrificing quality'.

Medtech interviewees envision AI as a pivotal tool for introducing innovative imaging techniques, integrating data and supporting decision-making. They see AI-driven tools as crucial for addressing inefficiencies, improving disease management and enhancing workflows and productivity.

5.5.2 Clinician satisfaction

Clinician satisfaction emerged as another significant value element identified by medtech professionals, though it received comparatively less emphasis in discussions with HCPs. Despite its importance, this aspect seems to be underrepresented in the broader conversation around healthcare solutions. A modality manager (medintw#4) highlighted the importance of this factor: 'I would put more gravity and priority on the clinicians' satisfaction'. This statement reflects a deep understanding that the well-being and satisfaction of clinicians are not just beneficial but essential for the successful implementation and adoption of medical technologies. When clinicians are satisfied, they are more likely to engage positively with new

technologies, leading to better patient outcomes, more efficient workflows and a more harmonious healthcare environment.

However, the relative absence of this topic in many discussions might stem from a prevailing assumption within the medtech industry that clinician satisfaction is a given - an intrinsic expectation that does not need to be explicitly articulated. Medtech professionals may perceive that ensuring clinicians are satisfied with the tools and technologies provided is so fundamental that it naturally underpins all other value elements. In other words, it is seen as a baseline requirement, rather than a separate, highlighted focus.

While medtech professionals see AI and clinician satisfaction as critical value drivers, these elements are not fully reflected in the current perceptions of HCPs. Emphasising AI's role in enhancing diagnostic capabilities and productivity, along with prioritising clinician satisfaction, could bridge this gap and align solution offerings more closely with the evolving needs of the healthcare industry.

5.6 Summary and discussion of results: Defining the key value drivers in transforming a medical device offering into a solution

The analysis of value elements emerging from the interviews with healthcare and medtech professionals has led to the findings regarding the value drivers that distinguish a solution offering from a mere medical device offering. The following points summarise these findings and are illustrated in Figure 5.1.

Technology-driven business innovation: A medical device, such as an imaging technology system, must fulfil its technical and clinical objectives safely, compliantly and cost-effectively. This baseline performance, often referred to as 'table stakes', represents the minimum expectation for any medical device. However, in transitioning to a solution offering, the focus expands beyond mere functionality to include the generation of new business opportunities and growth potential. In this context, medical technology is expected not only to meet its primary purpose but also to act as a catalyst for business innovation, driving advancements that extend beyond its fundamental function.

Technology management: The basic service associated with a medical device offering typically involves preventive and corrective maintenance to ensure safe and effective operation according to specifications. This maintenance is a fundamental expectation when evaluating a stand-alone imaging system. In contrast, a solution offering views medical devices as assets that require ongoing support to optimise utilisation and productivity. This approach necessitates the use of advanced tools, such as AI and DL applications, to monitor and measure KPIs, enabling predictive and continuous service improvement.

Enhancing personnel competences and improving diagnostic confidence: While the experience of clinicians is a critical consideration for both medtech vendors and HCPs when assessing and acquiring a medical device, a solution-oriented approach frames this satisfaction within a broader context. The goal of a servitised offering is to enhance the competencies of HCPs and increase their diagnostic confidence. Achieving this goal is a continuous process, requiring services that accompany the medical device throughout its lifecycle, thus ensuring sustained clinician satisfaction.

Sustainable patient-centred and innovative care: Patient satisfaction, traditionally measured by the interaction between the patient and the medical device, is influenced by factors such as patient experience and outcomes, which in turn affect adherence and perceptions (e.g. claustrophobia in an MRI scanner). In a solution approach, the patient is placed at the centre of the clinical care pathway, ensuring holistic and comprehensive disease management. This servitised model seamlessly integrates devices and services to address medical conditions within a connected clinical care pathway.

The research acknowledges the contribution of medical devices to local communities, such as healthcare facilities, hospitals, or diagnostic centres, by expanding clinical services, improving quality and enhancing access. A solution offering, however, goes beyond these immediate benefits by prioritising **innovation and sustainability**. The healthcare system benefits from sustainable innovations that not only advance healthcare services but also contribute to a better, more sustainable world.

A solution offering is expected to drive **process optimisation**, whether in clinical procedures or administrative workflows. Unlike a standard service, a servitised approach delivers evidence-based changes that enhance existing processes. These changes might involve optimising clinical workflows or ensuring the seamless connectivity and interoperability of systems and services. **Digitalisation** plays a crucial role in driving process improvements by leveraging technology to streamline workflows and enhance efficiency. This digital transformation not only optimises clinical and administrative processes but also ensures better integration and communication between systems, leading to improved patient outcomes and overall operational effectiveness.

The transition from a medical device offering to a solution offering is characterised by a shift in focus, from meeting basic functional expectations to driving innovation, enhancing clinician and patient experiences, contributing to community and environmental sustainability and implementing evidence-based process improvements. These value drivers collectively define the essence of a solution-oriented approach in the medtech industry.

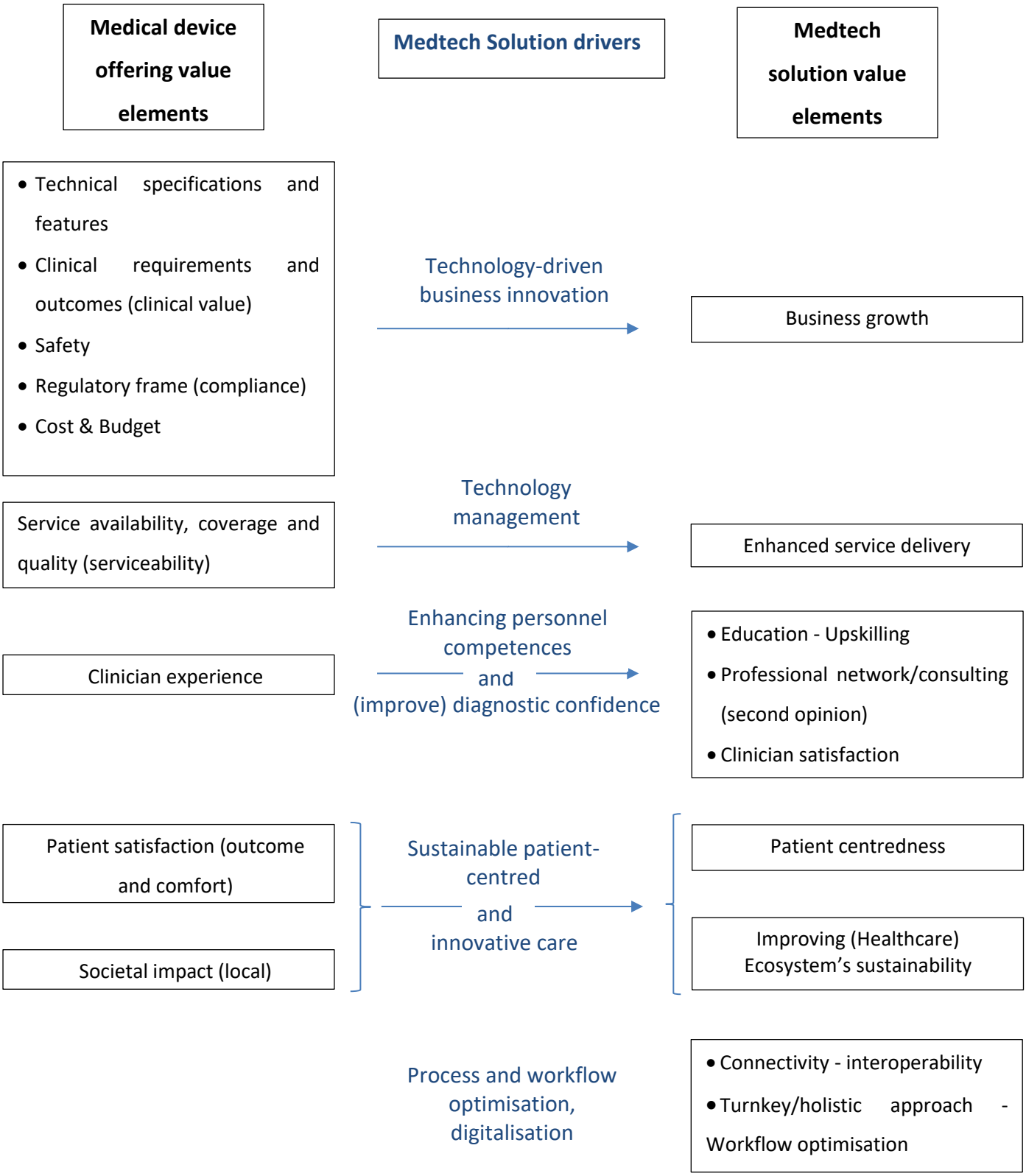

Figure 5.1: The medtech solution drivers - an illustration of the transformation from a medical device offering into a medtech solution.

6. Discussion

6.1 Introduction

In Phases 1 to 3, the value drivers that are perceived to transform a single medical device offering into a solution offering have been identified and summarised in Figure 5.1. Based on this knowledge, this chapter proposes three core value criteria for a value framework addressing a medtech solution assessment as below:

1. Enable business growth and operational excellence (organisational impact)
2. Achieve connected care through care pathways and digitalisation
3. Improve (healthcare) ecosystem's sustainability with patient focus

The value criteria are further discussed and analysed in sections 6.1.1- 6.1.3.

6.1.1 Enabling business growth and operational excellence (organisational impact)

Evaluating the value of medtech solutions necessitates a thorough examination of their organisational impact. This includes assessing contributions to business growth, technology management, personnel development, and diagnostic confidence. A robust value framework should also incorporate clinician satisfaction and the solution's ability to optimise processes through integration. Key areas for evaluation include digital tools, artificial intelligence, technical features, human resources management and financing schemes, all aimed at improving operational efficiency and supporting organisational development.

Interviews with HCPs and medtech professionals reveal that the value of a medtech solution extends beyond its basic functionality. While stand-alone imaging systems must meet essential clinical needs such as safety and effectiveness, HCPs now expect these systems to contribute to broader organisational objectives. As noted by a clinician, a solution should not only address immediate clinical requirements but also enhance diagnostic and therapeutic capabilities, thereby supporting the overall growth of the clinical unit (hcpintw#12). This perspective highlights that a solution is valued not just for its technology, but also for its

contribution to advancing organisational development. Technology, within a solution, is expected to drive business innovation and growth.

A servitised offering in the medtech industry includes more than the provision of a stand-alone device; it involves a suite of services and support designed to enhance operational efficiency and foster business growth. According to a CTO/biomedical engineer, modern solutions include tools for system utilisation, efficiency measurement and operational excellence, reflecting a shift towards comprehensive support (hcpintw#7). Healthcare providers now seek solutions that offer analytics, predictive interventions, lifecycle management and continuous support to optimise technology use and streamline processes. As emphasised by a clinician, ongoing technical support and vendor collaboration are crucial for addressing both anticipated and unforeseen challenges (hcpintw#6). The solution offering must approach the management of biomedical technology as a whole, rather than simply focusing on servicing. This entails a comprehensive management of medical devices as assets throughout their entire lifecycle.

Moreover, medtech solutions are expected to contribute to clinician professional development by expanding their skills and knowledge. This ongoing learning is vital for boosting diagnostic confidence and improving patient outcomes. As one biomedical engineer noted, the value of a solution is closely tied to its ability to enhance clinician expertise and confidence (hcpintw#9). Solutions should facilitate the handling of complex cases and expand service offerings, as highlighted by a clinical education leader who described how advanced devices enable broader case management and participation in cutting-edge procedures (medintw#9).

The integration of advanced technologies, such as AI, is also crucial for improving diagnostic accuracy and operational efficiency. AI tools are pivotal in augmenting diagnostic capabilities and supporting clinical decision-making, which ultimately leads to better patient care and cost reduction. Additionally, the relational aspect of using medical devices, including comfort and clinician satisfaction, has become increasingly important. HCPs seek a positive and engaging interaction with their technology, which contributes to their overall experience and satisfaction.

The impact of a medtech solution extends beyond clinical applications to include organisational and operational needs. These needs may be diverse and not always clearly defined, but solution providers are expected to identify and address them effectively. A comprehensive value framework should evaluate not only the clinical efficacy of medtech solutions but also their ability to drive organisational growth and operational excellence. By systematically assessing criteria related to clinical, operational and administrative needs, a framework ensures that the overall impact of medtech solutions aligns with organisational goals and contributes to enhanced efficiency and growth. Figure 6.1 illustrates the value criteria for assessing the impact of a medtech solution on a healthcare organisation.

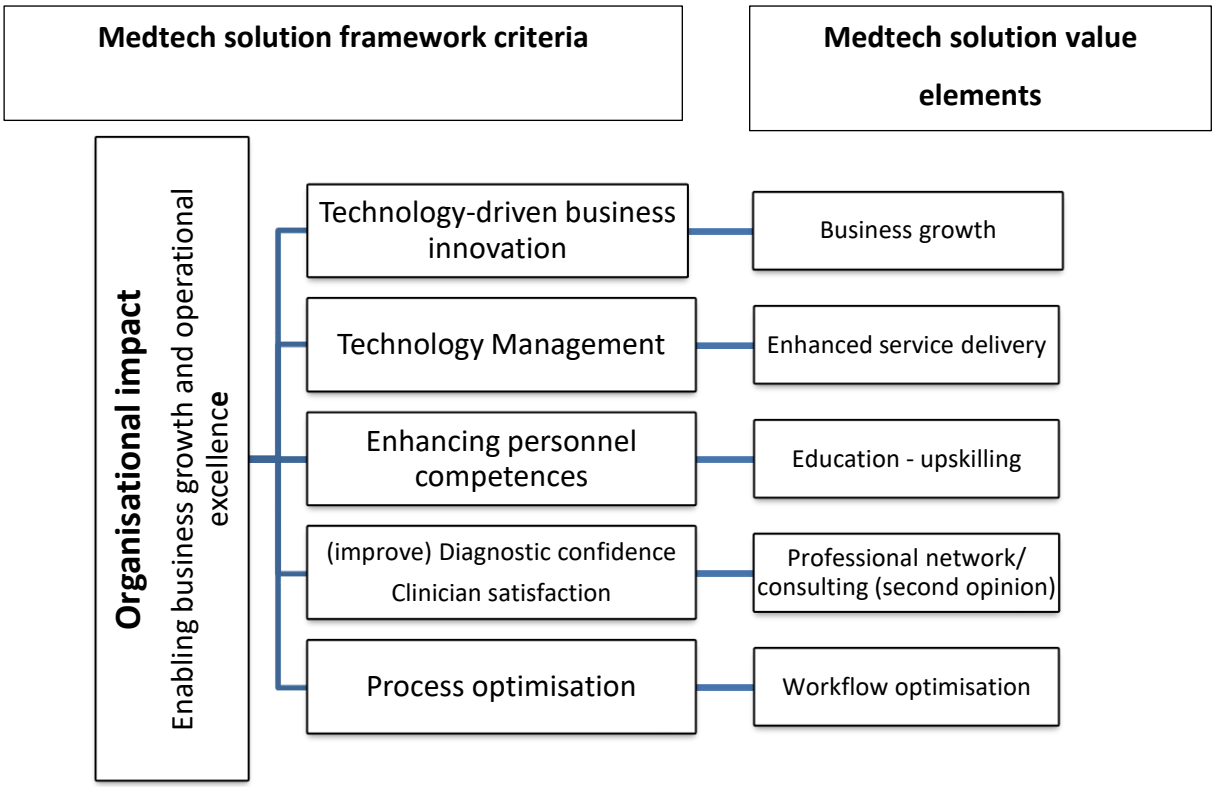

Figure 6.1: Organisational impact value criteria and their correlations with the medtech solution value elements

6.1.2 Connected care

In designing a value framework of medtech solutions, it is crucial to consider their capacity to achieve connected care - a comprehensive approach designed to address diverse healthcare needs holistically. Connected care goes beyond individual components, integrating diagnostic precision, clinical utilisation, financial viability and alignment with healthcare system needs to

enhance overall healthcare delivery. As one clinician observed, 'the whole is greater than the sum of its parts', highlighting the importance of integrating various elements to improve patient care (hcpintw#12).

At the heart of connected care are the principles of connectivity and interoperability. Connectivity facilitates seamless interaction between devices, enabling the transmission and processing of medical data and images - critical for collaboration among medical experts and remote data analysis. As noted by one participant, connectivity is often driven by 'software applications that provide solutions like 3D imaging or cloud-based applications' (hcpintw#12). Moreover, connectivity optimises workflows by streamlining patient information exchange across departments, thereby enhancing operational efficiency. This was emphasised by a medical physicist who pointed out the importance of 'optimising the workflow by considering workload, available personnel and interdepartmental interactions' to achieve efficient patient flow (hcpintw#11).

However, the ultimate goal of connectivity and interoperability extends beyond process improvement; it is to maximise the impact of technology on clinical outcomes. Healthcare providers seek solutions that integrate various products, tools and interventions through technology to achieve excellence in disease management and healthcare delivery. A holistic evaluation of value, as one healthcare professional emphasised, begins with 'solving an important clinical problem and fulfilling a significant medical need', thereby improving patient outcomes and decision-making processes (hcpintw#11).

Care pathways are integral to this framework, guiding patient journeys from disease management to health maintenance. These pathways incorporate a range of activities, processes, technologies and multidisciplinary teams, all aimed at facilitating evidence-based decision-making and continuity of care (Combi et al., 2017; K. S. Lee et al., 2021). They ensure that the right actions are taken at the appropriate times, leading to optimal patient outcomes, as described by HCPs who recognise the value of converting diagnostic data into actionable clinical insights (Allen et al., 2009).

Connected care also emphasises robust data management and its strategic use in healthcare decision-making processes. AI tools play a pivotal role in this domain, enabling the management and analysis of vast amounts of healthcare data and advancing precision medicine. AI applications and machine learning facilitate early detection and predictive analytics, thereby enhancing diagnostic accuracy and the quality of patient care. HCPs increasingly seek solutions that provide access to, or enable the development of, sophisticated, interactive applications, often in partnership with the medtech industry, that support data aggregation and insights. While digitalisation is viewed as a modern trend within the healthcare ecosystem and the commercial marketing of the medtech industry, HCPs see digital tools as essential for managing patient care pathways, ensuring that the right data is available, analysed and processed to achieve diagnostic accuracy, better outcomes and higher quality care.

The concept of Connected care represents a turnkey approach in healthcare, analogous to integrated solutions in construction projects. It embodies the pursuit of clinical excellence and superior patient outcomes through seamless, technology-enabled patient management. At the organisational level, it drives the optimisation of workflow, workload, productivity and efficiency, as outlined in Section 6.1.1. HCPs seek Connected care as an end-to-end solution for achieving the highest standards of patient care and clinical outcomes. A medtech solution's value framework should assess its potential to achieve Connected care. Figure 6.2 visually represents the correlation between Connected Care and the value elements of medtech solutions.

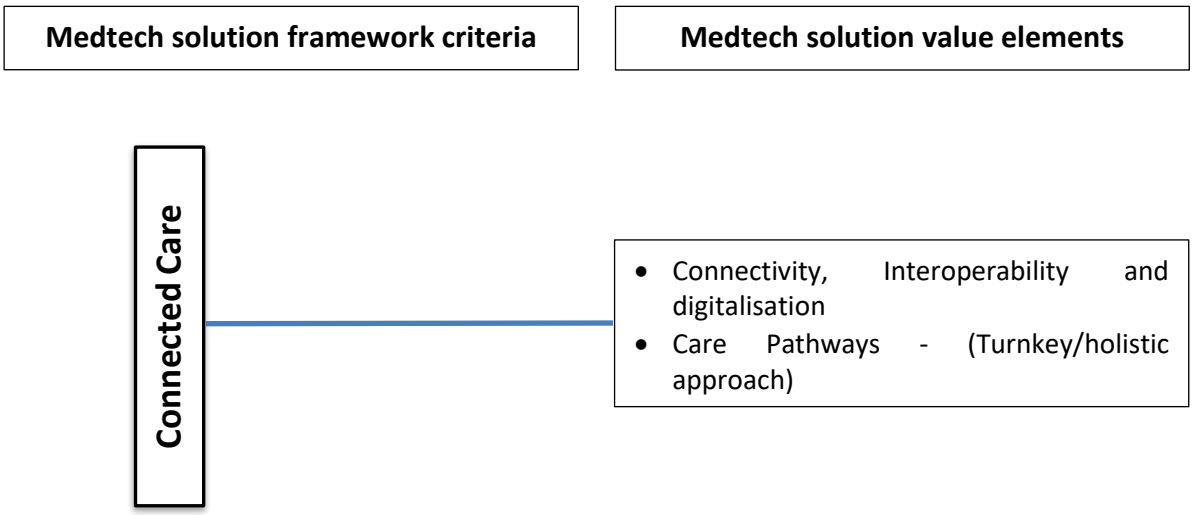

Figure 6.2: Connected Care value criterion and its correlations with the medtech solution value elements

6.1.3 Improving (healthcare) ecosystem's sustainability

The value framework for medtech solutions must include not only the financial and operational aspects of these technologies but also their broader societal impact and contributions to a sustainable healthcare ecosystem. HCPs emphasise that the role of medtech solutions extends beyond immediate clinical outcomes to include enhancing the overall sustainability of the healthcare environment. This sustainability is intricately linked to patient experience, where access to care and the durability of the healthcare system are central concerns. Key expectations from medtech solutions, as identified in the study, include a patient-centric approach that ensures optimal clinical outcomes and patient satisfaction. HCPs prioritise solutions that are environmentally friendly, reduce procedural delays and waste and promote standardisation and flexibility in accessing advanced medical technologies. These elements are seen as vital for both improving patient care and ensuring that healthcare systems remain resilient and responsive to future challenges.

The interviews with HCPs reveal a deep concern for the societal impact of medtech solutions, particularly in terms of improving access to healthcare services. For example, a radiologist (hcpintw#1) highlights that the true value of a medical device is not solely in its financial efficiency or volume of services but in its ability to meet essential healthcare needs. This

perspective highlights the importance of evaluating medtech solutions based on how they contribute to societal well-being and service delivery within the healthcare system: 'Value is related to the cost of the investment versus its performance, not commercially or in terms of how many exams it can deliver to be profitable, but in how it contributes to society. A medical device may be financially excellent because it performs many exams at a low cost, but its value is diminished if it does not meet the essential needs of the healthcare system' (radiologist, hcpintw#1).

Patient experience emerges as a central subject throughout the study, with both HCPs and medtech representatives recognising its critical significance. Medical devices are not just tools for delivering services; they have a direct impact on the patient journey. Optimal clinical outcomes are paramount, but the value perception also extends to broader aspects of patient satisfaction. A biomedical engineer pointed out that patient satisfaction in medtech involves ensuring comfort and minimising disruptions during care: 'There is no singular definition of value-based healthcare, but for me, patient satisfaction is a priority. Patient comfort means no surprises - no delays, postponements, or repeated examinations for patients using our services' (hcpintw#4).

Although sustainability is not always explicitly mentioned, it is implicitly referred to in the discussions with HCPs and medtech professionals. There is a consensus on the need for environmentally friendly healthcare technologies and practices. Participants stress the importance of reducing carbon emissions and promoting green development within the medtech industry. This includes innovations such as MRI scanners designed to minimise helium consumption, improve magnetic field generation efficiency and enhance operational stability. Green manufacturing practices, such as using renewable energy and reducing fuel consumption in production, are also highlighted as essential components of a sustainable healthcare system.

HCPs perceive these sustainable practices as not only an ethical imperative but also a strategic approach to achieving efficient healthcare delivery. They value outcomes like reduced power consumption per patient, increased accessibility to healthcare services, streamlined workflows and continuity of care as key indicators of a successful green approach in medtech.

A sustainable approach aligns technology investments with long-term health system goals, contributing to both operational efficiency and environmental stewardship.

Moreover, HCPs see the healthcare system as an interconnected ecosystem where their decisions and operations significantly impact overall system robustness. They recognise that technology-enabled services are crucial for sustaining this ecosystem by improving efficiency and accessibility. In this context, HCPs advocate for medtech solutions that streamline operations, reduce waiting times and eliminate procedural inefficiencies. The standardisation of processes, such as imaging protocols, is seen as essential for maintaining consistency and quality in healthcare delivery.

Additionally, HCPs seek flexibility in adopting the latest advancements in medical technology. This flexibility is essential for maintaining high standards of care and ensuring that healthcare providers can adapt to the evolving landscape of medical technology. An example of achieving this flexibility is through subscription-based models, such as Software as a Service (SaaS), that offer healthcare facilities the ability to remain current with technological innovations without incurring significant upfront costs associated with traditional purchasing models.

HCPs view the enhancement of healthcare delivery through medtech solutions as a multifaceted effort that balances patient outcomes, operational efficiency and sustainability. By integrating these elements, medtech solutions not only address immediate clinical needs but also contribute to the long-term sustainability and resilience of the healthcare ecosystem. Figure 6.3 visually represents the correlation between improving (healthcare) ecosystem's sustainability and the value elements of medtech solutions.

