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Table of contents

| | |
|---|-----------|
| Executive Summary | 3 |
| Context: The imperative for a broader, patient-centric definition of value | 6 |
| Guiding principles for effectively assessing value of a medical technology | 7 |
| Translating the principles into effective value-based decisions | 9 |
| Value Driver: Clinical Impact | 13 |
| Value Driver: Non-Clinical Patient Impact | 14 |
| Value Driver: Care Delivery Revenue and Cost Impact | 15 |
| Value Driver: Public/Population Impact | 16 |
| Value Driver: Environmental Impact | 17 |
| Conclusion | 21 |
| About AdvaMed's Strategic Value Initiative | 22 |

Executive Summary

The health care ecosystem is in the midst of a major shift from volume-based, fee-for-service (FFS) systems to value-based care (VBC) models. These payment reforms shift risk from payers to providers, with the dual goals of reducing the per-capita cost of health care and improving the patient experience, including quality of health outcomes and patient satisfaction.

In this emerging value-based world, choices on adoption of medical technologies are under increasing scrutiny from a range of stakeholders beyond the individual clinician – including patients, multiple decision-makers in care delivery, and payers. These stakeholders recognize the importance of medical technologies in improving patients' lives and the effectiveness of care delivery, and they play critical roles in making or influencing decisions about the use of medical technologies. Additionally, recent years have witnessed growth in the availability and advancements of new digital medical solutions, e.g., incorporation of artificial or augmented intelligence (AI) and machine learning (ML) into medical devices. This trend, along with a paradigm shift in industry towards Environmental, Social, and Governance (ESG) considerations, require stakeholders to assess the value of a medical technology with these market changes in mind.

It is a business imperative for medical technology developers to understand, demonstrate, and clearly articulate how their offerings can not only improve patient outcomes but also create value for each of the key stakeholders across the health care delivery continuum. In this paper, the range of ways in which medical technologies can impact the quality and cost of care are referred to as “value drivers.” Different stakeholders care about and prioritize different but overlapping sets of value drivers, against which they judge a medical technology's benefits. Therefore, medical technology developers must understand and speak effectively to each stakeholder's unique set of value drivers. This may require new insights into how a technology can improve the effectiveness and efficiency of care delivery for providers or payers, and how it goes beyond improving clinical outcomes for a patient population to deliver non-clinical patient benefits such as ease of recovery and reduced burden on caregivers.



The extent to which the medical technology (MedTech) industry clearly articulates value under the new value-based paradigm will drive appropriate adoption of medical technologies and support continued investment in MedTech innovations to benefit patients and the health care system.

AdvaMed launched a Strategic Value Initiative in 2017, in collaboration with Deloitte Consulting LLP, to develop principles and an approach for assessing the value of medical technologies that can be adopted by MedTech companies, health systems, payers, and other stakeholders. The viewpoints of multiple stakeholders from outside the MedTech industry were incorporated into the process of developing the approach, with the overall goal of encouraging the adoption of the proposed principles and supporting practices into existing frameworks and assessment models as they evolve over time.

Since 2017, the MedTech landscape has witnessed significant changes and advancements, especially with the advancements in digital medical technologies and a paradigm shift in industry towards Environmental, Social, and Governance priorities. Due to these recent market changes, the Value Framework has been refined and refreshed, incorporating important stakeholder viewpoints and feedback.

AdvaMed's recommended approach begins with a set of core principles that guide an effective process for comprehensively assessing the value of a medical technology. AdvaMed believes that these principles warrant broad adoption by all stakeholders involved in value assessments – payers, providers, health technology assessment (HTA) bodies, patient advocates, and medical technology companies.

- **The Comprehensiveness Principle:** Value assessments should consider a broad array of patient-centric value drivers and their relevance and importance for different stakeholders.
- **The Evidentiary Principle:** Value assessments should utilize an appropriate range of available evidence, and the type of evidence and assessment methodology should be based on technology type and the potential risk to patients.
- **The Cost Principle:** Value assessments should consider and report costs incurred and costs avoided over timeframes appropriate for the technology (including, where available, costs incurred and avoided outside the health care system).
- **The Specificity Principle:** Value assessments should account for representative patient populations and applicable timeframes for patient impact.
- **The Flexibility Principle:** Value assessments should be flexible to account for different types of medical technologies and utilize an appropriate range of impact analyses.
- **The Engagement Principle:** Value assessment processes should involve the perspectives of multiple stakeholders and provide sufficient opportunities and time for all to engage in the process.
- **The Transparency Principle:** Value assessment processes and methodologies should be transparent to all stakeholders.
- **The Relevancy Principle:** Value assessments should be updated regularly to keep pace with innovation in standards of care or when there is significant new evidence.