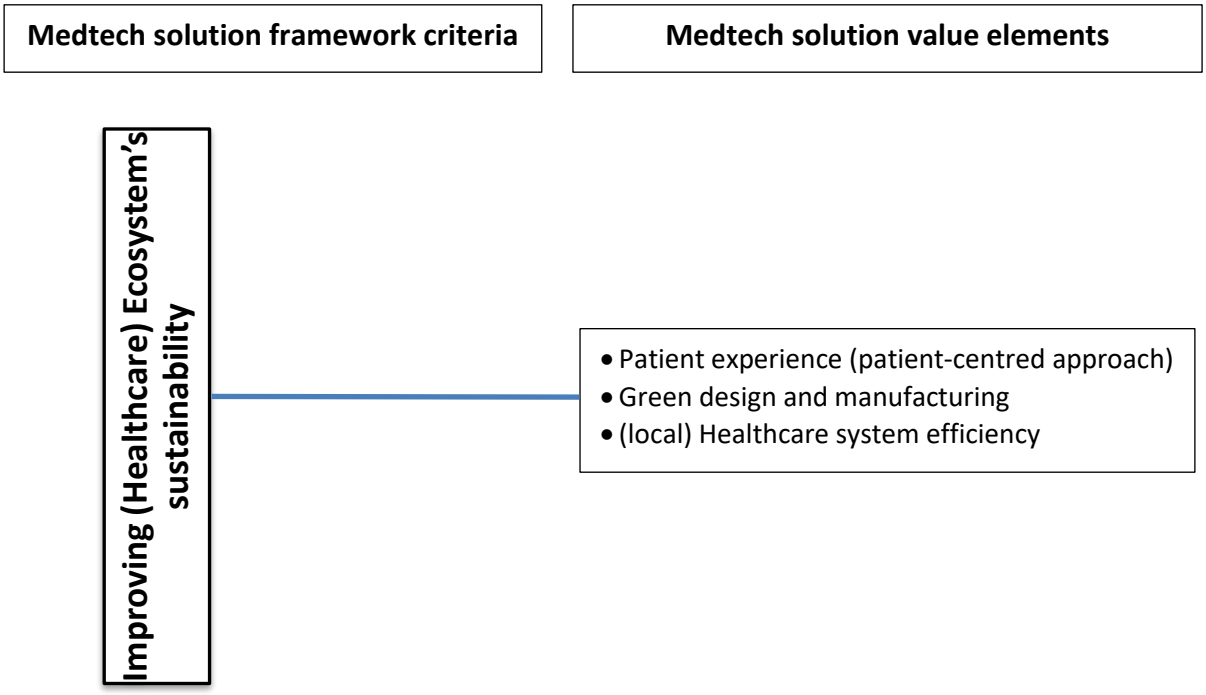

Figure 6.3: Improving (healthcare) ecosystem sustainability value criterion and its correlations to the medtech solution value elements

6.2 Discussion on the proposed value criteria and their contribution to the existing frameworks

This study introduces a value assessment framework that extends traditional HTA approaches by integrating dimensions essential to the evaluation of servitised medtech solutions. While established frameworks such as EUnetHTA, MEAT, AdHopHTA and MedtecHTA offer foundational models for assessing clinical and economic performance (Ciani et al., 2017; Fuchs et al., 2017), their product-centric design often overlooks the relational, systemic and lifecycle aspects that are essential when services are integrated into medtech solutions (O'Rourke et al., 2020; Sedrakyan et al., 2022).

Recent literature across HTA, digital health and servitisation theory highlights the need for rethinking value as a dynamic and co-created outcome, that is created over time through collaboration, responsiveness to changing conditions and alignment with broader healthcare system goals (Bobini & Cicchetti, 2024; Vandermerwe & Erixon, 2023; K. Zhang et al., 2023; Y. Zhang et al., 2024). Hospital-based HTA studies and European policy initiatives increasingly demand that medical technologies demonstrate long-term benefits, align with sustainability

targets and perform well in real-world settings, particularly in areas like digital health and advanced therapies (Avşar et al., 2024; Erdös et al., 2019; WHO, 2021). In this light, medtech solutions must not only deliver technical performance but also support adaptive capacity, institutional transformation and long-term system resilience. Servitisation literature similarly shifts focus from firm-level metrics to ecosystem collaboration and value co-creation (K. Zhang et al., 2023).

In response to these trends, this study proposes a framework built around three main criteria: **organisational impact, connected care and sustainability.** Each criterion is designed to reflect how value is created and delivered in healthcare systems today. The framework also aligns with newer approaches to MCDA, which highlight the importance of stakeholder input, future-oriented planning and integration across the healthcare system (Martelli et al., 2017; Oliveira et al., 2019). By shifting the focus from individual technologies to how solutions are integrated, adapted and expanded within healthcare settings, the framework supports more resilient and strategic decision-making.

A comparative overview in Table 6.1 shows how the proposed framework differs from existing ones, especially in the areas where traditional models offer limited guidance (indicated in grey-shaded cells). The detailed discussion that follows explains how each criterion challenges or extends established thinking about value in medtech evaluation.

Organisational impact - Expanded organisational assessment

The organisational impact criterion expands the traditional focus on operational efficiency by evaluating how well a medtech solution aligns with a healthcare provider's strategic objectives, supports workforce adaptability and integrates into existing workflows. While conventional HTA frameworks tend to focus on clinical efficacy and cost-effectiveness (Fuchs et al., 2016; Greenhalgh et al., 2017), this approach reflects a more dynamic understanding of value co-creation in servitised ecosystems, as seen in studies on B2B transformation and resource orchestration (K. Zhang et al., 2023; Y. Zhang et al., 2024), with relevance to healthcare contexts.

Effective implementation of service-based medtech solutions requires organisational readiness, agility and innovation capabilities (Johl et al., 2024; Kolagar et al., 2022). Studies show that when healthcare providers are able to adapt, experiment and reorganise around new solutions, the long-term benefits from such solutions increase (Heirati et al., 2024; Kohtamäki et al., 2022). New business models like Equipment-as-a-Service (EaaS), for example, offer ongoing support and flexibility rather than one-off product sales, making it easier for providers to plan, maintain and evolve their services (Sgambaro et al., 2024).

Studies show that the value of servitised and digital medtech solutions depends heavily on the context in which they are used (Kasoju et al., 2023; Sinha, 2024). Poor alignment with institutional goals can lead to implementation failure, even when technologies are technically sound (Bosco et al., 2024; Greenhalgh et al., 2017). Similarly, Zhang *et al.* (2024) emphasise that value in servitised ecosystems is created through dynamic coordination across institutions, requiring skills in interoperability, learning and redesign, principles that can be translated to digital healthcare contexts (Y. Zhang et al., 2024). These points reinforce the need to reconceive value not as a static economic outcome, but as a dynamic organisational asset. While frameworks like MEAT and AdHopHTA recognise workflow and resource issues (Erdös et al., 2019; Marsh et al., 2018), they do not fully address broader strategic needs like innovation alignment and adaptability. That is why this study emphasises not only operational fit but also the ability of a solution to support ongoing innovation and growth. This includes enabling staff to work more effectively, supporting changes in clinical practice and helping institutions respond to evolving challenges.

Organisational value in this context is not just about immediate results; rather, it is about building capacity for future success. Medtech solutions are increasingly seen not just as tools, but as long-term partners in delivering care. This is especially important as healthcare systems face growing pressure to adapt to new technologies, regulations and patient needs. For instance, organisational impact now includes the solution's ability to encompass innovation, support evolving clinical needs and enabling modular service upgrades. HCPs value technology not only for current utility but also for its ability to support continuous service innovation and institutional learning. They increasingly seek medtech solutions that do not merely integrate into current operations but also drive service expansion, improve organisational agility and

enhance competitive positioning in evolving healthcare markets. For instance, medtech start-ups contribute significantly to healthcare innovations, driving advancements in technology and enhancing treatment effectiveness (Kalinowska-Beszczyńska & Prędkiewicz, 2024).

This redefinition of business growth as a core dimension of value aligns with a broader shift toward hybrid service models and outcome-based procurement (Linde et al., 2023). As healthcare systems adopt more dynamic procurement strategies, medtech solutions are increasingly judged by their capacity to evolve with institutional goals, deliver lasting value and contribute to strategic positioning and system-wide resilience (Avşar et al., 2024; Kohtamäki et al., 2022). Healthcare providers now evaluate technologies not only on technical performance or immediate outcomes, but also on their ability to evolve with institutional needs and support future readiness. In this sense, medtech solutions become strategic assets, tools for competitive adaptation and sustainable growth. Thus, organisational impact becomes a critical criterion for evaluating medtech both on immediate functionality and on its role in enabling adaptive growth and ecosystem integration (Ciani et al., 2017).

While frameworks such as EUnetHTA and MedtecHTA acknowledge the relevance of staff training and user competence, they often position these aspects as secondary. In contrast, the organisational impact criterion place continuous education and competency development at the core of medtech solutions evaluation, recognising that the effectiveness of technology is deeply dependent on human capability and organisational learning.

Studies confirm that professional training and user support are essential for success, especially in digital health. Tailored training, professional development and user empowerment are consistently linked to successful implementation (Cresswell et al., 2021), while the WHO's Global Strategy on Digital Health highlights the necessity of sustained investments in digital literacy and workforce capacity (WHO, 2021). Hensher (2024) further emphasises that user preparedness and knowledge transfer frameworks are essential for integrating sustainable technologies in clinical settings, framing competence as a strategic asset rather than a support cost (Hensher, 2024). This view is affirmed by Bobini and Cicchetti (2024), who advocate for a shift in HTA paradigms to treat education and skill-building as long-term investments in system resilience (Bobini & Cicchetti, 2024). They argue for the inclusion of lifecycle learning

processes, institutional memory and professional evolution as formal dimensions of value. Supporting this perspective, researchers have found that integrating user preparedness and training burden into MCDA-based HTA enhances technology adoption and reduces post-implementation risk (Martelli et al., 2016).

Empirical findings from this study reinforce these insights. Healthcare professionals emphasised that medtech solutions derive value not only from their technical design but also from their alignment with human competencies. Education and skills development were seen as intrinsic to solution performance, influencing diagnostic precision, user satisfaction and care quality. This perspective reflects broader calls in the literature to prioritise people factors in smart health ecosystems (Grossmann & Marang-Van De Mheen, 2025; Lehane et al., 2019; McDonald et al., 2024). Studies further emphasise the importance of both everyday practices and frontline staff in shaping whether such solutions succeed, findings that align well with the qualitative insights from this study, which show how value is shaped by institutional culture and human factors (Löfberg et al., 2025).

Importantly, continuous education supports adaptive learning within institutions, enabling technologies to evolve alongside changing needs, evidence and service models. Building these competencies supports both the better use of technology and stronger, more resilient healthcare systems. Instead of seeing training as a cost, it should be seen as an investment in long-term value. The proposed framework thus reconceptualises competency building as a dynamic, ongoing process that links digital maturity with organisational transformation. This reflects a growing consensus in health technology policy and evaluation literature: that human adaptability is not a secondary enabler, but a central driver of technological value in healthcare (Doctor et al., 2023; McDonald et al., 2024). As technologies change, so too must the skills and practices of those who use them. Competency development becomes an ongoing process.

Connected Care - Connectivity, Interoperability, and Care Pathways

The connected care criterion focuses on the importance of technologies that work well across different systems, departments and care settings. It reflects the growing need for medtech solutions to be integrated, interoperable and responsive to patient needs, not just in

controlled clinical trials, but in everyday use across busy, complex healthcare environments (Guerra-Júnior et al., 2017). Technologies that operate in isolation can create inefficiencies, duplication or even safety risks. In contrast, solutions that enable integration and data sharing support more consistent and patient-centred care. The connected care criterion in the framework highlights this integration as a key factor in delivering consistent, patient-centred and efficient care across the continuum.

Modern healthcare systems increasingly rely on technologies that facilitate integration, data sharing and adaptability across the continuum of care (Kasoju et al., 2023; Sinha, 2024). Connected devices, such as digital vascular monitors and remote diagnostic tools, enable early interventions, reduce unnecessary admissions and improve diagnostic precision, yet their system-wide value is often not evaluated in conventional HTA (Akinola & Telukdarie, 2023). The findings of this study show that HCPs place high importance on technologies that enable real-time communication, improve and align with clinical workflow and support coordinated care delivery. When embedded effectively, connectivity enhances clinical decision-making, supports real-time coordination and enables continuity of care across institutional boundaries (Chen et al., 2024; Kohtamäki et al., 2022; Kühler et al., 2022). These features are not secondary; they are central to delivering value. Interviews with healthcare and medtech professionals in this study reinforce this view, highlighting that integration into clinical workflows and support for predictive, data-informed care are seen as core to technological value.

Digital transformation is also reshaping how value is created in healthcare. Iriarte *et al.* (2023) show that service design plays a key role in co-developing advanced, patient-centred offerings. Li *et al.* (2021) highlight how value is now co-created across networks of suppliers, users and digital platforms (Li et al., 2021). Doctor *et al.* (2023) propose maturity models to guide this transition, especially in complex, decentralised public systems (Doctor et al., 2023). Sinha (2024) adds that technologies like AI and edge computing have great potential to improve healthcare delivery but also raise challenges related to interoperability and governance, areas that traditional HTA frameworks are not yet equipped to assess (Sinha, 2024). Digital infrastructure studies confirm that interoperable systems reduce information silos, facilitate communication and improve care efficiency. Zhang *et al.* (2024) further suggest

conceptualising interoperability as a coordination capability that enhances institutional responsiveness, a finding aligned with this study's results. This broader perspective on value aligns with calls from Kasoju *et al.* (2023) and Sinha (2024) to improve governance, data sharing and ethical safeguards in the design of digital health systems (Kasoju et al., 2023; Sinha, 2024). In this view, connectivity becomes a strategic enabler of redesigning services to be more adaptive and efficient.

Medtech solutions should be evaluated not just for their stand-alone benefits, but for how well they connect with the broader system. This includes their ability to improve care pathways, enhance team-based care and reduce fragmentation. Connected care reframes medtech solutions as integral components of healthcare ecosystems rather than isolated tools. This approach calls for HTA metrics that capture system-level performance, care pathway optimisation and cross-organisational integration. Optimised care pathways, enabled by connected technologies, directly contribute to operational resilience, patient safety and continuity of care, thereby expanding the conventional scope of value assessment. In many cases, value lies not in the technology itself but in how well it incorporates integrated, coordinated service delivery. Consequently, care pathway transformation, supported by interoperable technologies, should be recognised as a primary outcome in both HTA and servitised medtech innovation.

Sustainability as a central value criterion

Sustainability is increasingly recognised as a central component of healthcare technology value, including environmental, operational and societal factors. While traditional HTA frameworks such as EUnetHTA and INTEGRATE-HTA acknowledge societal and environmental impacts, these are often treated as secondary to clinical and economic considerations (Angelis et al., 2020; Erdös et al., 2019; Fuchs et al., 2017). By contrast, this framework conceptualises sustainability not as an isolated dimension, but as an overarching evaluative logic that spans the entire lifecycle of medtech solutions, from design and manufacturing to usage, optimisation and disposal (Benedettini, 2022; Y. Zhang et al., 2024). It embeds circular economy principles and lifecycle thinking into the value assessment process, linking ecological responsibility with long-term operational efficiency, cost-effectiveness and systemic resilience (Corrêa, 2018; Montesinos et al., 2024).

The framework reconceptualises sustainability as a strategic enabler of value over time, not a compliance burden. It expands traditional environmental metrics to include lifecycle thinking, operational resilience and system-level efficiency (Manika et al., 2016; Y. Zhang et al., 2024). Integrating sustainability early in the design and evaluation of medtech aligns with recent calls to embed environmental goals within innovation and governance strategies (Hensher, 2024; Hinrichs-Krapels et al., 2022). Servitisation models play a key role in advancing sustainability. By promoting shared use, reprocessing, modular design and repair services, they extend device lifecycles and reduce environmental footprints (Benedettini, 2022; Corrêa, 2018; Szász & Seer, 2018). These practices also lower lifetime costs, aligning environmental benefits with financial sustainability.

Empirical evidence further supports the link between sustainability and strategic performance. Environmental, Social and Governance (ESG) frameworks increasingly shape procurement and investment decisions in healthcare, encouraging the adoption of energy-efficient technologies and sustainable service contracts (Bosco et al., 2024). For example, imaging equipment provided through contracts that include maintenance, upgrades and end-of-life recycling can reduce waste while enhancing long-term system value. Lifecycle management is central to this approach. Eco-design, recycling and repairability reduce the environmental burden across sourcing, usage and disposal stages. Digital tools and data coordination further support sustainable supply chains and resource optimisation (Sharma & Singh, 2017; Y. Zhang et al., 2024).

Sustainability intrinsically should be connected to patient-centred innovation. The patient experience is not treated as a downstream outcome but positioned at the heart of the healthcare ecosystem. Durable, reliable and resource-efficient technologies improve clinical workflows and reduce unnecessary interventions. Green procurement and energy-saving infrastructure have been shown to enhance both care quality and economic outcomes (Martelli et al., 2016; Vienken & Boccato, 2024). Innovative device designs, such as those using 4D printing and biodegradable materials, enable disassembly, reuse and safer disposal, particularly for high-waste segments like single-use devices. Moreover, sustainability contributes directly to healthcare resilience. Technologies that support early diagnosis, reduce unnecessary procedures or optimise supply chains can reduce environmental burdens and

improve outcomes (Akinola & Telukdarie, 2023). These benefits illustrate how sustainability and servitisation reinforce one another to support proactive, adaptive and efficient care.

The study presents a value assessment framework that responds to the limitations of traditional HTA models by introducing organisational impact, connected care and sustainability, as essential criteria to evaluate servitised medtech solutions. Together, these criteria reflect a shift from static, product-based assessments to dynamic, systems-level evaluations. By aligning with contemporary academic and policy developments, the proposed framework bridges theoretical advances in servitisation with empirical insights from healthcare practice. It supports a relational, systems-oriented view of value, where technologies are assessed not only for clinical or economic impact but also for their capacity to enable organisational learning, build partnerships and support the long-term resilience of healthcare systems. Additionally, it places people and learning at the heart of evaluation, recognising that education, stakeholder engagement and institutional capability are central to realising the full value of medtech solutions. Thus, it offers a comprehensive, future-oriented lens that captures multifaceted contributions to healthcare value.

Table 6.1: Overview of existing frameworks and corresponding value criteria aligned with the proposed medtech solution value criteria

Frame work	Organisational impact					Connected care		Improving (healthcare) ecosystem's sustainability		
	Technology - enabling business growth	Technology Management	Enhancing personnel competences	Improve diagnostic confidence Clinicians' satisfaction	Process Optimisation	Connectivity, Interopera-bility and digitalisation	Care pathways Holistic - turnkey approach	Patient experience	Green design and manufacturing	(local) healthcare system efficiency
ICER$_a$	**Benefits Beyond Health:** Mechanism of Action							**Benefits Beyond Health:** Complexity of regimen		**Special Ethical Priorities:** Disadvantaged or Undeserved Communities Caregiver and Family Impacts Return to Work and/or Productivity
EUnet HTA	**Health problem and current use of technology:** Reimburse-ment status	**Description and technical characteristics of technology:** Training and information needed to use the technology: *Qualification of people and quality assurance processes needed for the use of the technology and its maintenance*	**Description and technical characteri-stics of technology:** Training and information needed to use the technology: **Organisa-tional aspects:** Health delivery process: *What kind of process ensures proper education and*	**Clinical Effective-ness:** Change-in-manage-ment: *Improved detection of the condition* *Technology -related changes of physicians' manage-ment decisions*	**Health problem and current use of technology**: Utilisation: *New innovative, mode of care, add-on, modification of a standard mode, replacement of a standard mode* **Organisational aspects:** Health delivery process:		**Health problem and current use of technology:** Current management of the Condition **Organisa-tional aspects:** Health delivery process: *Patient/parti-cipant flow associated with the new technology*	**Clinical Effectiveness:** Patient satisfaction **Patient and Social aspects:** Patients' perspectives: *Expectations, wishes and gains expected from the technology by the patients* *Patients' perception of the technology*	**Safety:** Environmental safety: *Public and environmental risks*	**Health problem and current use of technology:** Consequences and burden of the disease for the society **Clinical effectiveness:** Change-in-management: *Modification of the need for hospitalisation* **Costs and economic evaluation:** Budget impact

Frame work	Organisational impact					Connected care		Improving (healthcare) ecosystem's sustainability		
	Technology - enabling business growth	Technology Management	Enhancing personnel competences	Improve diagnostic confidence Clinicians' satisfaction	Process Optimisation	Connectivity, Interopera-bility and digitalisation	Care pathways Holistic - turnkey approach	Patient experience	Green design and manufacturing	(local) healthcare system efficiency
			training of staff		*Technology effect on the current work processes*					
MEAT	**Outcomes:** Outcomes focus: *Willingness to offer outcomes-dependent risk-sharing* **Other benefits for key stakeholders:** Provider benefits: *Strategic fit for provider and support of strategy* *Alignment and support with reimbursement structure*	**Costs:** Product/ Maintenance: *Spare parts* *Technical staff time* *Service contract* **Other benefits for key stakeholders**: Provider benefits: *Maintanability, warranty & technical service support*	**Costs:** Care delivery/Operating - healthcare delivery: *Ongoing staff training* **Other benefits for key stakehol-ders:** HCP benefits: *Training and access to education*				**Other benefits for key stakeholders:** Provider benefits: *Support improving efficiency along patient pathway*	**Other benefits for key stakeholders:** Patients' secondary benefits: *Patient and/or relative comfort and convenience* *Patient flexibility and mobility* *Impact on patient adherence*	**Broader Impact on society:** Sustainability: *Environmental impact* *Socially responsible product value chain* **Costs:** Product/ Purchasing: *Compatibility: upgrades to systems/infrastructure* Product/Storage: *Replacement at end of shelf life* Product/Disposal: *Disposal/decommis-sioning*	**Broader Impact on society:** Innovation *Contribution to development of healthcare* **Other benefits for key stakeholders:** Health system benefits: *Reduced long term costs of treatment* *Reduction of rehospitalisation /# of treatments*
Adva Med		**Care Delivery Revenue and Cost Impact:** Care Efficiency:	**Care Delivery Revenue and Cost Impact:** Care Efficiency:	**Care Delivery Revenue and Cost Impact:**	**Care Delivery Revenue and Cost Impact:** Care Efficiency:			**Clinical Impact:** Clinical Efficacy and Effectiveness:	**Environmental Impact:** Monetary impact: *Cost impact from environmental*	**Non-clinical patient impact:** Patient Experience: *Reintegration/re-engagement of*

Frame work	Organisational impact					Connected care		Improving (healthcare) ecosystem's sustainability		
	Technology - enabling business growth	Technology Management	Enhancing personnel competences	Improve diagnostic confidence Clinicians' satisfaction	Process Optimisation	Connectivity, Interopera-bility and digitalisation	Care pathways Holistic - turnkey approach	Patient experience	Green design and manufacturing	(local) healthcare system efficiency
		Economic impact of improved system throughput & workflow/efficient time & resource utilisation	*Economic impact of improved adoption of new care practices due to easier/more effective training/ education*	Care Efficiency: *Economic impact of improved system throughput & workflow/efficient time & resource utilisation (i.e. physician's time and effort)*	*Economic impact of improved system throughput & workflow/efficient time & resource utilisation (i.e. i.e. disposable utilisation, operating room utilisation)*			*Improvement in compliance with plan of care* **Non-clinical patient impact:** Patient Experience: *More preferable site of care (ease of access)* *Predictability of care /experiences vs. expectations*	*initiatives and execution* *Increased asset optimisation by capital allocation in sustainable devices* Perception and Differentiation: *Impact of reduced net global emissions on company value proposition* *Reduction in regulatory, legal and activist shareholder interventions*	*patient into society* **Care Delivery Revenue and Cost Impact:** Quality of Care Economics: *Economic impact of performance-based reimbursement metrics* **Public and Population Impact:** Population Health Workforce productivity
Medtec HTA		**Manufacturer support** **Healthcare setting**	**Manufacturer support** **Learning curve and training needs**	**Clinical effective-ness** **User preferen-ces**	**Organisa-tional aspects**		**Organisa-tional aspects**	**Patient preferences**		**Costs and economic evaluation** **Incremental innovation**
AdHoc pHTA	**Political and Strategy aspect**	**Technology characteristics**	**Organisa-tional aspects**	**Clinical outcome/ effect size**	**Organisational aspects**		**Health problem** **Organisa-tional aspects**	**Costs and economic evaluation:** Societal point of view		**Social aspects:** Social **Costs and economic evaluation:**

Frame work	Organisational impact					Connected care		Improving (healthcare) ecosystem's sustainability		
	Technology - enabling business growth	Technology Management	Enhancing personnel competences	Improve diagnostic confidence Clinicians' satisfaction	Process Optimisation	Connectivity, Interopera-bility and digitalisation	Care pathways Holistic - turnkey approach	Patient experience	Green design and manufacturing	(local) healthcare system efficiency
										Societal point of view
INTE-GRATE -HTA	**Legal aspects:** Market authorisation: *Reimburse-ment in public healthcare systems* **Context domain**: Socio-economic Political		**Implementation domain:** Provider Organisation and structure	**Socio-cultural aspects:** Relation-ships between profession-nals providing the technology **Implement ation domain:** Provider	**Implementation domain:** Provider Organisation and structure			**Socio-cultural aspects:** Socio-cultural aspects of technology implementation and organisation		**Socio-cultural aspects:** Socio-cultural aspects of technology implementation and organisation **Context domain:** Socio-economic Political **Implementation domain:** Funding Policy
NICE	**New treatment:** New patient access scheme						**New treatment:** Clinical treatment pathway	**Condition:** Effect on QoL Psychological aspects **New treatment:** Adherence issues **Clinical effectiveness:** Long term effects		**Condition:** Effect on QoL: *Carer* *Family* **Clinical effectiveness:** Risk of recurrence/relapse **Cost effectiveness:** Economic model: *Model input:*

Frame work	Organisational impact					Connected care		Improving (healthcare) ecosystem's sustainability		
	Technology - enabling business growth	Technology Management	Enhancing personnel competences	Improve diagnostic confidence Clinicians' satisfaction	Process Optimisation	Connectivity, Interopera-bility and digitalisation	Care pathways Holistic - turnkey approach	Patient experience	Green design and manufacturing	(local) healthcare system efficiency
								Patient reported outcomes		*Treatment duration* **Other factors:** Innovation Uncaptured benefits

7. Conclusions, academic and managerial implications

7.1 Concluding thoughts

The medtech industry, much like sectors such as telecommunications and aerospace, is transitioning, from a product or service-based offering model to a servitised model, which integrates products and services into comprehensive solutions (Foote et al., 2001). This shift aligns with the value-based healthcare model, increasingly adopted by the healthcare ecosystem to maximise value for patient populations. For medtech companies, moving toward solutions represents an opportunity to address commoditisation challenges and deepen engagement with their customers.