In translating the guiding principles into effective decision-making, the AdvaMed approach starts by capturing the full spectrum of value that a medical technology may contribute ("value driver").

This approach takes into consideration the increasing possibility that a medical technology may go beyond a traditional product to include new types of services or data solutions, such as, digital health technologies or ESG initiatives used in combination with a technology to improve health and economic outcomes.

This paper identifies five broad categories of value drivers to be incorporated in an assessment process:

- **Clinical impact:** The extent of clinical utility and health outcomes associated with the medical technology offering.
- **Non-clinical patient impact:** The impact on non-medical benefits for the patient (or caregiver): patient experience and patient economics (such as out-of-pocket [OOP] costs).
- **Care delivery revenue and cost impact:** The impact of the technology on revenues or costs for a provider, payer, provider-sponsored plan, etc., via bonuses or penalties associated with care quality metrics, as well as the impact on clinical workflow and other sources of operating efficiency.
- **Public and population impact:** The impact of the technology on the health care system at large and employers or the public as a whole.
- **Environmental impact:** The impact of the technology due to environmental initiatives on an organization's perception or differentiation and monetary value of a medical technology (e.g., cost reduction in supply chain, device longevity).

These categories go beyond traditional clinical efficacy to capture newer patient-focused considerations and a technology's impact on the effectiveness and efficiency of care delivered under new value-based performance systems for providers, payers, provider-sponsored plans, and accountable care organizations (ACOs).

The AdvaMed approach seeks to ensure that appropriate analyses underpin value assessment. Stakeholders are interested in assessing the value of a specific medical technology; looking at the benefits to patients, providers and others; and considering the economic effects of adoption (including the cost of acquiring the technology as well as offsetting savings) and any relevant risks. AdvaMed believes that an effective assessment process will result in a final analysis of the expected "value proposition" that includes:

- Explicit description of each of the ways the medical technology will deliver an impact, together with scenarios to describe the magnitude of the impact (against both quantitative and qualitative metrics, where appropriate) and the costs of acquiring the technology, as well as other offsetting costs (such as changes to existing care protocols that require providers to train their staff prior to implementation), or reduction in waste generated in packaging or sterilizing as a response to environmental concerns;
- Consideration of the range of relevant time-frames over which the impact is expected to occur;
- Explicit acknowledgement of relevant patient sub-populations if impacts are likely to be significantly higher or lower than the scenario included in the baseline assessment.

This expected value proposition should be explicitly tied to available, credible evidence that supports the estimated impacts. This includes consideration of both qualitative and quantitative sources, even when agreed-to methodologies are still emerging (as is the case with patient-reported outcome [PRO]). For medical technologies, over-reliance on randomized controlled trials (RCTs) may limit the types of value impact that can be effectively investigated; therefore, considering a variety of appropriate evidence is necessary. There are multiple types of evidence that can, either independently or collectively, be used to support assessment of medical technologies,

including observational studies and PRO, which are defined later in this paper.

The level and types of evidence needed for assessment will depend on the technology's overall risk for patients, its product approval pathway or lifecycle stage, special payment provisions, special coverage or coding considerations and the practical limitations of evaluating the technology in a study. AdvaMed also believes that the assessment approach should allow a novel product with high expected value to be available for patient care while further evidence is generated – even if there is limited evidence at approval/launch. AdvaMed has developed a set of guidelines as a supplement to this paper to further describe its approach to the appropriate types of evidence and their relevance for different value assessments.

AdvaMed's Strategic Value Initiative is an iterative process. AdvaMed and its members will continue to engage in ongoing dialogue with payers, providers, and patient groups on value assessment and the need for a broad perspective on value drivers that should apply to the evaluation of medical technologies. As the US health care system increasingly shifts towards value-based payment models, AdvaMed encourages others to incorporate the principles and supporting practices contained in this paper into existing frameworks and assessment models as they evolve over time so patients can benefit from new medical innovations.