Delivering medtech solutions is ultimately aimed at creating value. However, the perception and assessment of value vary among healthcare stakeholders. Existing value frameworks are primarily designed to evaluate medications and treatments, with limited applicability to medical devices. Furthermore, these frameworks, whether used for technology assessment, reimbursement decisions, or value-based procurement, are typically focused on assessing medical devices as stand-alone units rather than as integrated solutions. This study proposes the essential value criteria that should form the core of a value framework for evaluating medtech solutions. These criteria are derived from insights into the value drivers that shift the perception of healthcare providers from viewing medical devices as isolated offerings to seeing them as integrated solutions.

The research was carried out in three phases using qualitative methods. In Phase 1, a thematic analysis was conducted on existing value frameworks, procurement guidelines, HTA frameworks and relevant research initiatives related to medical device evaluation. This analysis aimed to identify the key value criteria commonly used in the assessment of medical devices. Then, in Phase 2, HCPs provided their insights and perceptions about the value elements for medical devices and medtech solutions assessments, using imaging systems as typical medical devices affecting the healthcare ecosystem. In Phase 3, medtech experts from

a medtech company assisted in refining the understanding and content of the value drivers, since they routinely design the solutions under consideration.

This research reveals key value drivers that transform a traditional medical device offering into a medtech solution, based on insights from healthcare and medtech professionals. The findings show that while medical devices must fulfil essential technical and clinical requirements, such as safety, regulatory compliance and cost-effectiveness, solution offerings extend their role by promoting business innovation and growth beyond the device's primary function. In a solution-based approach, medical devices are viewed not just as products, but as integral assets that require continuous optimisation. This involves the application of advanced technologies, including AI and predictive analytics, to enhance performance and productivity over time, which is a marked departure from the basic maintenance typically associated with stand-alone devices. Additionally, the emphasis of a servitised solution is on enhancing the competencies of HCPs and improving diagnostic confidence throughout the lifecycle of the medical device. This goes beyond initial training, providing continuous support to ensure that clinicians can maximise the value of the technology. Moreover, the concept of patient-centred care is elevated in a solution offering. Patient satisfaction is no longer just a matter of device interaction but is integrated into a comprehensive care pathway, ensuring better disease management and overall outcomes. The research also highlights the broader impact that solution offerings can have on local communities and the healthcare ecosystem. Whereas medical devices contribute to clinical services at a local level, solution offerings emphasise sustainable innovation that can benefit the healthcare system as a whole, along with broader environmental and social considerations. This sustainable focus not only advances healthcare services but also aligns with the growing need for environmentally responsible practices in healthcare. Lastly, process improvement is a defining feature of solution offerings. Unlike the traditional medical device model, which emphasises functionality, a solution approach integrates evidence-based improvements into clinical and administrative workflows, ensuring more efficient and connected systems.

The transition from a product-oriented medical device offering to a solution-oriented approach fundamentally redefines the concept of value in the medtech industry. This shift

emphasises business innovation, enhanced clinician and patient experiences and sustainable improvements in healthcare delivery.

These findings offer valuable insights for designing a value framework that moves beyond traditional product-based models to more comprehensive, solution-oriented evaluations. Specifically, the findings indicate that a value framework for assessing servitised medtech offerings must focus on three key value criteria: (a) business growth and operational excellence (organisational impact), (b) integrated care pathways and digital connectivity (connected care) and (c) improved sustainability within the healthcare ecosystem, with a focus on patient outcomes. These criteria are condensed into three essential assessment questions for servitised offerings:

1. How does the medtech solution facilitate business growth, optimise organisational processes and contribute to operational excellence?
2. How do the connectivity and interoperability features of the medtech solution support the integration of care and the formation of care pathways within the healthcare system?
3. How does the medtech solution promote cost-effectiveness, budget sustainability, enhanced patient experiences and environmental sustainability?

These assessment questions are essential for evaluating the effectiveness and value of a medtech solution from the perspective of HCPs, ensuring that the offerings align with their operational, clinical and sustainability priorities. Figure 7.1 illustrates the medtech solution value framework, highlighting the value criteria, the value drivers that transform a medical device into a medtech solution and the key value elements of the solution. The value criteria of a medtech solution build upon the foundational criteria of technology quality and safety.

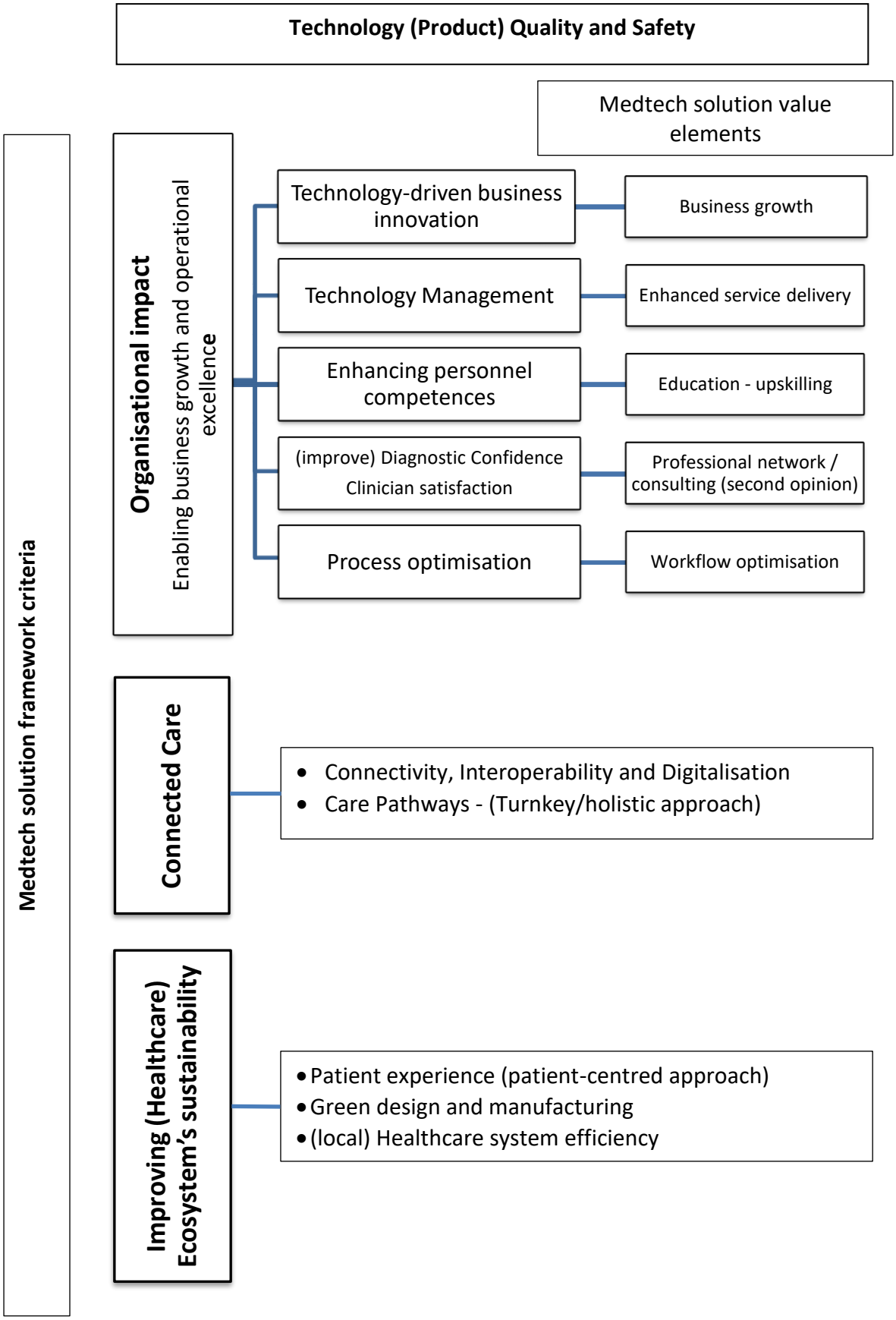

Figure 7.1: Medtech solution value framework

7.2 Contributions and limitations

The findings of this study, grounded in practitioner insights, offer value to both academic and professional audiences. Consistent with practice theory (Seidl & Whittington, 2014) the sayings and narratives thematically analysed through this research can translate into doings and practices within healthcare organisations and medtech innovation ecosystems.

7.2.1 Contribution to existing research

This research makes two primary contributions to the literature: (1) advancing value assessment frameworks in the context of servitised medtech solutions, and (2) enhancing understanding of value drivers from the perspective of HCPs. These contributions help bridge theoretical gaps and provide practical insights for evaluating servitised medtech solutions within integrated healthcare systems.

7.2.1.1 Advancing value frameworks in medtech

The study builds on existing value frameworks by incorporating the lens of servitisation, offering a more comprehensive assessment model for medtech. Traditional frameworks often emphasise clinical and economic outcomes, with limited attention to broader factors like organisational impact or care integration (ICER, 2023; Neumann & Tunis, 2023). This research introduces a comprehensive framework that accounts for business relevance, integrated care and sustainability.

The proposed framework reconceptualises value in medtech as the capacity of a solution to support business growth, operational resilience, cross-functional care coordination and long-term sustainability. It focuses on practical dimensions such as workforce adaptability, digital interoperability, care pathway integration and environmental performance across the lifecycle of a solution. This approach shifts the focus from isolated product performance to broader, real-world system outcomes, offering a more applicable basis for decision-making in complex healthcare environments (Y. Zhang et al., 2024).

The study contributes to academic literature of HTA and MCDA. It responds to ongoing calls for HTA to move beyond short-term clinical and economic outcomes toward real-world, lifecycle-oriented HTA approaches (Angelis et al., 2020; Oliveira et al., 2019). It introduces practical, context-specific criteria, such as operational excellence and business growth, connected care, interoperability and sustainability that are increasingly important for evaluating complex, service-oriented technologies. These additions, that are both clinically relevant and aligned with broader systemic value goals, help evolve MCDA by making it more responsive to the long-term goals and operational realities of modern healthcare systems (ICER, 2023).

Moreover, this study broadens the application of servitisation theory by exploring its relevance in the relatively overlooked domain of medtech and healthcare services. It moves beyond the theory's traditional focus on industrial and manufacturing sectors (Baines et al., 2024; Xing et al., 2023), as well as firm-focused models centred on efficiency and product-service integration. Instead, it adopts a more holistic perspective on value, one that emphasises collaboration among multiple stakeholders, outcomes at the system level and enduring partnerships within healthcare. Within this framework, operational excellence is redefined as a strategic driver of patient experience, clinical outcomes, organisational agility and the long-term transformation of healthcare systems (Sjödin et al., 2020).

Taken together, these contributions provide a theoretical and practical foundation for evaluating the next generation of medtech solutions. They support dynamic, system-informed frameworks that are better aligned with the realities of digital, integrated and value-based healthcare.

7.2.1.2 Understanding value drivers from the perspective of HCPs

This study contributes to the academic discourse on value co-creation in healthcare, digital health service innovation and servitisation in healthcare systems by providing an empirically grounded understanding of how HCPs perceive and operationalise value in the context of medtech solutions.

In the context of servitisation, recent research has examined several key developments in healthcare. These include the shift from product-focused to service-oriented models (Edvardsson & Tronvoll, 2022; Naeem et al., 2024), the role of stakeholder engagement in co-creating value within digital health services (Jat et al., 2024) and the importance of collaboration in designing effective digital health interventions (Laukka et al., 2024). A growing body of work also highlights the critical role of patient involvement in value co-creation, showing that active participation can lead to better healthcare outcomes (Sandhu et al., 2024). Additionally, studies on patient perceptions of digital value co-creation, particularly in the use of electronic health records, offer insights into how user characteristics influence the realisation of value (Rachmania et al., 2025). By bringing together these perspectives, this study contributes to a deeper understanding of how value is created and delivered in medtech solutions by:

Reframing medtech solutions as integrated service ecosystems that include clinical functionality, business processes, patient services and optimisation support, aligned with the operational goals of healthcare providers (Kohtamäki & Helo, 2015).

Highlighting connectivity and interoperability as critical value drivers, reflecting HCPs' emphasis on system integration and workflow coordination across care settings (Davies, 2004; Davies et al., 2006; Kasoju et al., 2023; Sinha, 2024; Windahl, 2015).

Positioning human-centric outcomes, such as staff learning, patient empowerment and equitable access, as core elements of value creation. This extends the concept beyond clinical performance to include organisational learning and community benefit (Levander et al., 2024; Smith & Colgate, 2007).

Emphasising multi-stakeholder collaboration as essential for the successful implementation and ongoing optimisation of medtech solutions, involving both internal and external actors (Laukka et al., 2024).

This research deepens value framework literature by grounding evaluation criteria in practitioner perspectives. It shows how medtech value is shaped not only by clinical

performance but by business relevance, interoperability and human-centric outcomes. These findings strengthen the theoretical foundation for assessing servitised medtech solutions and offer practical guidance for aligning solutions with the operational goals of modern healthcare systems.

7.2.2 Contribution to management

This study provides actionable contributions for medtech managers and industry practitioners by offering a framework that supports informed, strategic decision-making in the context of servitisation. Specifically, the framework contributes by:

Supporting strategic decision-making. As industry shifts toward integrated, service-based offerings, firms face increasing pressure to align their solutions with the strategic goals, operational needs and sustainability requirements of healthcare providers. This study supports medtech companies in making informed, evidence-based decisions about whether and how to pursue a servitisation strategy. While servitisation is increasingly promoted as a competitive pathway, it is not universally appropriate. Its success depends on factors such as organisational readiness, stakeholder alignment, system integration and long-term value delivery, dimensions often overlooked in trend-driven strategic decisions (Buck et al., 2025; Y. Zhang et al., 2024).

The framework developed in this research offers medtech firms a structured way to assess whether their solutions can meet the critical expectations of healthcare providers. By clarifying what HCPs value, such as business growth, workflow optimisation, user education, care pathway coordination and sustainability, the framework helps companies evaluate both the opportunities and demands of servitisation. This enables managers to avoid uncalculated shifts in business models and instead pursue servitisation only when their offerings, capabilities and market conditions justify it. By drawing on empirical insights from HCPs and integrating key academic perspectives, the proposed framework offers medtech firms and managers a decision-support tool to evaluate the suitability, readiness and impact of servitised solutions, helping them reduce the risk of poor performance linked to misaligned service transformation.

Guiding solution design and development. The proposed framework provides a practical tool for medtech managers to design solutions that are better aligned with the complex needs of modern healthcare systems and for medtech practitioners to design solutions that align with the dynamic healthcare environment. Given the complexity and fragmentation of healthcare systems, with a range of stakeholders from clinicians to administrators, servitised solutions must be flexible and adaptable. By applying the framework, practitioners can ensure that servitisation efforts improve both operational efficiency and clinical outcomes. The value criteria highlight areas where services can enhance product offerings, such as through better workflow integration, clinician support or patient management. It encourages companies to move beyond stand-alone devices toward system-oriented offerings that enable care pathway integration, support workforce adaptability and embed sustainability into both product design and service delivery. For instance, Equipment-as-a-Service (EaaS) models demonstrate how flexible, subscription-based service arrangements can replace traditional one-time purchases, offering continuous value throughout the care pathway (Sgambaro et al., 2024). By applying this framework, medtech companies can better design solutions and determine when and how these models generate value, ensuring their servitisation strategies remain both operationally efficient and strategically aligned with the evolving needs of the healthcare sector.

Procurement and market positioning. The framework supports medtech companies in responding to evolving procurement and reimbursement practices that prioritise outcome-based contracting and ESG criteria. It enables firms to align their offerings with the strategic goals of healthcare purchasers, such as sustainability mandates and long-term system performance, by highlighting value elements like workforce resilience, cross-organisational integration and lifecycle sustainability. By applying the framework, companies can improve procurement readiness, tailor service packages to specific market segments and position themselves as long-term strategic partners rather than transactional suppliers.

The framework helps medtech companies decide whether servitisation is the right strategy, avoiding trend-driven or misaligned choices. It also supports the design of adaptable, learning-oriented solutions that deliver long-term value. By aligning technology with organisational

goals, care pathways and sustainability, the framework gives managers clear criteria to improve relevance, procurement success and system-wide impact.

7.2.3 Limitations

This study follows an exploratory qualitative design, guided by a pragmatic paradigm, aiming to develop a value assessment framework for evaluating medtech solutions based on real-world insights from healthcare and medtech professionals. While the approach prioritises depth over generalisability, several limitations should be acknowledged and addressed in future research.

Sample size and scope

The study's qualitative design prioritised depth and contextual insight over statistical generalisability. In Phase 2, 13 HCPs from 12 healthcare organisations, located mostly in Greece, were purposively selected for their direct involvement in the procurement and use of CT and MRI systems, technologies well-suited to exploring servitised value models due to their complexity and service integration. Although participants held senior roles and some had international experience, the limited sample size and national focus may restrict the broader applicability of the findings.

In Phase 3, 12 senior professionals from a single medtech company were interviewed across key business functions. While this offered rich, cohesive insights into value construction within one firm, it may not fully reflect the heterogeneity of the medtech sector, which varies widely in terms of product type, market focus and service maturity. Despite these limitations, the study provides a robust foundation for understanding value perceptions in complex medtech settings. The selected participants were highly experienced and strategically positioned, allowing for meaningful insight into real-world practices. The framework developed is grounded in this domain expertise and offers a credible starting point for further research.

Stakeholder inclusion

This study focused on HCPs and medtech industry experts, who are directly involved in evaluating, procuring and implementing servitised medical technologies. This was appropriate

for the study's exploratory aim, as these stakeholders are well-positioned to speak to the operational and strategic aspects of value in practice.

However, this study did not include other key stakeholders such as patients, payors and regulators. As healthcare systems increasingly adopt patient-centred care and VBP models (Angelis et al., 2018; M. E. Porter & Lee, 2013), excluding these perspectives limits the framework's ability to fully reflect how value is understood and negotiated across the broader healthcare system. Including a wider range of stakeholders would offer a more complete picture of how value is co-created in practice and could help identify where different stakeholder priorities align or conflict.

Contextual generalisability across healthcare systems

One limitation of this study is that it did not fully examine how the proposed value framework applies in different types of healthcare systems. While participants came from organisations with both public and private sector characteristics, the study did not systematically explore how differences in governance, funding models or strategic goals shape value perceptions in fully public versus fully private systems.

Existing research suggests that these structural factors affect how technologies are assessed, procured and valued (Del Sarto et al., 2024; Ferraresi et al., 2021; García-Altés et al., 2023; Mbwasi et al., 2022; Meehan et al., 2017). Public systems often prioritise long-term outcomes, standardisation and equity, whereas private providers may focus more on flexibility, innovation and financial return (Kastanioti et al., 2013; Lingg et al., 2016; Trueba et al., 2021). These different priorities can influence how value is understood and operationalised. Although the study identified shared value themes across hybrid systems, it may not fully reflect the specific logics and constraints of purely public or private settings.

Scope and applicability

This study focuses on high-value diagnostic imaging technologies, specifically CT and MRI systems, which are capital-intensive, service-dependent and embedded in complex hospital workflows. These devices involve long procurement cycles, require ongoing support and training and are typically evaluated by multiple stakeholders, making them well-suited for

studying value in medtech solutions (Baines et al., 2024; Baines & Bigdeli, 2017). Because of these characteristics, the proposed framework is likely to be relevant for other complex technologies with similar profiles, such as surgical robots, radiotherapy platforms and laboratory automation systems. These devices also rely on lifecycle support and integration into clinical pathways, making them comparable in terms of how value is co-created and assessed.

However, the framework may be less applicable to lower-cost or stand-alone technologies, including consumables or basic diagnostic tools, where procurement is more transactional and focused on price or short-term utility. Similarly, technologies like implantables or wearable consumer devices may require additional evaluation criteria, such as ease of use, long-term patient engagement or data privacy. While the framework provides a solid foundation for assessing servitised solutions, its broader applicability should be tested across a wider range of device types and care settings.

Reliability and trustworthiness in thematic analysis

The study employed reflexive TA (Braun & Clarke, 2006, 2013, 2023), which fits well within a pragmatic research approach. The focus was on producing practically useful and contextually grounded insights rather than seeking universal or objective truths. In reflexive TA, themes are not seen as pre-existing in the data but are developed by the researcher through active and thoughtful engagement with the material.

While the coding process was developed and reviewed in collaboration with the supervisory team to enhance analytical rigour, no formal intercoder reliability metrics (e.g. Cohen's Kappa) were applied. This is consistent with Braun and Clarke's (2023) position that such statistical checks are not suitable for reflexive TA, which values reflexivity and interpretive judgement over agreement between coders. As Braun and Clarke (2023) caution, such metrics may be conceptually incoherent with reflexive TA, which views meaning as constructed rather than objectively discovered. Instead, analytical rigour was supported by regular discussions with the supervisory team, iterative code refinement and written memos to document thinking and decisions throughout the analysis. Providing additional detail on the collaborative coding process and theoretical positioning would further enhance the study's credibility. Additionally,

although informal member validation was conducted through follow-up communications with select participants, structured peer debriefing or participant workshops could have provided a more robust form of analytic triangulation and confirmability (Birt et al., 2016).

The credibility of the analysis was also strengthened by the domain expertise of both the participants and the researcher. Participants were selected for their hands-on involvement in medtech evaluation and implementation, making their input highly relevant. In parallel, the researcher brought deep professional experience in the medtech sector, which informed the interpretation of patterns and value themes. This reflects what Stierand and Dörfler (2014) call 'occupational wisdom', or the use of tacit, experience-based knowledge to make sense of complex problems (Stierand & Dorfler, 2014). As Polanyi (1966) and Tsoukas (2009) suggest, such intuitive knowledge, while not entirely neutral, is essential for meaningful interpretation in expert domains (Jha, 1997; Polanyi, 1966; Tsoukas, 2009).

Interdependencies between value criteria

While this study identifies key value criteria that shape how medtech solutions are assessed, it does not fully examine how these elements interact in practice. In real-world healthcare settings, value drivers rarely operate in isolation. For example, sustainability efforts may depend on interoperability with existing systems, while effective service integration may hinge on staff training and clinical adoption. These interdependencies are likely to vary across organisations, care pathways and system types. A deeper understanding of how value dimensions reinforce or constrain one another would help refine the framework and make it more applicable to different healthcare contexts.

This study relied on qualitative interviews to explore how healthcare professionals and industry experts assess value in medtech solutions. The absence of quantitative data means the study cannot determine how widely shared these views are or which value criteria are most important across different settings. Future research could address this by adopting a mixed-methods approach, combining qualitative interviews with quantitative tools such as surveys. This would allow researchers to measure the prevalence and relative weight of different value drivers and validate the framework across larger and more diverse samples.

7.3 Future research

Future research should build on the framework developed in this study by exploring its application across different healthcare settings, stakeholder groups and types of medtech solutions with the aim of strengthening its validity and usefulness in guiding real-world decision-making.

First, future studies should test the framework in a broader range of healthcare systems, particularly outside Greece and beyond high-cost imaging technologies. Applying the framework in diverse national and institutional contexts, including public and private systems with varying procurement models and policy environments, would help evaluate its adaptability and generalisability. Studies involving additional medtech firms, including those with different market orientations and service models, would further enhance the framework's robustness.

Second, the inclusion of a wider set of stakeholders is essential. While this study focused on healthcare professionals and industry experts, future research should incorporate the views of patients, payors, regulators and procurement authorities. These participants play critical roles in shaping how value is defined and prioritised. Their perspectives would offer a more complete understanding of how value is co-created and negotiated across the healthcare ecosystem.

Third, research should explore the framework's relevance across a wider range of medical technologies. While this study focused on complex, service-intensive systems such as CT and MRI scanners, other technologies, such as implantables, point-of-care diagnostics, wearables, and consumables, may require different value considerations. Testing the framework across these categories would clarify which value criteria are context-specific and which remain consistent.

Fourth, future work should investigate the dynamic relationships between value criteria. Elements such as sustainability, interoperability, education, and cost-effectiveness are often interdependent in practice. Exploring how these criteria interact, whether reinforcing or

constraining one another, would support more detailed evaluations and assist medtech developers and healthcare providers in navigating trade-offs during solution design.

Fifth, while this study relied on qualitative methods to generate deep, context-rich insights, mixed-methods research could provide broader validation. Combining interviews with surveys or other quantitative tools would allow researchers to examine the relative importance and prevalence of value drivers across different settings. Longitudinal studies could also track how value perceptions evolve throughout the lifecycle of technology, from procurement and implementation to sustained use and reassessment.

Finally, future research should continue to strengthen analytical rigour in qualitative studies. Reflexive thematic analysis was well suited to this study's aims, but further detail on the coding process, participatory validation methods, such as workshops with stakeholders could enhance credibility.

Addressing these areas will further refine the framework and ensure it is both theoretically grounded and practically relevant for guiding value-based innovation and decision-making in medtech.

8. References

AdvaMed & Deloitte. (2017). *A Framework for Comprehensive Assessment of Medical Technologies : Defining Value in the New Health Care Ecosystem* (Issue May).

AdvaMed & Deloitte. (2023). *A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem* (Issue January). https://www.advamed.org/wp-content/uploads/2023/06/framework-for-comprehensive-assessment-of-medical-technologies-report-long.pdf

Akinola, S., & Telukdarie, A. (2023). Sustainable Digital Transformation in Healthcare : Advancing a Digital Vascular Health Innovation Solution. *Sustainability*, *15*(10417), 1–23. https://doi.org/https://doi.org/10.3390/su151310417

Allen, D., Gillen, E., & Rixson, L. (2009). The Effectiveness of Integrated Care Pathways for Adults and Children in Health Care Settings: A Systematic Review. *JBI Library of Systematic Reviews*, *7*(3), 80–129. https://doi.org/10.11124/jbisrir-2009-182

Ambroise, L., Prim-Allaz, I., & Teyssier, C. (2018). Financial performance of servitized manufacturing firms: A configuration issue between servitization strategies and customer-oriented organizational design. *Industrial Marketing Management*, *71*, 54–68. https://doi.org/10.1016/j.indmarman.2017.11.007

Anderson, J. C., & Narus, J. A. (1998). Business marketing: understand what customers value. *Harvard Business Review*, *76*(6), 53–55, 58–5565.

Angelis, A., Lange, A., & Kanavos, P. (2018). Using health technology assessment to assess the value of new medicines: results of a systematic review and expert consultation across eight European countries. *European Journal of Health Economics*, *19*(1), 123–152. https://doi.org/10.1007/s10198-017-0871-0

Angelis, A., Linch, M., Montibeller, G., Molina-Lopez, T., Zawada, A., Orzel, K., Arickx, F., Espin, J., & Kanavos, P. (2020). Multiple Criteria Decision Analysis for HTA across four EU Member States: Piloting the Advance Value Framework. *Social Science and Medicine*, *246*(October 2019), 112595. https://doi.org/10.1016/j.socscimed.2019.112595

Assasi, N., Schwartz, L., Tarride, J. E., Campbell, K., & Goeree, R. (2014). Methodological guidance documents for evaluation of ethical considerations in health technology assessment: A systematic review. *Expert Review of Pharmacoeconomics and Outcomes Research*, *14*(2), 203–220. https://doi.org/10.1586/14737167.2014.894464

Assasi, N., Tarride, J. E., O'Reilly, D., & Schwartz, L. (2016). Steps toward improving ethical evaluation in health technology assessment: A proposed framework. *BMC Medical Ethics*, *17*(34), 1–16. https://doi.org/10.1186/s12910-016-0118-0

Avşar, T. S., Elvidge, J., Hawksworth, C., Kenny, J., Németh, B., Callenbach, M., Ringkvist, J., & Dawoud, D. (2024). Linking Reimbursement to Patient Benefits for Advanced Therapy Medicinal Products and Other High-Cost Innovations: Policy Recommendations for Outcomes-Based Agreements in Europe. *Value in Health*. https://doi.org/10.1016/j.jval.2024.07.007

Badakhshan, P., Conboy, K., Grisold, T., & vom Brocke, J. (2020). Agile business process management: A systematic literature review and an integrated framework. *Business Process Management Journal*, *26*(6), 1505–1523. https://doi.org/10.1108/BPMJ-12-2018-0347

Bain & Company. (2018). *Reaching Full Potential in Medtech Services*. https://www.bain.com/contentassets/85dc02110db642dd94b28e9ba65d836d/bain_brief_reaching_full_potential_in_medtech_services.pdf

Baines, T., & Bigdeli, A. Z. (2017). Servitization: revisiting the state-of-the-art and research priorities. *International Journal of Operations & Production Management*, *37*(2), 256–278. https://doi.org/http://dx.doi.org/10.1108/IJOPM-06-2015-0312

Baines, T., Bigdeli, A. Z., & Kapoor, K. (2024). *Servitization Strategy. Delivering Customer-Centric Outcomes Through Business Model Innovation*. Palgrave Macmillan. https://doi.org/https://doi.org/10.1007/978-3-031-45426-4

Baines, T., Lightfoot, H. W., Benedettini, O., & Kay, J. M. (2009). The servitization of manufacturing : A review of literature and reflection on future challenges. *Journal of Manufacturing Technology*, *20*(5), 547–567. https://doi.org/10.1108/MBE-09-2016-0047

Bandeiras, C. (2020). Advancing Technology for a Healthier Humanity. *IEEE Potentials*, *39*(2), 6–8. https://doi.org/10.1109/MPOT.2019.2959850

Banta, D. (2003). The development of health technology assessment. *Health Policy*, *63*(2), 121–132. https://doi.org/10.1016/S0168-8510(02)00059-3

Battista, R. N. (2006). Expanding the scientific basis of health technology assessment: A research agenda for the next decade. *International Journal of Technology Assessment in Health Care*, *22*(3), 275–280. https://doi.org/10.1017/S0266462306051130

Behl, R., & Rajagopal. (2023). *Paradigm Shift in Business - Critical Appraisal of Agile*

Management Practices (2023rd ed.). Palgrave Macmillan. https://doi.org/https://doi.org/10.1007/978-3-031-40439-9

Benedettini, O. (2022). Green Servitization in the Single-Use Medical Device Industry: How Device OEMs Create Supply Chain Circularity through Reprocessing. *Sustainability (Switzerland)*, *14*(19). https://doi.org/10.3390/su141912670

Benedettini, O., Neely, A., & Swink, M. (2015). Why do servitized firms fail? A risk-based explanation. *International Journal of Operations and Production Management*, *35*(6), 946–979. https://doi.org/10.1108/IJOPM-02-2014-0052

Bernardo Junior, R., & Padua, S. I. D. (2023). Toward agile Business Process Management: Description of concepts and a proposed definition. *Knowledge and Process Management*, *30*(1), 14–32. https://doi.org/10.1002/kpm.1737

Birt, L., Scott, S., Cavers, D., Campbell, C., & Walter, F. (2016). Member Checking: A Tool to Enhance Trustworthiness or Merely a Nod to Validation? *Qualitative Health Research*, *26*(13), 1802–1811. https://doi.org/10.1177/1049732316654870

Bobini, M., & Cicchetti, A. (2024). Integrating environmental sustainability into health technology assessment: An international survey of HTA stakeholders. *International Journal of Technology Assessment in Health Care*, *40*(1). https://doi.org/10.1017/S0266462324000631

Bosco, F., Di Gerio, C., Fiorani, G., & Stola, G. (2024). How to manage sustainability in healthcare organizations? A processing map to include the ESG strategy. *Journal of Public Budgeting, Accounting and Financial Management*, 636–659. https://doi.org/10.1108/JPBAFM-04-2023-0065

Boyatzis, R. E. (1998). *Transforming qualitative information: thematic analysis and code development*. Thousand Oaks, CA: Sage Publications.

Brady, A. P., Bello, J. A., Derchi, L. E., Fuchsjäger, M., Goergen, S., Krestin, G. P., Lee, E. J. Y., Levin, D. C., Pressacco, J., Rao, V. M., Slavotinek, J., Visser, J. J., Walker, R. E. A., & Brink, J. A. (2020). Radiology in the era of value - based healthcare : a multi - society expert statement from the ACR, CAR, ESR, IS3R, RANZCR, and RSNA. *Insights Imaging*, *11*(136), 1–8. https://doi.org/10.1186/s13244-020-00941-z

Brady, T., Davies, A., & Gann, D. M. (2005). Creating value by delivering integrated solutions. *International Journal of Project Management*, *23*(5), 360–365. https://doi.org/10.1016/j.ijproman.2005.01.001

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Braun, V., & Clarke, V. (2013). *Successful qualitative research: a practical guide for beginners*. Sage Publications.

Braun, V., & Clarke, V. (2023). Toward good practice in thematic analysis: Avoiding common problems and be(com)ing a knowing researcher. *International Journal of Transgender Health*, *24*(1), 1–6. https://doi.org/10.1080/26895269.2022.2129597

Braun, V., Clarke, V., Hayfield, N., & Terry, G. (2019). Thematic Analysis. In P. Liamputtong (Ed.), *Handbook of Research Methods in Health Social Sciences* (pp. 843–860). Springer Nature Singapore Pte Ltd.

Brax, S. (2005). A manufacturer becoming service provider – challenges and a paradox. *Managing Service Quality: An International Journal*, *15*(2), 142–155. https://doi.org/10.1108/09604520510585334

Bryman, A., & Bell, E. (2015). *Business Research Methods* (Fourth). Oxford University Press.

Buck, C., Floegel, N. O., Stöter, M. B., Desouza, K. C., & Robb, T. (2025). The performance effects of innovative service transition strategies. *Journal of Innovation and Knowledge*, *10*(2). https://doi.org/10.1016/j.jik.2025.100687

Cantù, C., Corsaro, D., & Snehota, I. (2012). Roles of actors in combining resources into complex solutions. *Journal of Business Research*, *65*(2), 139–150. https://doi.org/10.1016/j.jbusres.2011.05.014

Chahal, H., & Kumari, N. (2012). Consumer perceived value. *International Journal of Pharmaceutical and Healthcare Marketing*, *6*(2), 167–190. https://doi.org/http://dx.doi.org/10.1108/17506121211243086

Chen, Y., Lehmann, C. U., & Malin, B. (2024). Digital Information Ecosystems in Modern Care Coordination and Patient Care Pathways and the Challenges and Opportunities for AI Solutions. *Journal of Medical Internet Research*, *26*(1), 1–15. https://doi.org/10.2196/60258

Ciani, O., Wilcher, B., Blankart, C. R., Hatz, M., Rupel, V. P., Erker, R. S., Varabyova, Y., & Taylor, R. S. (2015). Health Technology Assessment of Medical Devices: a Survey of Non-European Union Agencies. *International Journal of Technology Assessment in Health Care*, *31*(3), 154–165. https://doi.org/10.1017/S0266462315000185

Ciani, O., Wilcher, B., van Giessen, A., & Taylor, R. S. (2017). Linking the Regulatory and

Reimbursement Processes for Medical Devices: The Need for Integrated Assessments. *Health Economics (United Kingdom)*, *26*, 13–29. https://doi.org/10.1002/hec.3479

Cicchetti, A., Iacopino, V., Coretti, S., Fiore, A., Marchetti, M., Sampietro-Colom, L., Kidholm, K., Wasserfallen, J. B., Kahveci, R., Halmesmäki, E., Rosenmöller, M., Wild, C., & Kivet, R. A. (2018). Toward A Contingency Model for Hospital-Based Health Technology Assessment: Evidence from AdHopHTA Project. *International Journal of Technology Assessment in Health Care*, *34*(2), 205–211. https://doi.org/10.1017/S0266462318000119

Cohen, J. (1960). A coefficient of agreement for nominal scales. *Educational and Psychological Measurement, 20*, 37–46. https://doi.org/10.1177/001316446002000104

Cohen, J. T., Anderson, J. E., & Neumann, P. J. (2017). Three Sets of Case Studies Suggest Logic and Consistency Challenges with Value Frameworks. *Value in Health*, *20*(2), 193–199. https://doi.org/10.1016/j.jval.2016.11.012

Combi, C., Oliboni, B., Zardini, A., & Zerbato, F. (2017). A Methodological Framework for the Integrated Design of Decision-Intensive Care Pathways—an Application to the Management of COPD Patients. *Journal of Healthcare Informatics Research*, *1*(2), 157–217. https://doi.org/10.1007/s41666-017-0007-4

Cooper, R. A., & Aiken, L. H. (2001). Human inputs: the health care workforce and medical markets. *Journal of Health Politics, Policy & Law*, *26*(5), 925–938. https://doi.org/10.1215/03616878-26-5-925

Corrêa, H. L. (2018). Servitization meets sustainability. *Future Studies Research Journal*, *10*(2), 358–364. https://doi.org/https://doi.org/10.24023/FutureJournal/2175-5825/2018.v10i2.370

Counte, M. A., Howard, S. W., Chang, L., & Aaronson, W. (2019). Global advances in Value-Based Payment and their implications for global health management education, development, and practice. *Frontiers in Public Health*, *6*(379), 1–7. https://doi.org/10.3389/fpubh.2018.00379

Cova, B., & Salle, R. (2008). Marketing solutions in accordance with the S-D logic: Co-creating value with customer network actors. *Industrial Marketing Management*, *37*(3), 270–277. https://doi.org/10.1016/j.indmarman.2007.07.005

Craig, P., Dieppe, P., Macintyre, S., Mitchie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: The new Medical Research Council guidance. *BMJ*,

337:a1655, 979–983. https://doi.org/10.1136/bmj.a1655

Cresswell, K., Sheikh, A., Franklin, B. D., Krasuska, M., Nguyen, H. T., Hinder, S., Lane, W., Mozaffar, H., Mason, K., Eason, S., Potts, H., & Williams, R. (2021). Interorganizational knowledge sharing to establish digital health learning ecosystems: Qualitative evaluation of a national digital health transformation program in England. *Journal of Medical Internet Research*, *23*(8). https://doi.org/10.2196/23372

Cunliffe, A. L. (2011). Crafting Qualitative Research: Morgan and Smircich 30 Years On. *Organizational Research Methods*, *14*(4), 647–673. https://doi.org/10.1177/1094428110373658

Davies, A. (2004). Moving base into high-value integrated solutions: A value stream approach. *Industrial and Corporate Change*, *13*(5), 727–756. https://doi.org/10.1093/icc/dth029

Davies, A., Brady, T., & Hobday, M. (2006). Charting a path toward integrated solutions. *Mit Sloan Management Review*, *47*(3), 39–48. https://doi.org/10.1225/SMR202

Davies, A., Brady, T., & Hobday, M. (2007). Organizing for solutions: Systems seller vs. systems integrator. *Industrial Marketing Management*, *36*(2), 183–193. https://doi.org/10.1016/j.indmarman.2006.04.009

De Folter, J., Trusheim, M., Jonsson, P., & Garner, S. (2018). Decision-Components of NICE's Technology Appraisals Assessment Framework. *International Journal of Technology Assessment in Health Care*, *34*(2), 163–171. https://doi.org/10.1017/S0266462318000090

Del Sarto, S., Gnaldi, M., & Salvini, N. (2024). Sustainability and high-level corruption in healthcare procurement: Profiles of Italian contracting authorities. *Socio-Economic Planning Sciences*, *95*(December 2023), 101988. https://doi.org/10.1016/j.seps.2024.101988

Deloitte. (2024). *2024 Global Health Care Sector Outlook - Navigating Transformation*.

Denzin, N. K. (2012). Triangulation 2.0. *Journal of Mixed Methods Research*, *6*(2011), 80–88. https://doi.org/10.1177/1558689812437186

Dewey, J. (1929). *The Quest for Certainty; a Study of the Relation of Knowledge and Action* (2nd ed.). MINTON, BALCH & COMPANY.

Doctor, E., Eymann, T., Fürstenau, D., Gersch, M., Hall, K., Kauffmann, A. L., Schulte-Althoff, M., Schlieter, H., Stark, J., & Wyrtki, K. (2023). A Maturity Model for Assessing the Digitalization of Public Health Agencies: Development and Evaluation. *Business and*

Information Systems Engineering, *65*(5), 539–554. https://doi.org/10.1007/s12599-023-00813-y

Doshi, J. A., & Willke, R. J. (2017). Advancing High-Quality Value Assessments of Health Care Interventions. *Value in Health*, *20*(2), 181–184. https://doi.org/10.1016/j.jval.2016.12.012

Dubois, R. W., Westrich, K., & Ma, K. W. (2019). As Value Assessment Frameworks Evolve, Are They Finally Ready for Prime Time? *Value in Health*, *22*(9), 977–980. https://doi.org/10.1016/j.jval.2019.06.002

Edvardsson, B., & Tronvoll, B. (2022). The Palgrave Handbook of Service Management. In *The Palgrave Handbook of Service Management*. Palgrave Macmillan. https://doi.org/10.1007/978-3-030-91828-6

Eggert, A., & Ulaga, W. (2002). Customer perceived value: a substitute for satisfaction in business markets? *Journal of Business & Industrial Marketing*, *17*(2/3), 107–118. https://doi.org/10.1108/08858620210419754

Eisenhardt, K. M. (1989). Building Theories from Case Study Research. *The Academy of Management Review*, *14*(4), 532–550. https://doi.org/https://doi.org/10.2307/258557

Erdös, J., Ettinger, S., Mayer-Ferbas, J., de Villiers, C., & Wild, C. (2019). European Collaboration in Health Technology Assessment (HTA): goals, methods and outcomes with specific focus on medical devices. *Wiener Medizinische Wochenschrift*, *169*(11–12), 284–292. https://doi.org/10.1007/s10354-019-0684-0

Ettinger, W. H. (1998). Consumer-Perceived Value:The Key to a Successful Business Strategy in the Healthcare Marketplace. *J Am Geriatr Soc.*, *46*(1), 111–113. https://doi.org/doi: 10.1111/j.1532-5415.1998.tb01024.x

EUnetHTA Joint Action. (2016). HTA Core Model Handbook. In *EUnetHTA Joint Action 2, Work Package 8. HTA Core Model ® version 3.0* (Vol. 2). https://www.eunethta.eu/wp-content/uploads/2018/03/HTACoreModel3.0-1.pdf

EY. (2023). *Pulse of the Industry : medical technology report 2023 - Accelerating medtech's digital opportunity*.

Fendt, J., Kaminska-Labbé, R., & Sachs, W. M. (2008). Producing and socializing relevant management knowledge : re-turn to pragmatism. *European Business Review*, *20*(6), 471–491. https://doi.org/10.1108/09555340810913502

Ferraresi, M., Gucciardi, G., & Rizzo, L. (2021). Savings from public procurement centralization

in the healthcare system. *European Journal of Political Economy*, *66*(October 2020), 101963. https://doi.org/10.1016/j.ejpoleco.2020.101963

Ferreira, F. N. H., Proença, J. F., Spencer, R., & Cova, B. (2013). The transition from products to solutions: External business model fit and dynamics. *Industrial Marketing Management*, *42*(7), 1093–1101. https://doi.org/10.1016/j.indmarman.2013.07.010

Foote, N. W., Galbraith, J., Hope, Q., & Miller, D. (2001). Making solutions the answer. *McKinsey Quarterly*, *3*, 84–93.

Fuchs, S., Olberg, B., Panteli, D., & Busse, R. (2016). Health Technology Assessment of Medical Devices in Europe: Processes, Practices, and Methods. *International Journal of Technology Assessment in Health Care*, *32*(4), 246–255. https://doi.org/10.1017/S0266462316000349

Fuchs, S., Olberg, B., Panteli, D., Perleth, M., & Busse, R. (2017). HTA of medical devices: Challenges and ideas for the future from a European perspective. *Health Policy*, *121*(3), 215–229. https://doi.org/10.1016/j.healthpol.2016.08.010

Funk, J., Jackson, S., Pain, L., & Consulting, L. E. K. (2017). Solving the Services Puzzle : Key Success Factors for Medtechs. In *Executive Insights - L.E.K Consulting: Vol. XVIII* (Issue 33).

Gallix, B., & Chong, J. (2019). Artificial intelligence in radiology: who's afraid of the big bad wolf? *European Radiology*, *29*(4), 1637–1639. https://doi.org/10.1007/s00330-018-5995-9

García-Altés, A., Mckee, M., Siciliani, L., Barros, P. P., Lehtonen, L., Rogers, H., Kringos, D., Zaletel, J., & Maeseneer, J. De. (2023). Understanding public procurement within the health sector : a priority in a post-COVID-19 world. *Health Economics, Policy and Law*, *18*, 172–185. https://doi.org/10.1017/S1744133122000184

Garrison, L. P., Kamal-Bahl, S., & Towse, A. (2017). Toward a Broader Concept of Value: Identifying and Defining Elements for an Expanded Cost-Effectiveness Analysis. *Value in Health*, *20*(2), 213–216. https://doi.org/10.1016/j.jval.2016.12.005

Garrison, L. P., Mestre-Ferrandiz, J., & Zamora, B. (2016). The Value of Knowing and Knowing the Value: Improving the Health Technology Assessment of Complementary Diagnostics. In *OHE White Paper* (Issue July).

Garrison, L. P., Neumann, P. J., Willke, R. J., Basu, A., Danzon, P. M., Doshi, J. A., Drummond, M. F., Lakdawalla, D. N., Pauly, M. V., Phelps, C. E., Ramsey, S. D., Towse, A., & Weinstein, M. C. (2018). A Health Economics Approach to US Value Assessment Frameworks—

Summary and Recommendations of the ISPOR Special Task Force Report [7]. *Value in Health*, *21*(2), 161–165. https://doi.org/10.1016/j.jval.2017.12.009

Gebauer, H. (2008). Identifying service strategies in product manufacturing companies by exploring environment-strategy configurations. *Industrial Marketing Management*, *37*(3), 278–291. https://doi.org/10.1016/j.indmarman.2007.05.018

Gebauer, H., Bravo-Sanchez, C., & Fleisch, E. (2008). Service strategies in product manufacturing companies. *Business Strategy Series*, *9*(1), 12–20. https://doi.org/10.1108/17515630810850073

Gebauer, H., Fleisch, E., & Friedli, T. (2005). Overcoming the Service Paradox in Manufacturing Companies. *European Management Journal*, *23*(1), 14–26. https://doi.org/10.1016/j.emj.2004.12.006

Gebauer, H., & Friedli, T. (2005). Behavioral Implications of the Transition Process from Products to Services. *Journal of Business & Industrial Marketing*, *20*(2), 70–78. https://doi.org/10.1108/08858620510583669

Gebauer, H., Friedli, T., & Fleisch, E. (2006). Success factors for achieving high service revenues in manufacturing companies. *Benchmarking: An International Journal*, *13*(3), 374–386. https://doi.org/10.1108/14635770610668848

Gebauer, H., Pütz, F., Fischer, T., & Fleisch, E. (2009). Service orientation of organizational structures. *Journal of Relationship Marketing*, *8*(2), 103–126. https://doi.org/10.1080/15332660902876687

Gerecke, G., Clawson, J., Pross, C., Verboven, Y., & Bax, H. (2020). How Procurement unlocks Value-Based Health Care. *Boston Consulting Group*, *January*.

Gerecke, G., Clawson, J., & Verboben, Y. (2015). Procurement: The Unexpected Driver of Value-Based Health Care. *BCG Report*.

Gerhardus, A. (2016). Integrated health technology assessment for evaluating complex technologies (INTEGRATE-HTA): An introduction to the guidances. In *INTEGRATE-HTA*.

Gerhardus, A., Oortwijn, W., & Van Der Wilt, G. J. (2017). How to avoid giving the right answers to the wrong questions: The need for integrated assessments of complex health technologies. *International Journal of Technology Assessment in Health Care*, *33*(5), 541–543. https://doi.org/10.1017/S0266462317001040

Giddens, A. (1984). *The Constitution of Society*. Polity Press.