Context: The Imperative for a Broader, Patient-centric Definition of Value

The health care ecosystem is in the midst of a major shift in emphasis from volume-based to value-based care (VBC). Health care payment reforms are shifting risk between payers and providers with the dual goals of reducing per-capita health care costs and improving the patient experience, including quality of health outcomes and patient satisfaction. These new payment models are being combined with or are replacing traditional fee-for-service performance measures and reimbursement methods. There have also been developments in the regulatory landscape and new payment models as digital health solutions are gaining popularity, such as growth of virtual-first health plans, Hospitals without Walls program, permanent telehealth changes etc.

In this emerging value-based world, medical technologies¹ continue to have an important role to play in delivering product and service innovations that can enable more effective care delivery and improve patients' lives. However, there are new challenges for all stakeholders – patients, providers, payers, and medical technology developers – in ensuring the appropriate adoption of technologies and services, as well as continued investment to develop and bring valuable innovations to patients and clinicians. While evolving policies tend to drive reimbursement and national payers seem inclined toward paying for digital solutions, many uncertainties remain for payers in the reimbursement of digital technologies, including challenges as to whether a digital technology poses risks for patients, is cost-effective, substitutes for clinicians' work, etc.

New risk-sharing and shared-savings systems are prompting providers and payers to re-evaluate their own performance, including how they select and use medical technologies. The new payment models often include incentives for providers to consider longer episodes of care beyond the traditional FFS “transaction” in a single setting, and define performance based on quality, cost, and patient experience metrics.² As financial risk is transferred from payers to providers, providers are entering a new era of cost-awareness and cost pressure. As a result, decisions about adopting medical technologies are under increasing scrutiny and individual clinician preferences are playing a lesser role than previously.

The MedTech industry's ability to continue to develop life-changing innovations will rely on demonstrating how medical technologies fit under the new value-based paradigm.

MedTech innovators are exploring new ways to partner with providers and payers and are offering services and solutions – used in combination with the product – in order to improve health care quality at a lower cost. Today, it is a business imperative for medical technology developers to understand, demonstrate, and clearly articulate how their offerings can improve patient outcomes and help health systems and payers create value. In this paper, the range of ways in which medical technologies can impact the quality and cost of care are referred to as “value drivers.”

Different stakeholders care about and prioritize different but overlapping sets of value drivers, against which they judge a medical technology's benefits. Therefore, medical technology developers must understand and speak effectively to each stakeholder's unique set of value drivers. This may require new insights into how a technology can improve the effectiveness and efficiency of care delivery for providers or payers, and how it goes beyond improving clinical outcomes for a patient population to deliver non-clinical patient benefits such as ease of recovery and reduced burden on caregivers.

Multiple frameworks³ already exist to assess the value of a life sciences product. These have been developed by organizations such as the American College of Cardiology – American Heart Association (ACC-AHA), American Society of Clinical Oncology (ASCO), the Institute for Clinical and Economic Review (ICER), Memorial Sloan Kettering Cancer Center, the National Comprehensive Cancer Network (NCCN), the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), and more. Most of these frameworks were not specifically developed to assess the value of medical technologies. Since then, the American Medical Association (AMA) developed in 2021 a “Return on Health” framework⁴ focused on articulating the value of virtual or digitally enabled care, pointing to the growing importance of digital technologies in health care delivery.

¹ Medical technologies initially covered in this value assessment approach include device-based offerings, imaging, and diagnostics. A paper on a value assessment approach with considerations specific to diagnostics has been developed and released separately.

² Examples of new reimbursement models from the Centers' for Medicare and Medicaid Services (CMS) include the older models such as Medicare Shared Savings Programs (MSSP), Next Generation Accountable Care Organization (ACO), as well as an increasing number of bundled payment programs such as the Bundled Payments for Care Improvement (BPCI) Initiative, the Comprehensive Care for Joint replacement (CJR) model, and recently announced models for coronary artery bypass grafts (CABG) and surgical hip/femur fracture treatment (SHFFT).