Gioia, D. A., Corley, K. G., & Hamilton, A. L. (2013). Seeking Qualitative Rigor in Inductive

Research: Notes on the Gioia Methodology. *Organizational Research Methods*, *16*(1), 15–31. https://doi.org/10.1177/1094428112452151

Goldkuhl, G. (2012). Pragmatism vs interpretivism in qualitative information systems research. *European Journal of Information Systems*, *21*, 135–146. https://doi.org/10.1057/ejis.2011.54

Goles, T., & Hirschheim, R. (2000). The paradigm is dead, the paradigm is dead ... long live the paradigm: the legacy of Burrell and Morgan. *Omega*, *28*(3), 249–268. https://doi.org/https://doi.org/10.1016/S0305-0483(99)00042-0

Green, M. H., Davies, P., & Ng, I. C. L. (2017). Two strands of servitization: A thematic analysis of traditional and customer co-created servitization and future research directions. *International Journal of Production Economics*, *192*, 40–53. https://doi.org/10.1016/j.ijpe.2017.01.009

Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., A'Court, C., Hinder, S., Fahy, N., Procter, R., & Shaw, S. (2017). Beyond adoption: A new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies. *Journal of Medical Internet Research*, *19*(11). https://doi.org/10.2196/jmir.8775

Grönroos, C. (2012). Conceptualising value co-creation: A journey to the 1970s and back to the future. *Journal of Marketing Management*, *28*(13–14), 1520–1534. https://doi.org/10.1080/0267257X.2012.737357

Grossmann, I., & Marang-Van De Mheen, P. J. (2025). Using data science to improve patient care: Rethinking clinician responsibility. *BMJ Quality and Safety*, 288–290. https://doi.org/10.1136/bmjqs-2025-018514

Guerra-Júnior, A. A., Pires De Lemos, L. L., Godman, B., Bennie, M., Osorio-De-Castro, C. G. S., Alvares, J., Heaney, A., Vassallo, C. A., Wettermark, B., Benguria-Arrate, G., Gutierrez-Ibarluzea, I., Santos, V. C. C., Petramale, C. A., & Acurcio, F. D. A. (2017). Health technology performance assessment: Real-world evidence for public healthcare sustainability. *International Journal of Technology Assessment in Health Care*, *33*(2), 279–287. https://doi.org/10.1017/S0266462317000423

Halmesmäki, E., Pasternack, I., & Roine, R. (2016). Hospital-based health technology assessment (HTA) in Finland: A case study on collaboration between hospitals and the national HTA unit. *Health Research Policy and Systems*, *14*(1), 1–9.

https://doi.org/10.1186/s12961-016-0095-2

Hatz, M. H. M., Schreyögg, J., Torbica, A., Boriani, G., & Blankart, C. R. B. (2017). Adoption Decisions for Medical Devices in the Field of Cardiology: Results from a European Survey. *Health Economics (United Kingdom)*, *26*, 124–144. https://doi.org/10.1002/hec.3472

Heirati, N., Thornton, S. C., Leischnig, A., & Henneberg, S. C. (2024). Capability configurations for successful advanced servitization. *International Journal of Operations and Production Management*, *45*(2), 329–354. https://doi.org/10.1108/IJOPM-03-2023-0226

Helkkula, A., Pihlström, M. H., & Kelleher, C. (2009). From Customer Perceived Value (PERVAL) to Value-in-Context Experience (VALCONEX). In E. Gummesson, C. Mele, & F. Polese (Eds.), *The 2009 Naples Forum on Service. Service-Dominant logic, service science and network theory, Capri, Italy, 16-19 June, 2009* (pp. 1–19). https://doi.org/10.1017/CBO9781107415324.004

Hensher, M. (2024). Health technology assessment and healthcare environmental sustainability: Prioritizing effort and maximizing impact. *International Journal of Technology Assessment in Health Care*, *40*(1). https://doi.org/10.1017/S0266462324000230

Hinrichs-Krapels, S., Diehl, J. C., Hunfeld, N., & van Raaij, E. (2022). Towards sustainability for medical devices and consumables: The radical and incremental challenges in the technology ecosystem. *Journal of Health Services Research and Policy*, *27*(4), 253–254. https://doi.org/10.1177/13558196221110416

Hofmann, B. M. (2008). Why ethics should be part of health technology assessment. *International Journal of Technology Assessment in Health Care*, *24*(4), 423–429. https://doi.org/10.1017/S0266462308080550

Hofmann, B. M., Oortwijn, W., Lysdahl, K. B., Refolo, P., Sacchini, D., Van Der Wilt, G. J., & Gerhardus, A. (2015). Integrating Ethics in Health Technology Assessment: Many Ways To Rome. *International Journal of Technology Assessment in Health Care*, *31*(3), 131–137. https://doi.org/10.1017/S0266462315000276

Huang, W., Yang, J., & Wei, Z. (2022). How Does Servitization Affect Firm Performance? *IEEE Transactions on Engineering Management*, *69*(6), 2871–2881. https://doi.org/10.1109/TEM.2020.3020852

ICER. (2020). 2020-2023 Value Assessment Framework. In *Institute for Clinical and Economic Review*. https://icer.org/wp-

content/uploads/2020/10/ICER_2020_2023_VAF_102220.pdf

ICER. (2023). Value Assessment Framework. In *Institute for Clinical and Economic Review*. https://icer.org/wp-content/uploads/2023/10/ICER_2023_VAF_For-Publication_101723.pdf

James, W. (1907). *Pragmatism, A New Name for Some Old Ways of Thinking*. Longmans, Green, and Company.

Jat, A. S., Grønli, T.-M., & Ghinea, G. (2024). Technological Utilization in Remote Healthcare: Factors Influencing Healthcare Professionals' Adoption and Use. *Journal of Health Informatics in Developing Countries*, *18*(1), 1–22. https://arxiv.org/abs/2403.11153

Jha, S. R. (1997). A New Interpretation of Michael Polanyi's Theory of Tacit Knowing: Integrative Philosophy with "Intellectual Passions." *Studies in History and Philosophy of Science*, *28*(4), 611–631. https://doi.org/0039-3681/97

Johl, S. K., Ali, K., Shirahada, K., & Oyewale, O. I. (2024). Green servitization , circular economy , and sustainability a winning combination analysis through hybrid SEM-ANN approach. *Business Strategy and the Environment*, *September 2023*, 1–16. https://doi.org/10.1002/bse.3950

Johnstone, S., Dainty, A., & Wilkinson, A. (2009). Integrating products and services through life: An aerospace experience. *International Journal of Operations and Production Management*, *29*(5), 520–538. https://doi.org/10.1108/01443570910953612

Jungmann, F., Jorg, T., Hahn, F., Pinto dos Santos, D., Jungmann, S. M., Düber, C., Mildenberger, P., & Kloeckner, R. (2021). Attitudes Toward Artificial Intelligence Among Radiologists, IT Specialists, and Industry. *Academic Radiology*, *28*(6), 834–840. https://doi.org/10.1016/j.acra.2020.04.011

Kalinowska-Beszczyńska, O., & Prędkiewicz, K. (2024). MedTech start-ups: A comprehensive scoping review of current research trends and future directions. *PLoS ONE*, *19*(8), 1–24. https://doi.org/10.1371/journal.pone.0307959

Karababa, E., & Kjeldgaard, D. (2014). Value in marketing : Toward sociocultural perspectives. *Marketing Theory*, *14*(1), 119–127. https://doi.org/10.1177/1470593113500385

Kasoju, N., Remya, N. S., Sasi, R., Sujesh, S., Soman, B., Kesavadas, C., Muraleedharan, C. V., Varma, P. R. H., & Behari, S. (2023). Digital health: trends, opportunities and challenges in medical devices, pharma and bio-technology. *CSI Transactions on ICT*, *11*(1), 11–30. https://doi.org/10.1007/s40012-023-00380-3

Kastanioti, C., Kontodimopoulos, N., Stasinopoulos, D., Kapetaneas, N., & Polyzos, N. (2013). Public procurement of health technologies in Greece in an era of economic crisis. *Health Policy*, *109*(1), 7–13. https://doi.org/10.1016/j.healthpol.2012.03.015

Kinnunen, R.-E., & Turunen, T. (2012). Identifying Servitization Capabilities of Manufacturers: A Conceptual Model. *The Journal of Applied Management and Entrepreneurship*, *17*(3), 55–78.

Kohtamäki, M., Baines, T., Rabetino, R., & Bigdeli, A. Z. (2018). Practices and Tools for Servitization. In M. Kohtamäki, T. Baines, R. Rabetino, & A. Z. Bigdeli (Eds.), *Practices and Tools for Servitization - Managing Service Transition* (p. 434). Palgrave Macmillan. https://doi.org/10.1007/978-3-319-76517-4

Kohtamäki, M., & Helo, P. (2015). Industrial services – the solution provider's stairway to heaven or highway to hell? *Benchmarking: An International Journal*, *22*(2), 170–185. https://doi.org/http://dx.doi.org/10.1108/MRR-09-2015-0216

Kohtamäki, M., Rabetino, R., Parida, V., Sjödin, D., & Henneberg, S. (2022). Managing digital servitization toward smart solutions: Framing the connections between technologies, business models, and ecosystems. *Industrial Marketing Management*, *105*, 253–267. https://doi.org/10.1016/j.indmarman.2022.06.010

Kolagar, M., Reim, W., Parida, V., & Sjödin, D. (2022). Digital servitization strategies for SME internationalization: the interplay between digital service maturity and ecosystem involvement. *Journal of Service Management*, *33*(1), 143–162. https://doi.org/10.1108/JOSM-11-2020-0428

Kotler, P. (2000). *Marketing management: The millennium edition*. Prentice Hall International Inc.

KPMG. (2024). *MedTech at the crossroads: Challenges and opportunities*.

Kühler, T. C., Schoenmakers, M., Shergold, O., Affolter, S., Bolislis, W. R., Foster, R., Gardner, P., Hruschka, S., Jomini, T., Kaveripakam, S., Mayerhofer, K., Scherini, T., Swierczynska, M., Vandal, G., & Fürst-Ladani, S. (2022). Development and Regulation of Connected Combined Products: Reflections From the Medtech & Pharma Platform Association. *Clinical Therapeutics*, *44*(5), 768–782. https://doi.org/10.1016/j.clinthera.2022.03.009

Laukka, E., Tuunanen, T., Jansson, M., Vanhanen, M., Hirvonen, N., Palukka, J., Vesinurm, M., & Torkki, P. (2024). Value Co-creation and Co-destruction in Digital Health Services: Protocol for a Systematic Review. *JMIR Res Protoc 2025*, *14:e63015*, 1–8.

https://doi.org/10.2196/63015

Lee, K. S., Yordanov, S., Stubbs, D., Edlmann, E., Joannides, A., & Davies, B. (2021). Integrated care pathways in neurosurgery: A systematic review. *PLoS ONE*, *16*(8). https://doi.org/10.1371/journal.pone.0255628

Lee, L. W., Chiu, Y. H., Liu, F. P., Lin, T. Y., & Chang, T. H. (2024). Valuating the efficiency of social security and healthcare in OECD countries from a sustainable development. *Cost Effectiveness and Resource Allocation*, *22*(1), 1–18. https://doi.org/10.1186/s12962-024-00555-y

Lee, S., Yoo, S., & Kim, D. (2016). When is servitization a profitable competitive strategy? *International Journal of Production Economics*, *173*(2016), 43–53. https://doi.org/10.1016/j.ijpe.2015.12.003

Lee, T. (2010). Putting the Value Framework to Work. *The New England Journal of Medicine*, *363*(26), 2481–2483. https://doi.org/10.1056/NEJMp1013111

Lehane, E., Leahy-Warren, P., O'Riordan, C., Savage, E., Drennan, J., O'Tuathaigh, C., O'Connor, M., Corrigan, M., Burke, F., Hayes, M., Lynch, H., Sahm, L., Heffernan, E., O'Keeffe, E., Blake, C., Horgan, F., & Hegarty, J. (2019). Evidence-based practice education for healthcare professions: An expert view. *BMJ Evidence-Based Medicine*, *24*(3), 103–108. https://doi.org/10.1136/bmjebm-2018-111019

Lehoux, P., & Williams-Jones, B. (2007). Mapping the integration of social and ethical issues in health technology assessment. *International Journal of Technology Assessment in Health Care*, *23*(1), 9–16. https://doi.org/10.1017/S0266462307051513

Levander, X. A., VanDerSchaaf, H., Barragán, V. G., Choxi, H., Hoffman, A., Morgan, E., Wong, E., Wusirika, R., & Cheng, A. (2024). The Role of Human-Centered Design in Healthcare Innovation: a Digital Health Equity Case Study. *Journal of General Internal Medicine*, *39*(4), 690–695. https://doi.org/10.1007/s11606-023-08500-0

Li, S., Peng, G., Xing, F., Zhang, J., & Zhang, B. (2021). Value co-creation in industrial AI: The interactive role of B2B supplier, customer and technology provider. *Industrial Marketing Management*, *98*(132), 105–114. https://doi.org/10.1016/j.indmarman.2021.07.015

Lin, C.-H., Sher, P. J., & Shih, H.-Y. (2005). Past progress and future directions in conceptualizing customer perceived value. *International Journal of Service Industry Management*, *16*(4), 318–336. https://doi.org/10.1108/09564230510613988

Linde, L., Frishammar, J., & Parida, V. (2023). Revenue Models for Digital Servitization: A Value

Capture Framework for Designing, Developing, and Scaling Digital Services. *IEEE Transactions on Engineering Management*, *70*(1), 82–97. https://doi.org/10.1109/TEM.2021.3053386

Lindgreen, A., & Wynstra, F. (2005). Value in business markets: What do we know? Where are we going? *Industrial Marketing Management*, *34*(7), 732–748. https://doi.org/10.1016/j.indmarman.2005.01.001

Lingg, M., Wyss, K., & Durán-Arenas, L. (2016). Effects of procurement practices on quality of medical device or service received: A qualitative study comparing countries. *BMC Health Services Research*, *16*(1), 1–13. https://doi.org/10.1186/s12913-016-1610-4

Löfberg, N., Åkesson, M., & Skålén, P. (2025). Realization and unrealization of servitization through everyday micro-level activities: The interplay between servitization practices, practitioners, and praxis. *Industrial Marketing Management*, *124*(November 2024), 195–211. https://doi.org/10.1016/j.indmarman.2024.11.013

Lysdahl, K. B., Mozygemba, K., Burns, J., Brönneke, J. B., Chilcott, J. B., Ward, S., & Hofmann, B. (2017). Comprehensive assessment of complex technologies: integrating various aspects in health technology assessment. *International Journal of Technology Assessment in Health Care*, *33*(5), 570–576. https://doi.org/10.1017/S0266462317000678

Lysdahl, K. B., Mozygemba, K., Burns, J., Chilcott, J. B., Brönneke, J. B., & Hofmann, B. (2016). *Guidance for assessing effectiveness, economic aspects, ethical aspects, socio-cultural aspects and legal aspects in complex technologies*. http://www.integrate-hta.eu/downloads/

Macdonald, E. K., Kleinaltenkamp, M., & Wilson, H. N. (2016). How Business Customers Judge Solutions: Solution Quality and Value in Use. *Journal of Marketing*, *80*(3), 96–120. https://doi.org/10.1509/jm.15.0109

Malleret, V. (2006). Value creation through service offers. *European Management Journal*, *24*(1), 106–116. https://doi.org/10.1016/j.emj.2005.12.012

Mandelblatt, J. S., Ramsey, S. D., Lieu, T. A., & Phelps, C. E. (2017). Evaluating Frameworks That Provide Value Measures for Health Care Interventions. *Value in Health*, *20*(2), 185–192. https://doi.org/10.1016/j.jval.2016.11.013

Manika, D., Gregory-Smith, D., Wells, V. K., Comerford, L., & Aldrich-Smith, L. (2016). Linking environmental sustainability and healthcare: The effects of an energy saving intervention in two hospitals. *International Journal of Business Science and Applied Management*,

11(1), 32–54.

Marsh, K., Thokala, P., Youngkong, S., & Chalkidou, K. (2018). Incorporating MCDA into HTA : challenges and potential solutions, with a focus on lower income settings. *Cost Effectiveness and Resource Allocation*, *16*(s1), 1–9. https://doi.org/10.1186/s12962-018-0125-8

Martelli, N., Devaux, C., Van Den Brink, H., Billaux, M., Pineau, J., Prognon, P., & Borget, I. (2017). Harmonizing Health Technology Assessment practices in university hospitals: To what extent is the mini-HTA model suitable in the French context? *International Journal of Technology Assessment in Health Care*, *33*(2), 307–314. https://doi.org/10.1017/S0266462317000393

Martelli, N., Hansen, P., van den Brink, H., Boudard, A., Cordonnier, A. L., Devaux, C., Pineau, J., Prognon, P., & Borget, I. (2016). Combining multi-criteria decision analysis and mini-health technology assessment: A funding decision-support tool for medical devices in a university hospital setting. *Journal of Biomedical Informatics*, *59*, 201–208. https://doi.org/10.1016/j.jbi.2015.12.002

Mathieu, V. (2001). Product services: From a service supporting the product to a service supporting the client. *Journal of Business & Industrial Marketing*, *16*(1), 39–61. https://doi.org/10.1108/08858620110364873

Mbwasi, R., Mbepera, D., Mfuko, W., Makanzo, J., Kikwale, M., Canavan, R., Stoermer, M., & Wiedenmayer, K. (2022). Assessing public – private procurement practices for medical commodities in Dar Es Salaam : a situation analysis. *BMC Health Services Research*, *22*(1523), 1–10. https://doi.org/10.1186/s12913-022-08923-1

McDonald, P. L., Foley, T. J., Verheij, R., Braithwaite, J., Rubin, J., Harwood, K., Phillips, J., Gilman, S., & Van Der Wees, P. J. (2024). Data to knowledge to improvement: creating the learning health system. *BMJ*, *384*(e076175). https://doi.org/10.1136/bmj-2023-076175

McKinsey & Company. (2019). Creating “beyond the product” partnerships between providers and medtech players. *McKinsey & Company*, *February*, 1–13. https://www.mckinsey.com/capabilities/operations/our-insights/creating-beyond-the-product-partnerships-between-providers-and-medtech-players

MedTech Europe, & BCG. (2015). *Procurement - The Unxpected Driver of Value-Based Health Care*. https://web-assets.bcg.com/img-src/BCG-Procurement-Dec-2015_tcm9-

62575.pdf

MedTech Europe, & BCG. (2017). *MEAT Value-Based Procurement - Guideline A: MEAT VBP Framework*.

Meehan, J., Menzies, L., & Michaelides, R. (2017). The long shadow of public policy; Barriers to a value-based approach in healthcare procurement. *Journal of Purchasing and Supply Management*, *23*(4), 229–241. https://doi.org/10.1016/j.pursup.2017.05.003

Miles, M. B. (1979). Qualitative Data as an Attractive Nuisance: The Problem of Analysis. *Administrative Science Quarterly*, *24*(4), 590–601.

Miles, M. B., Huberman, A. M., & Saldaäna, J. (2014). *Qualitative data analysis: A methods sourcebook* (3rd ed.). SAGE Publications, Inc.

Miller, K. L., & Woodcock, J. (2017). Value Assessment in the Regulatory Context. *Value in Health*, *20*(2), 296–298. https://doi.org/10.1016/j.jval.2016.11.010

Min, L., Wang, J., & Luo, Q. (2015). Does the Servitization Strategy Improve the Performance of Manufacturing Enterprises in China? *American Journal of Industrial and Business Management*, *05*(05), 281–287. https://doi.org/10.4236/ajibm.2015.55030

Montesinos, L., Checa Rifá, P., Rifá Fabregat, M., Maldonado-Romo, J., Capacci, S., Maccaro, A., & Piaggio, D. (2024). Sustainability across the Medical Device Lifecycle: A Scoping Review. *Sustainability*, *16*(1433), 1–25. https://doi.org/10.3390/su16041433

Morgan, D. L. (2007). Methodological Implications of Combining Qualitative and Quantitative Methods. *Journal of Mixed Methods Research*, *1*(1), 48–76. https://doi.org/10.1177/2345678906292462

Morgan, D. L. (2014). Pragmatism as a Paradigm for Social Research Qualitative Inquiry. *Qualitative Inquiry*, *20*(8), 1045–1053. https://doi.org/10.1177/1077800413513733

Morton, A., Bach, P. B., & Briggs, A. (2018). Enhancing the Value of the ASCO Value Framework. *MDM Policy and Practice*, *3*(1), 1–3. https://doi.org/10.1177/2381468318776223

Morton, A., & Cornwell, J. (2009). What's the difference between a hospital and a bottling factory? Service orientation. *BMJ*, *339*(B2727), 1–4.

Muir, J. M., Radhakrishnan, A., Freitag, A., Ozer Stillman, I., & Sarri, G. (2023). Reconstructing the value puzzle in health technology assessment: a pragmatic review to determine which modelling methods can account for additional value elements. *Frontiers in Pharmacology*, *14*, 1–12. https://doi.org/10.3389/fphar.2023.1197259

Murugesan, A., Patel, S., Viswanathan, V. S., Bhargava, P., & Faraji, N. (2023). Dear Medical

Students - Artificial Intelligence is Not Taking Away a Radiologist's Job. *Current Problems in Diagnostic Radiology*, *52*(1), 1–5. https://doi.org/10.1067/j.cpradiol.2022.08.001

Naeem, R., Kohtamäki, M., & Parida, V. (2024). Artificial intelligence enabled product–service innovation: past achievements and future directions. *Review of Managerial Science*. https://doi.org/10.1007/s11846-024-00757-x

Neap, H. S., & Celik, T. (1999). Value of a product: A definition. *International Journal of Value - Based Management*, *12*(2), 181–191. https://doi.org/10.1023/A:1007718715162

Neumann, P. J. (2019). Yes, Improve the US Value Frameworks, But Recognize They Are Already in Prime Time. *Value in Health*, *22*(9), 975–976. https://doi.org/10.1016/j.jval.2019.04.1929

Neumann, P. J., & Tunis, S. R. (2023). Turning CMS into a Health Technology Assessment Organization. *New England Journal of Medicine*, *389*(8), 682–684. https://doi.org/10.1056/nejmp2305280

NICE. (2018). *Guide to the processes of technology appraisal*. https://doi.org/10.2165/00019053-200826090-00002

Nordin, F., & Kowalkowski, C. (2010). Solutions offerings: a critical review and reconceptualisation. *Journal of Service Management*, *21*(4), 441–459. https://doi.org/10.1108/09564231011066105

Nowak, B. P. (2016). Hospice Value–Based Purchasing Program: A Model Design. *Journal of Pain and Symptom Management*, *52*(6), 892–900. https://doi.org/10.1016/j.jpainsymman.2016.05.028

Nudurupati, S. S., Lascelles, D., Wright, G., & Yip, N. (2016). Eight challenges of servitisation for the configuration, measurement and management of organisations. *Journal of Service Theory and Practice*, *26*(6), 745–763. https://doi.org/https://doi.org/10.1108/JSTP-02-2015-0045

O'Connor, C., & Joffe, H. (2020). Intercoder Reliability in Qualitative Research: Debates and Practical Guidelines. *International Journal of Qualitative Methods*, *19*, 1–13. https://doi.org/10.1177/1609406919899220

O'Rourke, B., Oortwijn, W., & Schuller, T. (2020). The new definition of health technology assessment: A milestone in international collaboration. *International Journal of Technology Assessment in Health Care*, *36*(3), 187–190. https://doi.org/10.1017/S0266462320000215

Oliva, R., & Kallenberg, R. (2003). Managing the transition from products to services. *International Journal of Service Industry Management*, *14*(5), 160–172. https://doi.org/10.1108/09564230310474138

Oliveira, M. D., Mataloto, I., & Kanavos, P. (2019). Multi-criteria decision analysis for health technology assessment: addressing methodological challenges to improve the state of the art. *European Journal of Health Economics*, *20*(6), 891–918. https://doi.org/10.1007/s10198-019-01052-3

Ollendorf, D. A., Kamal-Bahl, S., Gleason, P. P., Schrandt, S., & McElwee, N. (2019). Practical Next Steps in Improving Value Measurement and Use. *Value in Health*, *22*(6S), S29–S31. https://doi.org/10.1016/j.jval.2019.04.1913

Onwuegbuzie, A. J., & Leech, N. L. (2005). On Becoming a Pragmatic Researcher : The Importance of Combining Quantitative and Qualitative Research Methodologies. *International Journal of Social Research Methodology*, *8*(5), 375–387. https://doi.org/10.1080/13645570500402447

Oortwijn, W., Sampietro-Colom, L., & Habens, F. (2017). Developments in value frameworks to inform the allocation of healthcare resources. *International Journal of Technology Assessment in Health Care*, *33*(2), 323–329. https://doi.org/10.1017/S0266462317000502

Ormerod, R. (2006). The history and ideas of pragmatism. *Journal of the Operational Research Society*, *57*, 892–909. https://doi.org/10.1057/palgrave.jors.2602065

Paiola, M., Saccani, N., Perona, M., & Gebauer, H. (2013). Moving from products to solutions: Strategic approaches for developing capabilities. *European Management Journal*, *31*(4), 390–409. https://doi.org/10.1016/j.emj.2012.10.002

Patrício, L., Sangiorgi, D., Mahr, D., Čaić, M., Kalantari, S., & Sundar, S. (2020). Leveraging service design for healthcare transformation: toward people-centered, integrated, and technology-enabled healthcare systems. *Journal of Service Management*, *31*(5), 889–909. https://doi.org/10.1108/JOSM-11-2019-0332

Patton, M. Q. (2002). *Qualitative Research & Evaluation Methods* (3rd ed.). Sage Publications Inc.

Pawar, K. S., Beltagui, A., & Riedel, J. C. K. H. (2009). The PSO triangle: designing product, service and organisation to create value. *International Journal of Operations & Production Management*, *29*(5), 468–493. https://doi.org/10.1108/01443570910953595

Pecchia, L., & Craven, M. P. (2013). Early stage Health Technology Assessment (HTA) of biomedical devices. The MATCH experience. *IFMBE Proceedings*, *39 IFMBE*, 1525–1528. https://doi.org/10.1007/978-3-642-29305-4_401

Peirce, C. S. (1905). The architectonic construction of pragmatism. In *Collected Papers ofCharles Sanders Peirce, Vol. V* (Burks, A.W, pp. 3–6). Harvard University Press, Cambridge.

Penttinen, E., & Palmer, J. (2007). Improving firm positioning through enhanced offerings and buyer-seller relationships. *Industrial Marketing Management*, *36*(5), 552–564. https://doi.org/10.1016/j.indmarman.2006.02.005

Petticrew, M. (2011). When are complex interventions "complex"? When are simple interventions "simple"? *European Journal of Public Health*, *21*(4), 397–398. https://doi.org/10.1093/eurpub/ckr084

Pfadenhauer, L., Rohwer, A., Burns, J., Booth, A., Lysdahl, K. B., Hofmann, B., Gerhardus, A., Mozygemba, K., Tummers, M., Wahlster, P., & Rehfuess, E. (2016). *Guidance for the Assessment of Context and Implementation in Health Technology Assessments (HTA) and Systematic Reviews of Complex Interventions: The Context and Implementation of Complex Interventions (CICI) Framework*. http://www.integrate-hta.eu/downloads/

Phelps, C. E., & Madhavan, G. (2017). Using Multicriteria Approaches to Assess the Value of Health Care. *Value in Health*, *20*(2), 251–255. https://doi.org/10.1016/j.jval.2016.11.011

Polanyi, M. (1966). The Logic of Tacit Inference. *Philosophy*, *41*(155), 1–18. www.jstor.org/stable/3749034

Polisena, J., Castaldo, R., Ciani, O., Federici, C., Borsci, S., Ritrovato, M., Clark, D., & Pecchia, L. (2018). Health technology assessment methods guidelines for medical devices: How can we address the gaps? The International Federation of Medical and Biological Engineering perspective. *International Journal of Technology Assessment in Health Care*, *34*(3), 276–289. https://doi.org/10.1017/S0266462318000314

Porter, M. E., & Lee, T. H. (2013). The strategy that will fix health care. *Harvard Business Review*, *October*, 1–39. https://hbr.org/2013/10/the-strategy-that-will-fix-health-care

Porter, M., & Teisberg, E. (2006). *Redefining health care.* Harvard Business School Press.

Rachmania, I. N., Yudoko, G., Basri, M. H., & Setyaningsih, S. (2025). Understanding patient perception of digital value co-creation in electronic health record through clustering approach. *Scientific Reports*, *15*(1), 1–13. https://doi.org/10.1038/s41598-025-91287-3

Raddats, C., Baines, T., Burton, J., Story, V., & Zolkiewski, J. (2016). Motivations for servitization: The impact of product complexity. *International Journal of Operations & Production Management*, *36*(5), 572–591. https://doi.org/10.1108/IJOPM-09-2014-0447

Rawlins, M., Barnett, D., & Stevens, A. (2010). Pharmacoeconomics: NICE's approach to decision-making. *British Journal of Clinical Pharmacology*, *70*(3), 346–349. https://doi.org/10.1111/j.1365-2125.2009.03589.x

Rehfuess, E. A., & Gerhardus, A. (2017). INTEGRATE-HTA: Adopting and implementing an integrated perspective on complex interventions. *Journal of Public Health (United Kingdom)*, *39*(1), 209–212. https://doi.org/10.1093/pubmed/fdw119

Rodriguez Llorian, E., & Mann, J. (2022). Exploring the technology–healthcare expenditure nexus: a panel error correction approach. *Empirical Economics*, *62*(6), 3061–3086. https://doi.org/10.1007/s00181-021-02125-0

Saarni, S., Hofmann, B., Lampe, K., Luhmann, D., Makela, M., Velasco-Garrido, M., & Autti-Ramo, I. (2008). Ethical analysis to improve decision-making on health technologies. *Bulleting of the World Health Organization*, *8*(86), 617–623. https://doi.org/10.2471/BLT.08.051078

Sampietro-Colom, L., Lach, K., Cicchetti, A., Kidholm, K., Pasternack, I., Fure, B., Rosenmöller, M., Wild, C., Kahveci, R., Wasserfallen, J., & Kiivet, R. (2015). *The AdHopHTA handbook: a handbook of hospital-based Health Technology Assessment (HB-HTA)*. https://www.adhophta.eu/sites/files/adhophta/media/adhophta_handbook_website.pdf

Sanchez-Fernandez, R., & Iniesta-Bonillo, M. A. (2007). The concept of perceived value: a systematic review of the research. *Marketing Theory*, *7*(4), 427–451. https://doi.org/10.1177/1470593107083165

Sandhu, M. A., AlMeraikhi, M. H., Saleem, A., & Farooq, M. (2024). Effectiveness of value co-creation in healthcare system from patients' perspectives. *Benchmarking*. https://doi.org/10.1108/BIJ-10-2023-0688

Saunders, M., Lewis, P., & Thornhill, A. (2016). *Research Methods for Business Students*. Pearson Education.

Schmenner, R. W. (2009). Manufacturing, service, and their integration: Some history and theory. *International Journal of Operations and Production Management*, *29*(5), 431–443. https://doi.org/10.1108/01443570910953577

Schmitt, C. (2012). Pay for performance and health-care reform. *Techniques in Gastrointestinal Endoscopy*, *14*(1), 50–62. https://doi.org/10.1016/j.tgie.2011.12.002

Schnell-Inderst, P., Mayer, J., Lauterberg, J., Hunger, T., Arvandi, M., Conrads-Frank, A., Nachtnebel, A., Wild, C., & Siebert, U. (2015). Health technology assessment of medical devices: What is different? An overview of three European projects. *Zeitschrift Fur Evidenz, Fortbildung Und Qualitat Im Gesundheitswesen*, *109*(4–5), 309–318. https://doi.org/10.1016/j.zefq.2015.06.011

Schnipper, L. E., & Bastian, A. (2016). New Frameworks to Assess Value of Cancer Care: Strengths and Limitations. *The Oncologist*, *21*(6), 654–658. https://doi.org/10.1634/theoncologist.2016-0177

Sedrakyan, A., Marinac-Dabic, D., Campbell, B., Aryal, S., Baird, C. E., Goodney, P., Cronenwett, J. L., Beck, A. W., Paxton, E. W., Hu, J., Brindis, R., Baskin, K., Cowley, T., Levy, J., Liebeskind, D. S., Poulose, B. K., Rardin, C. R., Resnic, F. S., Tcheng, J., … Pappas, G. (2022). Advancing the Real-World Evidence for Medical Devices through Coordinated Registry Networks. *BMJ Surgery, Interventions, and Health Technologies*, *4*(e000123), 1–11. https://doi.org/10.1136/bmjsit-2021-000123

Seidl, D., & Whittington, R. (2014). Enlarging the Strategy-as-Practice Research Agenda: Towards Taller and Flatter Ontologies. *Organization Studies*, *35*(10), 1407–1421. https://doi.org/10.1177/0170840614541886

Sgambaro, L., Chiaroni, D., & Urbinati, A. (2024). The design and servitization of products according to the circular economy principles: An ecosystem perspective in the building industry. *Journal of Cleaner Production*, *454*(April), 142322. https://doi.org/10.1016/j.jclepro.2024.142322

Sharma, M. G., & Singh, K. N. (2017). Servitization, Coopetition, and Sustainability: An Operations Perspective in Aviation Industry. *Vikalpa*, *42*(3), 145–152. https://doi.org/10.1177/0256090917721772

Sinha, R. (2024). The role and impact of new technologies on healthcare systems. *Discover Health Systems*, *3*(96). https://doi.org/10.1007/s44250-024-00163-w

Sjödin, D., Parida, V., Kohtamäki, M., & Wincent, J. (2020). An agile co-creation process for digital servitization: A micro-service innovation approach. *Journal of Business Research*, *112*, 478–491. https://doi.org/10.1016/j.jbusres.2020.01.009

Smith, J. B., & Colgate, M. (2007). Customer Value Creation: A Practical Framework. *Journal of*

Marketing Theory and Practice, *15*(1), 7–23. https://doi.org/10.2753/mtp1069-6679150101

Solow, B., & Pezalla, E. J. (2018). ISPOR's Initiative on US Value Assessment Frameworks: The Use of Cost-Effectiveness Research in Decision Making among US Insurers. *Value in Health*, *21*(2), 166–168. https://doi.org/10.1016/j.jval.2017.12.004

Sorenson, C., Lavezzari, G., Daniel, G., Burkholder, R., Boutin, M., Pezalla, E., Sanders, G., & McClellan, M. (2017). Advancing Value Assessment in the United States: A Multistakeholder Perspective. *Value in Health*, *20*(2), 299–307. https://doi.org/10.1016/j.jval.2016.11.030

Stanberry, B., Bothma, G., & Harrison, K. (2021). Using the MEAT VBP Framework to analyse and understand the value of surgical gloves: an explanatory case study. *Health Economics Review*, *11*(1), 1–14. https://doi.org/10.1186/s13561-021-00325-z

Stierand, M., & Dorfler, V. (2014). Researching intuition in personal creativity. In M. Sinclair (Ed.), *Handbook of Research Methods on Intuition* (pp. 249–263). Edward Elgar Publishing. https://doi.org/https://doi.org/10.4337/9781782545996

Stomper, R. (2018). Ancient Theories of Value: As Viewed from Modern Economic Theory. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.3007103

Storbacka, K. (2011). A solution business model: Capabilities and management practices for integrated solutions. *Industrial Marketing Management*, *40*(5), 699–711. https://doi.org/10.1016/j.indmarman.2011.05.003

Strandvik, T., Holmlund, M., & Edvardsson, B. (2012). Customer needing: a challenge for the seller offering. *Journal of Business & Industrial Marketing*, *27*(2), 132–141. https://doi.org/10.1108/08858621211196994

Szász, L., & Seer, L. (2018). Towards an operations strategy model of servitization: the role of sustainability pressure. *Operations Management Research*, *11*(1–2), 51–66. https://doi.org/10.1007/s12063-018-0132-0

Tarricone, R., Torbica, A., & Drummond, M. (2017). Challenges in the Assessment of Medical Devices: The MedtecHTA Project. *Health Economics*, *26*(Supp.1), 5–12. https://doi.org/10.1002/hec.3469

Taylor, R. S., & Iglesias, C. P. (2009). Assessing the clinical and cost-effectiveness of medical devices and drugs: Are they that different? *Value in Health*, *12*(4), 404–406. https://doi.org/10.1111/j.1524-4733.2008.00476_2.x

Trueba, M. L., Bhutta, M. F., & Shahvisi, A. (2021). Instruments of health and harm: How the procurement of healthcare goods contributes to global health inequality. *Journal of Medical Ethics*, *47*(6), 423–429. https://doi.org/10.1136/medethics-2020-106286

Tsoukas, H. (2009). A dialogical approach of the creation of new knowledge in organizations. *Organization Science*, *20*(6), 941–957.

Tukker, A., & Tischner, U. (2006). Product-services as a research field: past, present and future. Reflections from a decade of research. *Journal of Cleaner Production*, *14*(2006), 1552–1556. https://doi.org/10.1016/j.jclepro.2006.01.022

Tuli, K. R., Kohli, A. K., & Bharadwaj, S. G. (2007). Rethinking Customer Solutions: From Product Bundles to Relational Processes. *Journal of Marketing*, *71*(3), 1–17. https://doi.org/10.1509/jmkg.71.3.1

Ulaga, W., & Reinartz, W. J. (2011). Hybrid Offerings: How Manufacturing Firms Combine Goods and Services Successfully. *Journal of Marketing*, *75*(6), 5–23. https://doi.org/10.1509/jmkg.75.6.5

Vaismoradi, M., Turunen, H., & Bondas, T. (2013). Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nursing and Health Sciences*, *15*, 398–405. https://doi.org/10.1111/nhs.12048

Vaittinen, E., Martinsuo, M., & Ortt, R. (2018). Business customers' readiness to adopt manufacturer's new services. *Journal of Service Theory and Practice*, *28*(1), 52–78. https://doi.org/10.1108/JSTP-03-2017-0053

Valtakoski, A. (2017). Explaining servitization failure and deservitization: A knowledge-based perspective. *Industrial Marketing Management*, *60*, 138–150. https://doi.org/10.1016/j.indmarman.2016.04.009

Vandermerwe, S., & Erixon, D. (2023). Servitization of business updated: Now, new, next. *European Management Journal*, *41*(4), 479–487. https://doi.org/10.1016/j.emj.2023.07.007

Vandermerwe, S., & Rada, J. (1988). Servitization of Business: Adding Value by Adding Services. *European Management Journal*, *6*(4), 314–324. https://doi.org/10.1016/0263-2373(88)90033-3

Vargo, S. L., & Lusch, R. F. (2004). The Four Service Marketing Myths: Remnants of a Goods-Based, Manufacturing Model. *Journal of Service Research*, *6*(4), 324–335. https://doi.org/10.1177/1094670503262946

Vienken, J., & Boccato, C. (2024). Do medical devices contribute to sustainability? The role of innovative polymers and device design. *International Journal of Artificial Organs*, *47*(4), 240–250. https://doi.org/10.1177/03913988241245013

Wahlster, P., Brereton, L., Burns, J., Hofmann, B., Mozygemba, K., Oortwijn, W., Pfadenhauer, L., Polus, S., Rehfuess, E., Schilling, I., Van Der Wilt, G. J., & Gerhardus, A. (2017). An integrated perspective on the assessment of technologies: INTEGRATE-HTA. *International Journal of Technology Assessment in Health Care*, *33*(5), 544–551. https://doi.org/10.1017/S0266462317000484

Weber, B., & Wener, W. (2004). Application of Lean and Agile Principles to Workflow Management. In Eckstein, J. & H. Baumeister (Eds.), *Extreme Programming and Agile Processes in Software Engineering. XP 2004. Lecture Notes in Computer Science*. Springer Cham. https://doi.org/https://doi.org/10.1007/978-3-540-24853-8_36

Weeks, R., & Benade, S. (2015). The development of a generic servitization systems framework. *Technology in Society*, *43*, 97–104. https://doi.org/10.1016/j.techsoc.2015.09.003

WHO. (2021). *Global strategy on digital health 2020-2025* (World Health Organization (ed.)).

Willke, R. J. (2019). New Approaches to Value Assessment: Towards More Informed Pricing in Healthcare - An Introduction. *Value in Health*, *22*(6), S1–S3. https://doi.org/10.1016/j.jval.2019.04.1912

Willke, R. J., Chapman, R. H., Seidman, J. J., Schnipper, L. E., & Gleason, P. P. (2019). Current Value Frameworks—What's New? *Value in Health*, *22*(6), S7–S11. https://doi.org/10.1016/j.jval.2019.04.1916

Windahl, C. (2015). Understanding solutions as technology-driven business innovations. *Journal of Business & Industrial Marketing*, *30*(3/4), 378–393. https://doi.org/10.1108/JBIM-11-2013-0253

Windahl, C., & Lakemond, N. (2010). Integrated solutions from a service-centered perspective: Applicability and limitations in the capital goods industry. *Industrial Marketing Management*, *39*(8), 1278–1290. https://doi.org/10.1016/j.indmarman.2010.03.001

Windler, K., Jüttner, U., Michel, S., Maklan, S., & Macdonald, E. K. (2017). Identifying the right solution customers: A managerial methodology. *Industrial Marketing Management*, *60*, 173–186. https://doi.org/10.1016/j.indmarman.2016.03.004

Wise, R., & Baumgartner, P. (1999). Go Downstream: The New Profit Imperative in

Manufacturing. *Harvard Business Review*, *77*(5), 133–141.

Woodruff, R. B. (1997). Customer Value: The Next Source for Competitive Advantage. *Journal of the Academy of Marketing Science*, *25*(2), 139–153. https://doi.org/10.1007/BF02894350

World Economic Forum. (2024). Transforming Healthcare: Navigating Digital Health with a Value-Driven Approach. In *World Economic Forum* (Issue January).

Xing, Y., Liu, Y., & Davies, P. (2023). Servitization innovation: A systematic review, integrative framework, and future research directions. *Technovation*, *122*(August 2022), 102641. https://doi.org/10.1016/j.technovation.2022.102641

Yin, R. K. (2009). *Case Study Research - Design and Methods* (2nd ed., Vol. 5). Sage Publications Inc.

Zhang, K., Feng, L., Wang, J., Lin, K. Y., & Li, Q. (2023). Servitization in business ecosystem: a systematic review and implications for business-to-business servitization research. *Technology Analysis and Strategic Management*, *35*(11), 1480–1496. https://doi.org/10.1080/09537325.2021.2010698

Zhang, W., & Banerji, S. (2017). Challenges of servitization: A systematic literature review. *Industrial Marketing Management*, *65*(September), 217–227. https://doi.org/10.1016/j.indmarman.2017.06.003

Zhang, Y., Wang, H., Wang, Z., Han, F., & Liu, M. (2024). Toward Economic Sustainability: Exploring Business Model Innovation in Servitization Transformation Enterprises through Resource Orchestration. *Sustainability*, *16*(7998). https://doi.org/https://doi.org/10.3390/ su16187998

9. Appendices

9.1 Appendix 1: EUnetHTA domains, topics and issues

Tables 9.1 – 9.9 present the EUnetHTA domains, topics and issues, along with descriptions and clarifications for each topic. The topics (in bold) are listed as they appear in the framework, while the issues and descriptions have been paraphrased to capture the key information and essence of each topic, including examples in some cases.

Table 9.1: Topics and Issues in the Health Problem and Current Use of Technology domain

Topic	***Issue***	***Description/Clarification***
Target population	*Target population*	The technology is designed for a specific population, often defined by the severity of the condition, the appropriate timing (e.g. early stages), or underlying risks. Defining and identifying this target population influences both the technology's effectiveness and safety. Moreover, it aligns with current trends in health policy favouring personalised medicine.
	Number of individuals constituting the target population for the technology	The size of the target population informs resource requirements for implementing the technology, including future projections of population changes.
Target condition	*Disease and health condition within the scope*	It outlines the specific health condition being targeted.
	Risk factors	The risk factors associated with the disease or health condition give light to the overall value of the use of the technology. They influence comparator selection and overall technology value assessment.
	Natural course of the disease	Understanding the disease progression is crucial for evaluating the technology's overall value. The impact of technology on life-threatening conditions differs from self-limiting ones. For instance, treatment targeting life-threatening conditions like severe coronary artery disease contrasts with managing symptoms in self-limiting illnesses such as the common cold. Similarly,

Topic	*Issue*	*Description/Clarification*
		early diagnosis aids treatment in time-sensitive cases like oncology, where technologies like PET/CT scans can reveal metastasis risks sooner.
	Symptoms and burden of the disease for the patient (patient's perception)	The assessment should detail the patient's symptoms pre-intervention, including their severity, urgency and whether they are persistent, intermittent, or fluctuating across different disease stages. The description of patients' perception of the disease and its symptoms is crucial because it influences patient comfort, quality of life and satisfaction and may diverge from scientific or clinical expressions and can significantly impact decisions regarding the adoption of a technology. For instance, back pain, while not life-threatening, significantly impacts quality of life and work ability.
	Consequences of the disease or health condition for the society	The societal burden of the disease also influences decision-making in healthcare planning and investments.
	The aspects of the disease consequences or burden addressed by the technology	Technology may target all or just some of the symptoms or burden of the health condition, for instance mortality but not symptoms or disability.
Current management of the condition	*Alternatives to using the technology under assessment*	Overview of the alternative technologies currently in use, for addressing the targeted health condition, including those often utilised independently by individuals, without professional healthcare guidance such as self-testing, self-treatment or alternative medicine.
	Current diagnosis of the disease or health condition according to published guidelines and in practice	The diagnosis of the disease follows clinical guidelines, utilisation reviews, expert surveys and real-world practice. The effectiveness of an intervention can vary depending on the diagnostic methods used for different populations.
	Current Management of the disease or health condition according to published guidelines and in practice (including information on whether the	Assessing the impact of the technology on current disease management and determining if it supplements or replaces existing practices is essential. Different disease stages may require varied approaches, highlighting the need to specify how and where the technology integrates into the care pathway.

Topic	*Issue*	*Description/Clarification*
	technology is an add-on or replacement for existing options)	
Utilisation	*Health conditions, populations and purposes for using the technology*	A technology can be applied to multiple conditions and populations, designed for a specific health condition, and serve multiple purposes, functioning differently across various patient groups. For instance, a tomosynthesis option for the mammography unit may be used for the dense breast diagnosis but also for screening purposes.
	Current and future utilisation rate of the technology (market access, actual usage, level of development: experimental, emerging, established, obsolete)	The utilisation rate of a technology demonstrates its adoption and integration into clinical practice. Hospital-level usage of a medical device reflects the adherence of both personnel and patients to the technology. Understanding variations in utilisation provides insights into the technology's phase (experimental, emerging, established, or obsolete), impacting evidence availability and uncertainty levels.
	Variations in use across countries/regions/settings	The use of technology can vary between countries or regions. For example, cardiology devices may be more widely used in areas with poor dietary habits or demographics historically burdened by cardiovascular diseases.
	Key decision-makers about which people are eligible for the technology and on what basis	Decisions regarding the use of technology and its suitability for patient groups can be made at either the national level, such as in screening programs, or at the individual level, such as by healthcare professionals for specific treatments or surgical procedures. This information further clarifies the context of the technology's impact in terms of safety, efficacy and ethical implications.
	Is the technology a new, innovative mode of care, an add-on, a modification of a standard mode, or a replacement of a standard mode?	The introduction of a technology into the patient pathway aims to bring about a change or improvement in addressing a health condition. This can be achieved through entirely new developments, additions, modifications, or innovative approaches. The impact and scale of these changes resulting from the introduction should be evaluated.

Topic	*Issue*	*Description/Clarification*
Regulatory status	*Indications for which the technology has received marketing authorisation or CE marking*	Market authorisation systems exist internationally and nationally, with pharmaceuticals having more established processes compared to devices and procedures. Diagnostic technologies, including imaging devices and imaging substances like radiotracers, typically require approval. It is important to obtain an overview of authorisation system statuses, highlighting key processes such as CE marking or EMA/FDA approval.
	Reimbursement status	In most countries, reimbursement status significantly influences technology adoption. It varies depending on its intended use, such as treatment versus prevention and includes details on full coverage, co-payments and conditions for coverage.

Table 9.2: Topics and Issues in the Description and Technical Characteristics of Technology domain

Topic	***Issue***	***Description/Clarification***
Features of the technology	*Technology and its comparators description*	The description of a medical device includes its type, technique, procedure, or therapy, along with its biological rationale mechanism of action, intended purpose and significant distinctions from products made by other manufacturers. The technology and comparator should be described separately.
	Claimed benefit of the technology in relation to the comparators	Assessing new technologies with uncertain benefits is critical because recent medical devices or technologies are expected to enhance the management of specific health issues. This improvement can elevate safety, health benefits, accuracy and patient compliance, influencing clinical outcomes, effectiveness and organisational, social, or ethical considerations. Understanding these aspects informs the choice of comparators and outcomes for assessment, contributing to the overall evaluation.
	Phase of development and implementation of technology and the comparator(s)	A technology can be assessed at various stages of its development or implementation. This may occur during the early phase of an innovative technology or later through a modification or addition to an existing technology. Assessments may also involve exploring the use of the same technology for different indications.
	Who decides about the use of the technology, who administers the technology and the comparator (health professional, patient, caregiver etc), in what context and level of care (self-care, primary, secondary, tertiary etc)?	The technology's application and administration involve decisions by healthcare professionals, such as nurses and doctors, along with patient or caregiver involvement. For instance, an individual may choose to use a home sphygmomanometer independently at home. Conversely, an X-ray scan is conducted in a medical setting solely at the request of a healthcare professional. Professionals select patients, initiate technology use and interpret outcomes based on specific criteria like skills and training. The technology may be used across various levels of care (self-care, primary, secondary, tertiary), either in outpatient or inpatient settings, serving roles as a replacement, add-on, or for triage within the management pathway.
	Reference values or cut-off points have been established?	Clear and explicit interpretation of findings from a technology requires well-defined cut-off points and reference values.

Topic	*Issue*	*Description/Clarification*
Regulatory status	*Indications for which the technology has received marketing authorisation or CE marking*	As outlined earlier in Table 9.1
	Reimbursement status	As outlined earlier in Table 9.1
Investments and tools required to use the technology	*Investments in devices, machinery and materials necessary for technology use and the comparator(s)*	Medical devices, including imaging equipment like MRI systems, often require specific conditions for installation and operation. For example, radiation protection measures are essential for imaging devices and MRI systems require Faraday cages for radiofrequency shielding. Clearly defining and addressing these requirements is crucial as they affect both investments and the safe, effective utilisation of the technology.
	Need for special premises to use the technology and the comparator(s)	Numerous technologies require specialised facilities like radiation-protected areas, Faraday cages, patient dressing rooms, or dedicated spaces for chemotherapy pharmaceuticals with fume cupboards. These facility requirements should be clearly defined, taking into account variations in primary and secondary care settings across different countries.
	Disposable items necessary for the use of the technology and the comparator(s), such as contrast media, syringes etc	The technology or medical device may also necessitate specific disposable items for its operation, such as syringes, reagents, fluids, etc. For instance, a Computed Tomography (CT) system may require contrast media for certain examinations.
	Need of data/records/registry for monitoring the use of technology and comparator(s)	Monitoring the safety and real-world effectiveness of a technology relies on gathering comprehensive data from various sources, including registries, vigilance systems and databases for pharmaceuticals and medical devices. Key data elements include clinical indications, specified patient populations, prescriber details, inpatient or outpatient use, test results, review periods and health outcomes.

Topic	*Issue*	*Description/Clarification*
Training and information needed to use the technology	*Qualification of people and quality assurance processes needed for the use of the technology and its maintenance*	Training is essential for the safe and effective operation and maintenance of a technology. It aims to familiarise users with the technology and equip them with the skills needed for appropriate and efficient use. Training programs can be customised for different users, including nurses, technologists, doctors, patients, caregivers and technical personnel responsible for device maintenance. Regular standardisation and quality checks, such as Continuing Medical Education (CME) points, may also be necessary. These training and quality assurance measures significantly impact the efficacy and safety of the technology.
	Skills and training needed for personnel and caregivers for using the technology	The training needed for a technology or medical device varies based on its complexity and usage environment. It can range from basic written or verbal instructions to comprehensive classroom sessions or hands-on training. For instance, sophisticated imaging devices often require several days of training involving actual patient interactions. For technologies requiring skill development over time (learning curve), an estimate of the number of patients treated per year to reach proficiency should be provided.
	Training material and resources for the patient and his/her family	Training plans for technology directly used by patients or their families may require adaptation. This includes tailored training materials ((written, translated, or adapted) and sessions (individual or group), designed to meet the needs of non-specialised personnel.
	Information about the technology which should be provided to patients outside the target group and to the general public	Information regarding a technology or medical device, including manufacturer data, effectiveness studies, observational research and user instructions, should be made accessible to patients and the public for training and informational purposes. The type of information materials, such as written content or translations, needed for training should be specified.
Other	*Manufacturers of the technology*	This includes information regarding the technology's manufacturer.