³ For a sample of perspectives on existing value assessments, please refer to: Senior, M. 2015. Scoring Value: New Tools Challenge Pharma's US Pricing Bonanza, In Vivo. Oct. 2015. Neumann, P and Cohen, J. 2015. Measuring the Value of Prescription Drugs. N Engl J Med 2015; 373:2595-2597, NHC Patient Centered Value Model Rubric: <http://www.nationalhealthcouncil.org/sites/default/files/Value-Rubric.pdf>

⁴ American Medical Association 2021 “Return on Health: Moving beyond Dollars and Cents in Realizing the Value of Virtual Care”: <https://www.ama-assn.org/system/files/ama-return-on-health-report.pdf>

From a MedTech industry perspective, widespread implementation of these frameworks “as is” would not lead to consistently appropriate decisions on the adoption of high-value medical technologies that improve patient lives. Value assessment practices must begin to account for and give adequate weight to a medical technology’s comprehensive set of potential value drivers, including those captured by patient-centric measures. Indeed, many constituencies outside the MedTech industry are sharing their perspectives on the effectiveness of existing frameworks, with the developers of alternative frameworks recognizing the need for ongoing learning and evolution.⁵

AdvaMed and its members saw a need for assessment processes to sufficiently consider and reliably measure the breadth of ways that a medical technology can create value (“value drivers”) since some of these – beyond the traditional clinical and safety outcomes of a product – have either been ignored or not given appropriate weight in existing frameworks. Additionally, AdvaMed and its members recognized that a collaborative approach to developing guidelines and supporting practices could spur greater alignment among stakeholders – payers, providers, HTA bodies, patient advocates and medical technology companies – on the appropriate use of the various types of quantitative and qualitative evidentiary support.

In contrast to some other value frameworks in use today, AdvaMed’s value assessment approach is not intended to provide a “calculator” tool that produces a single financial estimate that weighs and combines the different contributions to value. Given the need to incorporate new patient-centric drivers of value along with other broad metrics and considerations (e.g., specific patient sub-populations, appropriate timeframes for the medical technology to be in use, differences in available supporting evidence), attempting to distill the expected impacts of a technology down to a single financial figure makes the assessment insufficiently transparent, especially for patients, and prevents the full scope of medical technology impacts from being reflected.

Guiding principles for effectively assessing value of a medical technology

AdvaMed believes that an effective process for assessing the value of a medical technology should be guided by a core set of principles and that these principles warrant adoption by all stakeholders involved in these assessments – payers, providers, HTA bodies, patient advocates, and MedTech companies.

AdvaMed members developed these guiding principles after carefully reviewing existing published principles and discussing real-world practices and experiences. The principles have been reviewed and discussed with multiple payers, providers, and patient groups. To date, there has been general agreement that these principles are consistent with the prevailing philosophies at other stakeholder organizations, and that they represent a practical summary of the most important factors in making effective decisions.

These principles cover both specific aspects of determining expected impacts (such as what types of value and costs to include) as well as the nature of the assessment process itself (such as the degree of transparency into how the assessment is conducted). A summary of the proposed principles is shown in Figure 1.

These guiding principles can serve as a foundation for determining how to assess effectively and equitably the value of a medical technology. Individual organizations could design their specific technology assessment process to meet these overarching principles while still differentiating in their assessment processes and supporting methodologies.

⁵ For example see Forbes article on Value Frameworks’ Role In Shaping Sustainable Patient-Centric Healthcare, AMA’s effort to re-envision the value framework for virtual care, or [ICER’s national call for comments to its value assessment framework](#)