Table 9.3: Topics and Issues in the Safety domain

Topic	***Issue***	***Description/Clarification***
Patient safety	*Safety of the technology versus to the comparator(s) - direct harms from the use and administration*	Direct harms shall be identified, described and categorised based on their frequency and severity. They shall also be reported according to indication or target group. If the harms associated with a technology and its comparators are found to be similar, the increased risk of harm occurrence will be specifically identified.
	Relation of use and dosage with harms - sensitivity to (even small) changes	The sensitivity to changes in dosage or the effects of repeated dosage or testing shall be investigated. For example, the radiation dose from ionising imaging devices like CT scanners shall be managed and carefully considered.
	Variation of the safety profile of the technology between different settings - frequency and severity of harms	The safe use of a technology or medical device can differ based on the user's profile or the organisational context. For example, one radiographer may use higher dose protocols to achieve higher resolution images, while another radiographer (even within the same organisation) participating in a dose reduction program may obtain sufficiently diagnostic images at a lower dose.
	Susceptible Patient groups with increased likelihood to be harmed by the technology	Certain patient groups, such as elderly individuals, children, those with co-medications, patients with rare diseases and immunosuppressed individuals, may experience harmful effects from a technology or medical device. The interaction between potential contraindications of the technology and these specific groups shall be described and reviewed.
	Consequences of false positive, false negative and incidental findings generated by the technology use	Incorrectly identifying sick people as healthy (false negative) or healthy people as sick (false positive) can lead to incorrect treatment decisions, resulting in either undertreatment or overtreatment. For example, a computer-assisted diagnostic tool for breast imaging may generate false negative or false positive results, impacting the accuracy of the diagnosis accordingly.
	User-dependent harms	Health professionals, patients, caregivers, or other individuals may use a device or technology. The familiarity, training and expertise of the user significantly influence the proper operation and functioning of the device, as well as the potential risks for harm. This also applies to individuals

Topic	*Issue*	*Description/Clarification*
		responsible for maintaining the device. User-dependent concerns or potential causes of harm must be assessed.
Occupational safety	*Occupational harms*	Occupational risks for professionals using the device are also critical. For instance, with imaging devices, professionals are mandated by regulatory authorities and radio-protection legislation in most countries to continuously monitor radiation exposure over time.
Environmental safety	*Public and environmental risks*	Various components of technology can pose risks to environmental safety. Toxic materials, hazardous chemicals (like mercury) and radiation are examples of environmental hazards. For instance, installing a cyclotron to produce radiopharmaceuticals necessitates rigorous environmental audits and obtaining appropriate permits.
Safety risk management	*Requirements for reducing safety-risks for patients*	The risks linked to the potential harmful impact of technology can be reduced or entirely prevented through the implementation of safety management plans. These plans may include training, instructions, the establishment of risk-minimisation protocols and more. Imaging manufacturers, for instance, create dose-reduction algorithms aimed at minimising radiation exposure to patients and operators. Furthermore, stringent regulatory guidelines ensure the correct and safe utilisation of the technology.
	Requirements for reducing safety-risks for professionals	
	Requirements for reducing safety-risks for environment	
	Need of data/records/registry for monitoring the use of technology and comparator(s)	As outlined in Table 9.2

Table 9.4: Topics and Issues in the Clinical effectiveness domain

Topic	*Issue*	*Description/Clarification*
Mortality	*Expected beneficial effect of the technology on mortality*	Mortality serves as the primary objective endpoint in assessments of life-threatening conditions, categorised into overall mortality (all-cause) and disease-specific mortality (a portion of overall mortality). The positive impact of the technology or medical device on mortality, whether overall or disease-specific, shall be detailed. The assessment shall include scenarios where the technology reduces or eliminates mortality from a specific disease but may potentially increase mortality from other causes.
Morbidity	*How does technology modify the effectiveness of subsequent interventions?*	Different diagnostic tests may identify different subpopulations as test-positive, impacting subsequent diagnostic and treatment outcomes for test A versus test B positives. For example, treatments may vary in efficacy between cases identified through screening versus those diagnosed during routine physician appointments. Additionally, the impact of using technology, such as MRI scans with brain functionality tools and mapping, before related surgeries, can influence the efficacy of subsequent interventions.
	Technology effect to symptoms and findings of the disease or health condition.	The assessment evaluates how the technology affects disease outcomes, including physical and psychological changes. It measures effectiveness by comparing changes in symptom severity, frequency and recurrence with the comparator, using both absolute and relative measures.
	How does the test-treatment intervention modify the magnitude and frequency of morbidity?	The technology's role in enhancing treatment efficacy and effectiveness should be clarified. For example, a more accurate replacement test improves treatment outcomes. A satisfactory triage test minimises adverse outcomes from other tests. An add-on test boosts sensitivity, ensuring more patients receive suitable treatment and achieve better outcomes.
	Technology effect on progression (or recurrence) of the disease or health condition	The evaluation of the technology should focus on its impact on targeted health conditions, assessing potential outcomes such as complete cure, delaying disease progression, or altering disease stage. Results should include absolute and relative measures of complete cure, progression-free survival and time-to-event (e.g. next stage of disease, relapse) compared to the comparator.

Topic	*Issue*	*Description/Clarification*
Function	*Technology effect on patient body functions*	The effects of the technology or medical device on the human body and its functions.
	Technology effect on work ability	The impact of the technology on the patient's work capacity, including absenteeism, presenteeism, retirement and related factors.
	Technology effect on return to previous living conditions	The effect of a technology or medical device on achieving the goal of returning to pre-admission living conditions.
	Technology effect on activities of daily living	Daily living primarily involves self-care activities such as personal care, community engagement and domestic tasks. The ways in which technology may influence these activities shall be described and evaluated.
Health-related quality of life	*Technology effect on generic health-related quality of life (HRQL)*	According to the World Health Organisation (WHO), Health-Related Quality of Life (HRQL) covers key aspects including physical health, psychological well-being, level of independence and social relationships. The impact of the technology or medical device on these areas shall be described and evaluated.
	Technology effect on disease-specific quality of life	Disease-specific quality of life provides a depiction of health-related quality of life tailored to patients with a specific diagnosis. Unlike generic HRQL, disease-specific measures are more responsive to changes because they assess factors that are particularly relevant to patients with the targeted disease, thereby offering greater specificity.
Quality of life	*Does the knowledge of the test result affect the patient's non-health-related quality of life?*	The technology or test result could impact symptoms positively or negatively, affecting quality of life, despite no direct impact on the primary outcome.
Patient satisfaction	*Were the patients satisfied with the technology?*	The patient's perception of the technology's value is crucial, influencing its acceptability and potentially indicating its broader adoption.
Test-treatment chain	*Is there an effective treatment for the condition the test is detecting?*	The presence or absence of an effective treatment for the condition that the test/device/technology is designed to detect is crucial. For example, a brain MRI scan may indicate the risk or early signs of dementia or Alzheimer's disease, but until recently, treatment options were not available.

Topic	*Issue*	*Description/Clarification*
Test accuracy	*Accuracy of the test against reference standard*	Accuracy primarily refers to specificity, sensitivity and other measures and studies of precision.
	How does the test compare to other optional tests in terms of accuracy measures?	Comparing the technology to other developmental stages of the same technology
	What is the reference standard and how likely does it classify the target condition correctly?	If there are no common or appropriate reference standards available, a reference method shall be developed or defined as described above.
	What are the requirements for accuracy in the context the technology will be used?	The evaluation of accuracy should consider acceptable levels of false negatives and false positives.
	Optimal threshold value	The optimal threshold value represents the best balance between specificity and sensitivity.
	Does the test reliably rule in or rule out the target condition?	A technology should be evaluated for its accuracy in reliably determining the need for further testing. This is crucial to avoid over-testing and the associated costs.
	Variation of the accuracy of the result in different settings	The accuracy of a technology or test may vary based on patient group, disease prevalence, or disease severity. Understanding these accuracy characteristics and their applicability to different settings is crucial for determining the technology's use across diverse populations. For instance, a plain mammography scan may be less effective for screening dense breasts compared to a mammography scan followed by tomosynthesis.
	Intra- and inter-observer variation in test interpretation (i.e. imaging tests)	The accuracy of certain technologies or medical devices can depend on the user's subjective assessment. For example, the accuracy of interpreting an image from an X-ray machine or a CT scanner and the resulting diagnosis, relies on the expertise and judgment of the radiologist.
	Existence of evidence that the replacing test is more specific or safer than the old one	When effectiveness and sensitivity are assumed, specificity and safety become two key factors in assessing a technology.

Topic	*Issue*	*Description/Clarification*
Patient safety	*Consequences of false positive, false negative and incidental findings generated by the technology use from the viewpoint of patient safety*	Incorrectly identifying sick individuals as healthy (false negatives) or healthy individuals as sick (false positives) can lead to inappropriate treatments, resulting in either undertreatment or overtreatment.
Change-in-management	*Modification of the need for hospitalisation*	The impact of a technology or medical device on the need for hospitalisation is crucial. Reducing the length of hospital stays or avoiding hospitalisation altogether is a primary goal for most healthcare systems. Additionally, assessing the technology‘s effect on the intensity of hospitalisation, such as the need for intensive care versus ward care, is important.
	Improved detection of the condition	A technology or test may produce superior quality results. However, these results may not necessarily contribute to the decision-making process. The impact of the technology on clinical decision-making should be described and evaluated.
	Technology-related changes of physicians’ management decisions	A technology or medical device may significantly influence a physician’s decision by offering new options, enhancing knowledge and improving capabilities. The effect of a medical device on a physician’s decision-making should be evaluated.
	Detection of other potential health conditions that can impact the subsequent management decisions	A technology may reveal or detect additional potential health conditions beyond the targeted disease, influencing testing and treatment decisions.
Benefit-harm balance	*Overall benefits and harms of the technology*	The primary objective of the domain is to consolidate all information regarding the benefits and risks of a technology and establish a balance between these factors.

Table 9.5: Topics and Issues within the Cost and Economic Evaluation domain

Topic	*Issue*	*Description/Clarification*
Resource utilisation	*Resource-use identification - types of resources used*	The resources utilised in implementing the technology and its comparators.
	Resource-use measurement - amounts of resources used	The number of resources used with the technology and its comparators.
	Resource-use valuation - measured/or estimated costs	The costs related to the technology and its comparators may include various aspects such as usage costs, patient expenses and societal impacts.
	Impact and modification of the need for other technologies and use of resources	A technology can impact the necessity and associated costs of other technologies or resource utilisation. For example, technologies like interventional radiology and vascular interventions may reduce the requirement for open surgery.
	Budget impact of implementing the technologies being compared	The implementation and adoption of a technology will affect the healthcare budget, whether for healthcare institutions or government healthcare programs. Assessing the budgetary impact of comparative technologies is crucial for decision-makers across different levels of technology management.
Measurement and estimation of outcomes	*Outcome identification, measurement and valuation*	The health outcomes associated with a technology, which may stem from clinical effectiveness analyses and be further expressed in alternative forms like QALYs.
Examination of costs and outcomes	*Estimated differences in costs and outcomes between the technology and its comparator(s)*	The comparison of the assessed technologies may be represented in various forms, including tabular data reporting, Incremental Cost-Effectiveness Ratio ($ICER_b$) and other metrics.
Characterising uncertainty	*Uncertainties surrounding the costs and economic evaluation(s)*	The uncertainty in assessing costs and outcomes can impact economic evaluations and should be duly reported.
Characterising heterogeneity	*Differences in costs, outcomes, or 'cost-effectiveness' be explained by variations between any subgroups using the technology and its comparator(s)*	The variability among patient groups or other factors could contribute to differences in costs and outcomes in economic evaluations. This variability should be investigated and documented.

Validity of the model(s)	*Methodological assumptions*	The economic evaluation models rely on specific assumptions, including time horizons, discount rates, resource scope, effectiveness aspects and others. These assumptions and factors must be clearly specified and transparently reported.
	Process of validation and types of validation	The model validation process should be clearly articulated.

Table 9.6: Topics and Issues in the Ethical analysis domain

Topic	*Issue*	*Description/Clarification*
Benefit-harm balance	*Symptoms and burden of disease for the patient*	Patient perception of symptoms, their severity, urgency and the perceived burden of the disease before undergoing the technology often differ from clinical assessments of disease seriousness or severity.
	Balance between benefits and harms (by implementing or not implementing the technology) including the perception of the patients/users	The evaluation includes assessing the balance between benefits and harms, health improvements, stakeholders impacted and potential harm to individual patients. Additionally, it is valuable to consider patient perceptions of the benefits and harms.
	Balance between benefits and harms for other patient groups, relatives, caregivers, organisations, commercial entities, society	The assessment should include the societal benefits and harms across various dimensions: physical, financial, social and other aspects of life. A technology or test may indirectly impact groups beyond the patient, as seen with genetic testing or screening for rare diseases. Furthermore, ethical considerations related to over-diagnosis or medicalisation should be explored. Additionally, the symbolic impact of technology, such as its influence on healthcare system demands, should be considered.
	Hidden or unintended consequences of the technology and its applications to patients, relatives, other patients, organisations, commercial entities, society.	Consideration should be given to the implications of combining the technology with other technologies and whether this combination leads to unforeseen side effects or ethical questions that have not yet been identified or addressed? Furthermore, the method of administration or the necessity for additional tests in implementing the technology should be carefully examined and assessed. Does this mode of delivery impact the understanding or management of the disease, for example, transforming it from a non-treatable condition to a chronic disease?
	Ethical obstacles for evidence generation regarding the benefits and harms of the intervention	Ethical challenges in evaluating interventions include ethical dilemmas related to providing treatment alternatives, concerns regarding vulnerable populations' ability to consent and issues of research integrity, such as privacy and conflicts of interest.
Autonomy	*Right and Justification for using the technology used on individuals that are especially vulnerable?*	Consideration of the justification for using technology on vulnerable individuals like pregnant women, critically ill patients, or those with limited decision-making capacity (children or individuals with cognitive disabilities).

Topic	*Issue*	*Description/Clarification*
	Does the implementation or use of the technology affect the patient's capability and possibility to exercise autonomy?	Many technologies can impact a person's autonomy by influencing their decision-making capacity and requiring specific behaviours (e.g. dietary restrictions for faecal blood tests). Patients have the right to make informed decisions about treatment, understanding alternatives, risks and potential impacts on daily life choices like driving or nutrition.
	Need for specific interventions or supportive actions concerning information in order to respect patient autonomy when the technology is used?	Ensuring patients are informed comprehensively about the technology, including its risks, challenges and side-effects, to facilitate well-informed decision-making. This includes detailing its impact on aspects like personality, nutrition, sleep, daily life and lifestyle. Patients should be informed of any special challenges or risks associated with the technology, such as potential false positives leading to unnecessary treatments or serious side effects like invasive surgery or unexpected outcomes in off-label use.
	Impact on patient-physician relationship, change or challenge of professional values, professional ethics or traditional values	Technologies can alter the patient-physician relationship and challenge professional ethics by potentially compromising trust, confidentiality and professional autonomy. Aligning technologies with ethical standards is crucial for their successful implementation, as discrepancies can lead to conflicts where patients may seek technologies for various reasons, while professionals may view them as unnecessary or potentially harmful (e.g. antibiotics, sleep medicine, antidepressants, whole body MRI scans).
Respect for persons	*Effect on human dignity*	Technologies applied to individuals with reduced autonomy (children, mentally impaired, severely ill) may violate human dignity by labelling them or implying they are less valuable. This includes technologies that may incorrectly label healthy individuals as sick or less worthy, such as prostate-specific antigen (PSA) testing for prostate cancer or psychiatric medication for behavioural issues and prenatal screening programs that suggest disability as a reason for abortion.
	Effect on patient's moral, religious or cultural integrity	How does the technology impact or confront religious, moral and cultural convictions, beliefs, preferences and commitments? Certain technologies can undermine integrity by conflicting with patients' moral convictions, values, or self-identity, especially affecting vulnerable groups. They can also disrupt societal norms and views, such as perceptions of disabilities. Additionally, they may cause a reaction due to religious convictions, such as blood transfusion, or even drive an ethical violation, such as lying about a health status so that a better treatment is achieved.

Topic	*Issue*	*Description/Clarification*
	Invasion in the sphere of privacy of the patient/user	Privacy can be breached through virtual and physical means. Considerations include: Does the technology impact individuals' control over personal data? Is the collection and dissemination of patient information justified?
Justice and Equity	*Effect on the distribution of healthcare resources*	Across various applications, technologies often bring substantial costs, potentially requiring reallocation of resources like human capital, funding and training. Such shifts can impact different patient groups and strain the healthcare system, necessitating careful study of effects on prioritisation and distribution of benefits and losses. In diagnostic technologies, there is a risk of symbolic value driving demand for tests not justified on health grounds, as seen with foetal ultrasound and PSA tests. For instance, conducting an ultrasound scan, only because it creates an abstract expectation of health benefit, perceived by the patient as important.
	How are technologies with similar ethical issues treated in the health care system?	Similar ethical issues suggest the potential for applying similar health policies or reevaluating existing ones. These similarities include technological, economic, organisational, legal, or social dimensions.
	Factors preventing a group or person from gaining access to the technology	This issue focuses on health inequality and the European Commission's goal to reduce it for social cohesion. It questions whether the technology can ensure equitable access based on need, addressing potential barriers like discrimination based on geography, gender, ethnicity, religion, employment, or insurance.
Legislation	*Effect to the realisation of basic human rights*	This issue refers to the universal rights crucial for humanity, including equality, non-discrimination, safety, adequate standard of living and healthcare, which are particularly relevant in HTA.
	Ethical challenges that have not been considered in the existing legislations and regulations	A modern technology may require new regulations or amendments due to emerging ethical issues, prompting the need for legislative adjustments guided by ethical reflection. For instance, screening and diagnostic technologies often face different regulatory frameworks compared to treatments like medications.
	Ethical considerations of the choice of endpoints, cut-off values and	Due to the challenge of directly linking clinical effectiveness to a disease, endpoints, cut-off values, or comparators/controls may be necessary. Choosing sensitivity and specificity cut-off values

Topic	*Issue*	*Description/Clarification*
Ethical consequences of the HTA	*comparators/controls in the assessment*	should align with the ethical implications of results; for instance, high specificity is crucial when false positives lead to serious consequences.
	Ethical problems related to the data or the assumptions in the economic evaluation	Ethical concerns may arise from the data, assumptions, or valuations used in economic evaluations, such as the fair valuation of indirect costs.
	Ethical consequences of conducting the technology assessment at this point in time	The timing of technology assessment affects which patient groups gain access to new options, raising ethical issues around prioritisation that require attention. For instance, methodological and ethical gaps may prevent filling knowledge gaps, affecting patient access.

Table 9.7: Topics and Issues in the Organisational aspects domain

Topic	*Issue*	*Description/Clarification*
Health delivery process	*Technology effect on the current work processes*	A technology may alter the entire process and continuity of care across professional and organisational boundaries, by adding or removing activities within an organisation, between organisations, or across the wider healthcare system. This primarily impacts care pathways at the organisational level, influencing target populations, patient numbers, processes and the relationships among involved organisations.
	Patient/participant flow associated with the new technology	A new technology may alter the patient's care pathway from an individual perspective, affecting waiting times, preparation needs, result turnaround times and home monitoring requirements. The impact of a technology on patient flow within care pathways is an important factor to consider. This issue also assesses the technology's impact on current care pathways such as shifts towards community or inpatient care.
	What kind of involvement has to be mobilised for patients/participants and important others and/or caregivers	The role of the technology in task distribution among care providers is significant. For instance, a technology may reduce patient or caregiver involvement and require more activity from health professionals. Conversely, it may grant more independence to patients and caregivers, shifting some care responsibilities from specialised healthcare professionals to them.
	What kind of process ensures proper education and training of staff	A new technology may necessitate new professionals or new tasks for current personnel. Training is critical for the performance and effectiveness of a technology. It involves not only enhancing existing skills but also acquiring new ones, especially when a technology significantly changes healthcare delivery. Such changes can impact the organisation, alter job roles and perception and affect job satisfaction.
	What kind of co-operation and communication of activities have to be mobilised	The patient pathway relies on cooperation and communication among multiple stakeholders, such as healthcare professionals, organisations, departments, vendors, caregivers and the patient. Implementing technology in this pathway can change how operations and communication occur, potentially modifying their structure. For example, conducting a home X-ray scan with a mobile unit requires a different collaboration between the technologist and patient compared to the same scan in a radiology department.

Topic	*Issue*	*Description/Clarification*
	How is the quality assurance and monitoring system of the new technology structured?	A new technology impacts quality assurance not only within the organisation but also across different healthcare levels. Ensuring quality assurance and compliance with standards is imperative in medical technology. The methods and systems used to achieve these goals may be influenced by technology, thereby impacting organisational and management practices both within and outside the healthcare organisation implementing the technology. For example, managing radiation doses from CT scanners or other ionising radiation medical devices is a responsibility that affects healthcare organisations, healthcare authorities and even patient societies.
Structure of health care system	*How do de-centralisation or centralisation requirements influence the implementation of technology*	Healthcare settings (primary, secondary, tertiary care) vary among countries based on their healthcare systems. Decentralisation may offer economic and quality advantages, while centralisation can limit technology access. Typically, expensive technologies are centralised in tertiary care units staffed with specialised professionals.
	Processes ensuring access to the new technology for patients/participants?	The extent of a technology's use influences its accessibility. Acceptance, reflected in utilisation, can be observed at individual, population-specific and health system levels, influenced by factors including culture, economy, society and geography.
Process-related costs	*Costs of processes related to acquisition and setting up the new technology*	Implementing technology often necessitates specific infrastructure, which can be both demanding and costly. The expenses associated with this infrastructure significantly influence funding allocation and investment decisions. For example, PET/CT scanners require extensive radiation protection measures and associated costs. Similarly, MRI scanners necessitate the construction of radio-frequency shielding (Faraday cages) and other electrical works. Consideration should be given to investments at all stages of the process.
	How does the technology modify the need for other technologies and use of resources?	A technology in clinical care pathways can supplement existing technologies, potentially replacing them. For instance, contrast-enhanced breast scans might obviate the need for MRI scans. Alternatively, a technology might prompt the adoption of additional treatments, such as oncologic radiotherapy after a PET/CT scan. Less invasive interventions can reduce the need for surgeries, yet some treatments may still require regular monitoring and hospital visits.

Topic	*Issue*	*Description/Clarification*
	Likely budget impacts of implementing the technologies being compared	Introducing a technology into the patient pathway and healthcare system carries budgetary implications. Whether managed by governments, insurers, employers, or patients themselves, affordability is critical for evaluating the technology. Assessing affordability and budget impact requires data analysis from various stakeholders and actors involved.
Management	*Management problems and opportunities attached to the technology*	Technology impacts various organisational aspects significantly, including management. Risk management, safety, administrative demands, resource investment, monitoring and control are among the areas influenced by technology introduction, requiring careful evaluation. Consideration should include relevant data and information management systems associated with each of these aspects.
	Who decides which people are eligible for the technology and on what basis	The inclusion criteria for technology and the key decision-making factors and stakeholders are crucial in its assessment. National policymakers, healthcare professionals (e.g. doctors) and individual patients may serve as decision makers for its adoption. For example, a policy or reimbursement decision may discourage or limit an examination, potentially reducing surgical procedures or impacting the quality of life for patients with specific conditions (e.g. PSMA PET/CT scans to detect prostate cancer throughout the body. Specifically, PSMA PET targets the prostate-specific membrane antigen (PSMA), a protein found on the surface of prostate cancer cells).
Culture	*How is the technology accepted*	The acceptability of the technology from the viewpoints of organisation, personnel and patients or their families across different healthcare levels is a critical factor in its assessment. Acceptance can be influenced by various reasons, including organisational challenges, personnel discomfort, or considerations about the organisation's image.
	How are the other interest groups taken into account in the planning/implementation of the technology?	Understanding the stakeholders and their cooperation and interaction is valuable. Stakeholders include pharmaceutical and screening technology companies, national or regional authorities, registries, administrative bodies, municipalities, policymakers, staff groups, primary care physicians and patient organisations. It is important to assess whether patient organisations have been involved in the evaluation process, either from the planning stages or later as commentators.

Table 9.8: Topics and Issues within the Patient and Social aspects domain

Topic	*Issue*	*Description/Clarification*
Patients' perspectives	*What are the experiences of living with the condition*	This issue examines how patients manage their daily lives while dealing with a disease, including the burden of illness and treatment, limitations in daily activities (work, family, social life, self-care, leisure), psychological challenges (stigma, anxiety, fear, social acceptance) and financial implications requiring aids for daily living.
	Expectations, wishes and gains expected from the technology by the patients and the caregivers	Patients and caregivers expect the technology to delay disease progression, improve symptom management, such as fatigue and mobility issues, increase treatment tolerance, enhance survival rates and improve daily living, social interactions and psychological well-being. Assessing the significance of these effects is critical in evaluating the technology.
	Patient perception of the technology	Patient perspectives on the evaluated technology include their understanding, perceptions and emotional responses. This includes how the technology impacts their daily life and self-image, as well as the challenges they encounter in its application and daily use. Managing potential side-effects is also crucial. Furthermore, the technology's influence on their psychological well-being, social interactions and financial status is examined.
	Burden on the caregivers	The challenges and demands placed on caregivers, family members and colleagues due to the patient's use of the technology will be outlined and taken into account. These challenges may be physical or emotional, requiring resources and substantial engagement for effective management.
Social group aspects	*Are there groups of patients who currently do not have good access to available therapies?*	Ensuring equitable access to healthcare treatments is essential in preventing inequality, discrimination and exclusion. Does the technology cater exclusively to specific patient groups, thereby excluding others? This restricted access can exacerbate disparities. How are these issues of inequality addressed and mitigated? This issue includes concerns about unequal access to healthcare therapies, potential discrimination against special groups like children, older adults, specific age groups, individuals with genetic mutations or disabilities, people in remote areas, ethnic minorities and those with particular types of diseases.