Figure 1. Principles for Effective Value Assessments

| Principle | Summary Description | Detailed Description |
|--|---|---|
| The Comprehensiveness Principle | Value assessments should consider a broad array of patient-centric value drivers and their relevance and importance for different stakeholders. | <ul style="list-style-type: none"> Value drivers under consideration should include both clinical and non-clinical sources of value, as well as the corresponding metrics that will be used to track them. The assessment should take into account the relevant stakeholder(s), their incentives and priorities, and how the value drivers of a technology align with those priorities. |
| The Evidentiary Principle | Value assessments should utilize an appropriate range of available evidence and the type of evidence and assessment methodology should be based on technology type and the potential risk to patients. | <ul style="list-style-type: none"> The assessment should acknowledge that there are several types of evidence which, on their own or in combination, can serve as appropriate evidentiary support, including patient-centered and patient-generated data. The level and types of evidence needed for assessment will depend on the technology's overall risk, product approval pathway, special payment provisions, or special coverage or coding considerations. The assessment approach should allow a novel product with high expected value to be available for patient care while further evidence is generated, even if there is limited evidence at approval/ launch. This may require new ways of partnering to accumulate evidence and support adoption of the technology with the appropriate patient populations. |
| The Cost Principle | Value assessments should consider and report costs incurred and costs avoided over timeframes appropriate for the technology (including, where available, costs incurred and avoided outside the health care system). | <ul style="list-style-type: none"> The assessment cost analysis needs to look at two aspects of cost – costs incurred and costs avoided over time. While cost incurred is a relatively straightforward calculation, analysis of costs avoided should encompass multiple metrics resulting from benefits such as elimination of follow-up and revision surgeries, reduced length of stay (LOS), fewer days off work, etc. Incurred and avoided costs should cover all of the health care delivery system costs for payers, providers, and patients. These include general health care costs and savings, as well as other types of costs and savings outside the health care system, such as lost time at work, personal care costs, etc. The cost impact of adopting a new technology should be included (such as taking staff away from patient care for training on a new technology). |
| The Specificity Principle | Value assessments should account for representative patient populations and applicable timeframes for patient impact. | <ul style="list-style-type: none"> The assessment should view the value drivers of a medical technology over a time frame that is appropriate to capture the extent of the benefit to a patient beyond the immediate episode of care. The value analyses need to capture not only the impact, but also how that impact accrues value over time. The assessment should consider how value drivers can vary for different patient populations (e.g., a knee replacement which lasts 20 years typically represents a higher value for patients under 60 than for those above 80. The value propositions for the two groups would be different). |
| The Flexibility Principle | Value assessments should be flexible to account for different types of medical technologies and utilize an appropriate range of impact analyses. | <ul style="list-style-type: none"> Results of a value assessment should include quantified estimates but should not force-weight and arbitrarily sum across categories of value or discard relevant qualitative analyses. Choices on how best to summarize impact across different value drivers will depend on the specific technology and its unique profile of value – for example, what is useful to aggregate into financial quantifications and where to keep original metrics distinct. |
| The Engagement Principle | Value assessment processes should involve the perspectives of multiple stakeholders and provide sufficient opportunities and time for all to engage in the process. | <ul style="list-style-type: none"> The assessment should include the perspectives of multiple stakeholders, from initiation through completion. The assessment should represent the value drivers that are important for each stakeholder in addition to the standard assessment of clinical impact. A balanced assessment process is one that aligns the scope of assessment and depth of the process with the likely magnitude of the decision for patients and providers. The assessment can be triggered by one of several situations (e.g., hospital buyer vs. payer vs. CMS coverage vs. internal portfolio investment, etc.), each of which require a different type of engagement and conversation among stakeholders. Assessments by payers and HTA bodies should include opportunities for stakeholder comments and meetings on both draft and final assessments. |
| The Transparency Principle | Value assessment processes and methodologies should be transparent to all stakeholders. | <ul style="list-style-type: none"> The assessment should be characterized by complete transparency, and thorough documentation of the entire assessment process and underlying key assumptions and methodologies. Thorough documentation of the entire assessment process includes, but is not limited to, how/ why the assessment process was initiated and developed, who was involved, its purpose, and the decision-making process for reaching final assessments based on the value analyses. |
| The Relevancy Principle | Value assessments should be updated regularly to keep pace with innovation in standards of care or when there is significant new evidence. | <ul style="list-style-type: none"> The assessment should be updated regularly to keep pace with the rapid changes characteristic of the MedTech industry. These changes usually take the forms of newly available technologies, such as digital technologies, as well as developments in alternative (non-technology) treatment choices and standards of care. |