Topic	*Issue*	*Description/Clarification*
	Are there factors that could prevent a group or person from gaining access to the technology	Factors hindering patient groups' access to technology must be identified and assessed. These barriers may stem from geographical, religious, gender-related, or disease-specific limitations like genetic mutations. For example, obesity might limit a patient's access to an MR scan due to the weight capacity limits of the MR table.
Communication aspects	*How are treatment choices explained to patients?*	Patients' access to resources, information and tools to comprehend their condition and treatment options is crucial. These resources enhance patients' awareness, understanding and engagement in their healthcare decisions. Patients should be active participants in deciding on technology use. For example, a claustrophobic patient might suggest an Open-MRI scan instead of a conventional standard or wide-bore gantry MRI scan.
	What specific issues may need to be communicated to patients to improve adherence	The information and clear instructions needed by patients to alleviate fear and anxiety about the technology or treatment.

Table 9.9: Topics and Issues within the Legal aspects domain

Topic	*Issue*	*Description/Clarification*
Autonomy of the patient	*What kind of legal requirements are there for providing appropriate information to the user or patient and how this be addressed when implementing the technology?*	The rules governing information sharing with patients about the benefits or potential harms of a technology should be thoroughly explored and described. These rules help those implementing the technology provide appropriate information and counselling, especially for high-risk technologies, those offering non-relevant information and in emergencies where patients lack time for decision-making.
	Who is allowed to give consent for minors and incompetent persons?	The rules and laws governing information and consent for children and incompetent persons must be considered. An incompetent person can be described as someone with an unsound, deranged, or functionally impaired mind due to factors like low IQ, cognitive deterioration, illness, or psychosis. Special considerations are required for informed consent from minors, typically under 18 and individuals with impaired mental function, requiring consent from a legal guardian or authorised representative.
Privacy of the patient	*Is there a possibility that the use of the technology produces additional information that is not directly related to the current care of the patient and may violate their right to respect for privacy?*	Data privacy and the confidentiality between patients and healthcare providers must be protected and assessed during technology evaluation. EU laws safeguard sensitive personal data, upholding doctor-patient confidentiality. However, computerised records and genetic diagnostics may challenge this principle.
	What do laws/binding rules require about informing relatives about the results?	In some cases, breaching patient privacy may be necessary if a condition suggests family members face similar health risks. Procedures must be established to decide whether to inform relatives, following relevant legislation. This includes handling demands for results in cases of suspected treatment malpractice, sudden deaths, or highly infectious diseases.
	What do laws/binding rules require with regard to appropriate measures for securing patient data and how should this be addressed when implementing the technology?	The framework governing the management of data from the evaluated technology should be studied, including laws, policies and practices. This includes identifying potential scenarios for data handling, risks of leakage or mishandling and measures to prevent such issues. Legal requirements cover who can store patient data, its location, duration and access controls. Additionally, any extra data generated - potentially relevant for insurance, marketing, or safety - must be protected. The

Topic	*Issue*	*Description/Clarification*
		impact of data protection on care quality, such as complications in data transfer, should also be assessed, with practical solutions ensuring compliance and security.
Equality in health care	*What do laws/binding rules require with regard to appropriate processes or resources which would guarantee equal access to the technology?*	Equal access to healthcare is a key principle in the Biomedicine Convention, the EU Charter of Fundamental Rights and many national constitutions. It is important to consider the laws and rules ensuring this equality, as well as to examine specific national challenges and solutions that could inform decision-makers in other countries.
	What are the consequences of various EU-level and national regulations for the equal access to the technology?	National laws and practices, such as reimbursement, pricing and access criteria, that affect healthcare equality should be explored. Additionally, the impact of the EU Directive on cross-border healthcare, including these national processes, should be considered for insights beyond one's own country.
Ethical aspects	*Does the implementation or use of the technology affect the realisation of basic human rights?*	Human rights must be respected in all cases. The United Nations Declaration of Human Rights outlines universal rights essential for Health Technology Assessment (HTA), including equality, non-discrimination, safety, adequate living standards and healthcare.
	Can the use of the technology pose ethical challenges that have not been considered in the existing legislations and regulations?	New technologies may pose ethical challenges that existing legislation and regulations might not address. It is important to review the legal framework to ensure it remains fair and adequate. As ethical issues arise, particularly with the different regulation of screening, diagnostic technologies and treatments, ethical reflection is essential to identify if legislative or regulatory changes are needed.
Authorisation and safety	*What authorisations and register listings does the technology have?*	The necessary authorisations, registrations and certifications required for the technology, including market access, safety and reimbursement shall be identified.
	What do laws/binding rules require with regard to the safety of the technology and how should this be addressed when implementing the technology?	The legislation and regulations on safety and quality of care will be examined to ensure they are respected and maintained during the technology's implementation, such as compliance with radioprotection and electrical safety rules.

Topic	*Issue*	*Description/Clarification*
Ownership and liability	*What should be known about the intellectual property rights and potential licensing fees?*	Intellectual property regulations must be considered when introducing and implementing technology to avoid infringement. Violations can limit technology use and impact acquisition contract terms and licensing fees.
	What should be known about the legal or binding rules regarding the width, depth and length of the manufacturers guarantee?	Manufacturers often provide guarantees for technologies and understanding these guarantees is crucial for decision-makers to determine their claim rights and the manufacturer's liability. The user guide also helps define the extent of the manufacturer's liability.
Regulation of the market	*What kind of legal price control mechanisms are there that are relevant to the technology?*	Understanding legal price control mechanisms, such as paybacks for managing healthcare budget overruns, provides insights into controlling health expenditures related to technology implementation. Describing these economic measures offers valuable guidance for decision-makers in other countries, even if not directly transferable.
	What kind of regulation exists for the acquisition and use of the technology?	Regulations govern the acquisition and use of technologies, particularly for expensive technologies and high-risk pharmaceuticals.
	What legal restrictions are there for marketing the technology to the patients?	The legislation governing the marketing of health products and technologies to the public, including general principles and restrictions, shall be described.
	What should be known about the legal issues in cases of new technologies where the current legislation is not directly applicable?	The novelty of technologies, such as those used in clinical trials or 'compassionate use', can expose gaps in existing legislation and highlight the need for amendments. Key issues include liability and patient participation.
	Are there concerns about conflicts of interest regarding the preparation of binding rules and their implementation?	Concerns about partiality or conflicts of interest in binding guidance can offer valuable insights for decision-makers regarding the importance of implementing a technology.

9.2 Appendix 2: AdvaMed framework - Value categories, subcategories and drivers

Table 9.10 outlines the AdvaMed value categories, value subcategories and value drivers, along with descriptions and clarifications for each value subcategory and its respective drivers. The value categories and subcategories (in bold) and the value drivers (in italics) are presented as they appear in the framework. The descriptions and clarifications reflect the essence derived from the sample questions and value metrics of the framework for each value subcategory.

Table 9.10: AdvaMed framework - Value categories, subcategories and drivers

Value Categories	***Value Subcategories***	***Value Drivers***	***Description/Clarification***
Clinical Impact	**Clinical Efficacy and Effectiveness**	*Improvements in clinical outcomes include disease-specific morbidity measures, reduced mortality, slower disease progression and decreased burden of follow-up care*	The clinical outcomes of the medical technology are described and evaluated, considering metrics such as survival rates, morbidity endpoints related to disease progression, improved diagnostic accuracy and speed and reduced length of hospital stay.
		Improvement in compliance with plan of care	Patient adherence to the care plan is evaluated.
	Patient Safety and Tolerability	*Improved patient safety and tolerability vs. alternative treatments*	Patient safety is assessed by evaluating complications, adverse effects and other risks compared to alternative options.
		Effect on patient risk trade-offs based on safety profile and outcomes	Assessment of the impact on patient risk trade-offs.
		Impact on security (technology and data)	Data security and privacy.
	Quality of Life	*Improvement in quality of life (physical and social well-being)*	Evaluation of the technology's impact on quality of life (QoL), including physical and social well-being, using metrics such as Quality-Adjusted Life Years (QALYs) and Disability-Adjusted Life Years (DALYs).

Value Categories	*Value Subcategories*	*Value Drivers*	*Description/Clarification*
Non-clinical Patient Impact	**Patient Experience**	*More preferable site of care (ease of access)*	Consideration of the preferential aspects of technology, such as a claustrophobic patient's preference for an open or wide-bore MRI scanner over a standard-bore MR scanner.
		Predictability of care/experiences vs. expectations	Patient experience can be evaluated using various metrics, including invasiveness, frequency of procedures and the need for follow-ups.
		Reintegration/reengagement of patient into society	The impact of technology on the speed at which patients return to their daily routines.
		Reduced burden on caregivers due to better patient experience and outcomes	The impact of technology on caregiver burden, including physical, financial, or social aspects. For example, a technology may be clinically effective but require significant caregiver involvement for its safe administration.
	Patient Economics	*Impact on out-of-pocket (OOP) patient expenses*	Out-of-pocket expenses can be a substantial cost during a health condition, potentially affecting affordability for patients and their families.
		Reduced time to return to activities of daily living (ADLs)	The return to a productive and social life for both patients and their caregivers also has an economic impact that should be assessed.
Care Delivery Revenue and Cost Impact	**Quality of Care Economics**	*Economic impact of performance-based reimbursement metrics (e.g hospital-acquired infections, readmissions, Length of Stay (LOS), cost efficiency)*	The costs associated with the performance and impact of a medical technology, including expenses for post-care complications, readmissions and repeat procedures. For example, this may include the cost of re-scanning a patient with an MR scanner due to poor image quality or additional mammography screenings due to inadequate image acquisition.
	Care Efficiency	*Economic impact of improved system throughput & workflow/efficient time & resource utilisation (physician's time and effort, automation, disposable utilisation, site of care, staff utilisation,*	The impact of the technology on the operational aspects of an organisation or healthcare system, including resource requirements, such as materials and staff, necessary infrastructure and workflow optimisation.

Value Categories	*Value Subcategories*	*Value Drivers*	*Description/Clarification*
		Operating Room (OR) utilisation, service/maintenance, LOS, time in Intensive Care Unit (ICU)	
		Impact of costs associated with clinical outcomes variance	Reducing variance can lead to increased efficiencies and cost savings. For example, standardised scanning protocols for specific anatomies or clinical cases across different sites or users can decrease examination times, improve waiting times and boost productivity.
		Economic impact of improved adoption of new care practices due to easier/more effective training/education	Enhanced usability, ongoing education and training can increase the acceptability of the technology among both healthcare professionals and patients.
Public and Population Impact	**Population Health**	*Improved population health (burden of illness/disease)*	The impact of technology on population health can be observed through various factors, including life expectancy, QALYs, patient access and societal re-engagement.
		Impact to overall private and public healthcare cost	The overall healthcare cost per capita.
		More efficient private and public spending	The efficiencies a technology can bring to healthcare spending.
	Workforce productivity	*Increased employee productivity (reduce absenteeism, improve presenteeism)*	Employee productivity.
		Increased caregiver productivity (reduced absenteeism, improved presenteeism)	Caregiver productivity.

Value Categories	*Value Subcategories*	*Value Drivers*	*Description/Clarification*
Environmental Impact	**Monetary Impact**	*Cost impact from environmental initiatives and implementation*	The impact of technology to cost reduction through environment-friendly initiatives in manufacturing, packaging, use and disposal. This includes reductions in single-use plastics, waste from packaging or sterilising, upstream and downstream waste, energy savings compared to alternatives and the total energy and percentage of renewable energy used in manufacturing.
		Increased asset optimisation by capital allocation in sustainable devices	The contribution to investment returns over time by extending the life of the medical device through factors such as device longevity, recyclability and the availability of closed-loop recycling.
	Perception and Differentiation	*Impact of reduced net global emissions on company value proposition*	The support of sustainable practices by reducing net global emissions, enhancing stakeholder perception and differentiating value. Key factors include greenhouse gas emissions, water usage and the safety of materials and packaging.
		Reduction in regulatory, legal and activist shareholder interventions	The contribution of technology in compliance with environmental best practices, reporting environmental metrics and ensuring price transparency by addressing financial penalties, claims for compensation and legal costs.

9.3 Appendix 3: The INTEGRATE-HTA project

Table 9.11 presents the categories and subcategories of the socio-cultural aspects of the INTEGRATE-HTA project. The categories (in bold) and subcategories (in italics) are listed as they appear in the framework, while the descriptions and clarifications aim to capture the essence of each aspect, with examples provided in some cases. Similarly, Table 9.12 presents the nine core issues of the legal aspects of the framework, retaining the issue names as they appear in the framework. Tables 9.13 and 9.14 present the context and implementation domains from the complex intervention checklist of the INTEGRATE-HTA project, preserving the names as they appear in the framework and offering paraphrased descriptions that convey their core meaning.

Table 9.11: The socio-cultural aspects

Category	***Subcategory***	***Description/Clarifications***
Social construction/understanding of health issue		People's socio-cultural context shapes their perceptions and experiences of health issues, which can influence both technology design and adoption. For example, prenatal ultrasound screening might be seen as a duty or an interference with nature, depending on cultural and social perspectives.
Social image/understanding of technology and use	*Perceived usefulness and the idea of benefit*	Perceptions of a technology's benefits and important outcomes are culturally influenced and can affect the understanding of its effectiveness and safety. These views should be collected from various stakeholders, including professionals, patients, relatives and policymakers.
	Knowledge about and understanding of technology	The social image of a technology is shaped by the knowledge and understanding of it. The assessment should investigate how this knowledge is socially constructed, culturally shaped and ultimately legitimised to form the basis for evaluation.
	Attitudes and acceptance of technology and use	A technology's social image can impact its acceptance or rejection. Stakeholders' attitudes, shaped by social and cultural

Category	*Subcategory*	*Description/Clarifications*
		contexts, may evolve as they become more familiar with the technology.
	Risk reception and handling	Perceptions and handling of risk can vary among stakeholders due to differences in cultural backgrounds and views on safety, technology's impact on the body and personal identity.
Socio-cultural aspects of technology implementation & organisation of use	*Socio-cultural aspects of target groups*	Socio-cultural characteristics, including age, gender, ethnicity, religion, education and social networks, can impact a target group's acceptance, compliance, or rejection of a technology or treatment.
	Social inequality and technology use	The implementation of a technology can be influenced by social inequality and access disparities among diverse groups, potentially leading to stigmatisation and discrimination. It is crucial to assess these impacts, as different cultural groups may encounter varied challenges in accessing the technology.
	User-professional relationship and decision-making	The relationships between patients (and their caregivers) and health professionals are shaped by cultural context, influencing perceptions of a technology's usefulness. The socio-cultural assessment should consider mutual expectations, communication, roles and the balance of responsibility and autonomy between users and professionals.
	Relationships between professionals providing the technology	Professional status and workplace culture can affect technology perceptions. Factors such as social power, cooperation styles (i.e. interdisciplinary) and team structures should be described in the socio-cultural context.

Table 9.12: Legal aspects in INTERGRATE-HTA Model

Group Legal Term	***Legal issue***	***Description/Clarifications***
Autonomy of the patient	*Informed Consent*	Informed consent must be evaluated to safeguard patient autonomy when a technology is used in direct or psychological interactions.
	Alternative forms of Consent	Alternative forms of informed consent should be pursued if the patient is unable to consent due to factors such as age or emergencies.
	Privacy and Data Protection	If a technology involves collecting and processing patient data, informed consent is required to ensure patient autonomy and privacy.
Market authorisation	*Authorisation of Medical devices*	In the European market, medical devices must have CE mark authorisation to ensure compliance with safety and quality standards for introduction, trade and use.
	Authorisation of Medicinal products	Medicinal products must be authorised before they can be introduced to the market.
	Clinical Trials	Clinical trials are governed by legal norms to protect patient rights. If an HTA involves clinical trials, their legal aspects must be assessed.
	Intellectual property	Technologies and patents may be protected or eligible for protection under intellectual property laws.
	Reimbursement in public healthcare systems	Reimbursement decisions for a treatment are based on clinical, economic and safety assessments from the HTA process. However, reimbursement prerequisites should be clarified in advance.
	Special medical fields	Legal aspects of technologies in specialised medical fields, like organ transplantation or prenatal screening, must be thoroughly examined.

Table 9.13: Context domains (Pfadenhauer et al., 2016)

Context domains	*Definition (as per INTEGRATE-HTA Guidance)*
Setting	This category includes the geographical location (city, region, country) and the type of site where the assessment is conducted, such as hospitals or primary care facilities. It also involves the number of study sites, their physical characteristics and the work environment. Additionally, it considers how the location impacts stakeholders and any relevant changes that occur over time.
Geographical	This category includes geographic factors, such as the location climate, land use patterns and infrastructure. It also considers access to the healthcare system, geographical isolation and any relevant changes over time that might impact the study or intervention.
Epidemiological	This category includes demographic factors including population characteristics, such as density, fertility patterns and family size. It also involves the incidence, prevalence and severity of diseases, as well as morbidity and mortality rates. Additionally, it examines how disease is spatially distributed across different geographical areas and any significant changes over time, including epidemics.
Socio-economic	This category addresses various aspects of social and economic status, including financial conditions, occupational factors and living standards. It also considers the specific needs of individuals affected by a disease or condition, the overall burden of the disease and the fiscal and market environments. Access to healthcare services is an important element, as are changes over time, such as inflation, recession and economic crises, which may impact these factors.
Socio-cultural	This category includes a range of socio-cultural factors. It includes the primary languages and communication methods utilised within the community, as well as the cultural symbols, rituals and practices that influence social behaviour. Attitudes towards fate, destiny, religiosity and spirituality also play a significant role in shaping health views. Furthermore, it addresses how communities understand health issues, available solutions and the benefits and drawbacks of technologies. Lifestyle patterns, such as dietary habits, smoking and substance use, are also considered. Instances of discrimination and biases within the community are examined, along with the social capital derived from resources and support available through social networks, including elements of trust and reciprocity. The strength of social bonds, including material, political and relational dimensions, is analysed, as well as informal social control mechanisms. Finally, the impact of both historical and current social power dynamics on community interactions is explored.
Political	This category examines the political system and civil society structure, including key players, interests, resources and objectives. It covers formal and informal rules, distribution of power, political culture and socio-political climate. It assesses state-society relations, political stability, government effectiveness and aspects like voice and accountability, corruption control, rule of law, regulatory quality and transparency. It also includes economic management, market policies, politics and gender, international integration, ideologies and the influence of key figures and funding policies.

Context domains	*Definition (as per INTEGRATE-HTA Guidance)*
Legal	This category covers regulatory provisions for healthcare personnel, including their rights and duties, guidelines for care delivery, decision-making processes and information sharing with indirectly affected stakeholders. It also includes relevant legislation and changes over time, such as new regulations or laws.
Ethical	This category addresses morality and beliefs shaping individual and institutional behaviour, standards of conduct, autonomy, moral stress, privacy and conflicting interests. It also considers relevant changes over time, such as shifts in conduct standards within healthcare organisations.

Table 9.14: Implementation domains and subdomains (Pfadenhauer et al., 2016)

Implementation domains	*Definition (as per INTEGRATE-HTA Guidance)*
Provider	This category includes personality traits (e.g. openness, curiosity), skills, knowledge and emotional factors like memory and attention. It includes beliefs about consequences, self-efficacy and optimism, as well as attitudes toward interventions or technologies. It also covers motivation, intention, goals, behavioural regulation and social or professional roles and identities.
Organisation and Structure	This category includes the continuity of organisational aspects, such as information and staffing, team coordination and collaboration, cooperation with external providers and organisational size and structure. It also covers networks and communication, cosmopolitanism, policies, guidelines and practices. Key elements include organisational culture and climate, team dynamics, leadership, supervision, training and knowledge transfer. Additionally, it involves the implementation climate, system readiness for change, peer pressure and change agents.
Funding	This category includes funding and reimbursement programs, purchaser-provider contracts and financial incentives at all levels. It covers changes in income for providers, pay-for-performance incentives and alterations in costs for patients, practices and healthcare systems. It also considers the economic climate, resource availability, service availability, research and grant funding and payment models. Additionally, it addresses the continuity of funding, fiscal support linked to federal and state policies, alignment with existing service funds and the flexibility of funding sources to adjust requirements.
Policy	This category includes donor policies and their prioritisation on societal agendas, political culture and climate, such as ideology, short-term thinking, contracts, influential figures, corruption and political stability. It also includes external mandates, public or benchmark reporting, political directives and incentives. It addresses meeting societal needs, navigating health and social systems and ensuring social protection for all stakeholders. Additionally, it covers legislation, policies, programs and regulations that support or impact the implementation of interventions or technologies, as well as policymakers' use of evidence-based practices and advocacy efforts.

9.4 Appendix 4: NICE technology appraisal

Table 9.15 presents the 125 NICE technology appraisal decision factors as analysed by De Folter *et al.* (2018). These factors are hierarchically organised into eight domains: Clinical Effectiveness, Cost Effectiveness, Condition, Current Practice, Clinical Need, New Treatment, Studies, and Other Factors. The top-level domains are displayed in the first column of the table, with sub-factors further analysed. The repetition of some decision factors among top-level domains emphasises their interdependency.

Table 9.15: The 125 NICE technology appraisal decision factors as per De Folter *et al.* (2018) analysis

Top level domains	***Sub-factors level 1***	***Sub-factors level 2***	***Sub-factors level 3***
Condition	Condition Management		
	Effect on Quality of Life (QoL)	Patient	
		Carer	
		Family	
	Psychological aspects		
Current practice	Currently available treatments		
	Current treatment pathway		
	Variation in current practice		
	Clinical management		
	Treatment impact		
	Treatment in current practice		
	Level of success of current treatment		
	Stigma of expert treatment		
	Treatment service		
	Treatment duration		
	Uptake		
Clinical need	Clinical need for treatment		
	Clinical need for additional treatment		
	Clinical need for better practice	Improved monitoring	
		Improved dosing	
	Clinical need of particular sub group		
New treatment	Treatment safety		
	Adverse events		
	Treatment duration		
	Long term treatment effects		
	Treatment effectiveness		
	New patient access scheme		
	Comparator treatment	Comparator validity	
	Clinical treatment pathway		

Top level domains	*Sub-factors level 1*	*Sub-factors level 2*	*Sub-factors level 3*
	Prescription setting		
	Adherence issues		
	Adjuvant treatment		
Studies	Study relevance		
	Study method		
	Study quality		
	Statistical significance		
	Population group		
	Population generalisability		
	Generalisability to current practice		
Clinical effectiveness	Treatment effectiveness		
	Relative effectiveness/comparisons		
	Sub group effectiveness		
	Sub group comparison		
	Application in current practice		
	Relevance to clinical practice		
	Evidence/ New evidence	Evidence reliability	
		Evidence availability	
		Evidence suitability	
		Evidence validity	
		Population generalisability	
		Effect on QoL	
		HRQoL	
		HRQoL measurement	
		Analysis method	
	Additional analysis	Post hoc efficacy analysis	
		Post hoc subgroup analysis	
		Manufacturer's post hoc analysis	
		ERG's exploratory analysis	
		Sensitivity analysis	
		Scenario analysis	
	Relevance comparison		
	Long term effects		
	Adverse effects		
	Risk of recurrence/relapse		
	Patient reported outcomes (PROM)		
	Health utility	Estimation of utility	
Cost effectiveness	Cost effectiveness analysis		
	Manufacturer's economic analysis		
	Validity		
	$ICER_b$	Estimated $ICER_b$(s)	

Top level domains	*Sub-factors level 1*	*Sub-factors level 2*	*Sub-factors level 3*
		Most appropriate/plausible $ICER_b$	
	Additional analysis	Manufacturer's sensitivity analysis	
		Manufacturer's new cost effectiveness estimates	
		Evidence review group (ERG) amendments	Impact
			Treatment length in practice
			Treatment application in practice
	Economic model	Key drivers	
		Model validity	
		Model limitations	
		Model relevance	
		Model suitability	
		Model structure	
		Model time horizon	
		Model input	HRQoL
			Treatment in current practice
			Treatment duration
			Subgroup effectiveness
			Treatment effectiveness
			Long term treatment effects
			Health utility
			Adverse events
			Changes in model input
		Model outcome	Sensitivity to model input
			Long term outcome prediction
			Effect on QoL
		Model corrections	
	Comparison scenario	Most appropriate comparison scenario	
		Representation of current scenario	

Top level domains	*Sub-factors level 1*	*Sub-factors level 2*	*Sub-factors level 3*
		Limitations	
	Risk of recurrence/relapse		
Other factors	Innovation		
	Rare condition		
	Children		
	Lack of recent advances in field treatment		
	Equality issues	Protected characteristics	
	Stigmatisation of condition		
	Impact on family		
	Uncaptured benefits	Health benefits	
		HRQoL	Patient
			Family
		Benefits to particular population groups	
	Displacement of other treatments		
	End of Life considerations		