Translating the Principles into Effective Value-Based Decisions

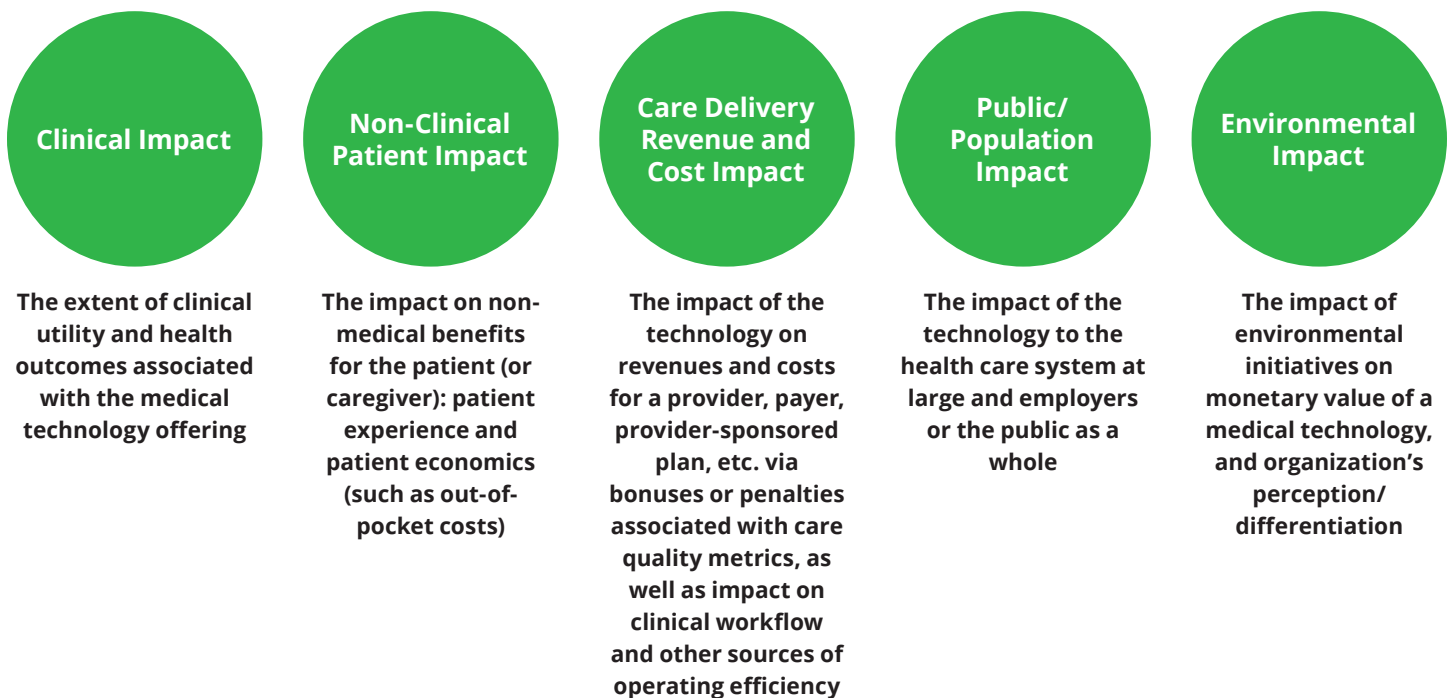
1. Capturing the full spectrum of value that a medical technology contributes

The AdvaMed approach to value assessment identifies five broad categories of “value drivers” to be incorporated in the assessment process in order to capture the full spectrum of ways a medical technology may have impact (Figure 2).

These categories go beyond traditional clinical efficacy to capture newer patient-focused and ESG-focused considerations. They consider the impact on the effectiveness and efficiency of care delivered under new value-based performance metrics and reimbursement models. And while health economics and outcomes research (HEOR) experts have long analyzed societal impact in different ways, there is

increased emphasis on improving the health of populations as providers take on risk for patients over longer timeframes and payers are incented in new ways for both their commercial and Medicare populations. Disparities in health outcomes and related access to care across patient sub-populations are also becoming more transparent, leading to a new focus on finding ways to address the root causes of these and measure results. Moreover, environmental impact is also becoming a relevant consideration for various stakeholders for value assessment of a medical technology, although at a very nascent stage. Ultimately, these categories directly align value assessments with health reform initiatives to improve the patient care experience, improve population health, and reduce the per-capita cost of health care.

Figure 2. Five broad value categories



It is important to recognize that these five categories are relevant across the health care ecosystem and are intended to reflect the perspectives and priorities of many different stakeholders – payers, providers, new “at-risk” providers who must think like payers, government agencies and, of course, patients, caregivers, and patient groups. These stakeholders are highlighted in Figure 3.

While all stakeholders place a high value on clinical impact, they also value the categories identified in this framework –

but they may prioritize them differently. As market dynamics and priorities shift under emerging value- based payment models, the prominence of patient-centric measures is growing. Providers are also beginning to look at efficiency in new ways, including analyzing opportunities across the care continuum – not just within a specific institution or site of care. Stakeholders will likely continue to prioritize categories in different ways but there is now a greater push to emphasize these broader drivers of value – especially patient-centered measures – across all stakeholder groups.

Figure 3. A schematic of key stakeholder groups



2. Ensuring that robust analyses underpin the value assessment

AdvaMed believes that an effective assessment process will result in a final analysis of the expected “value proposition” that:

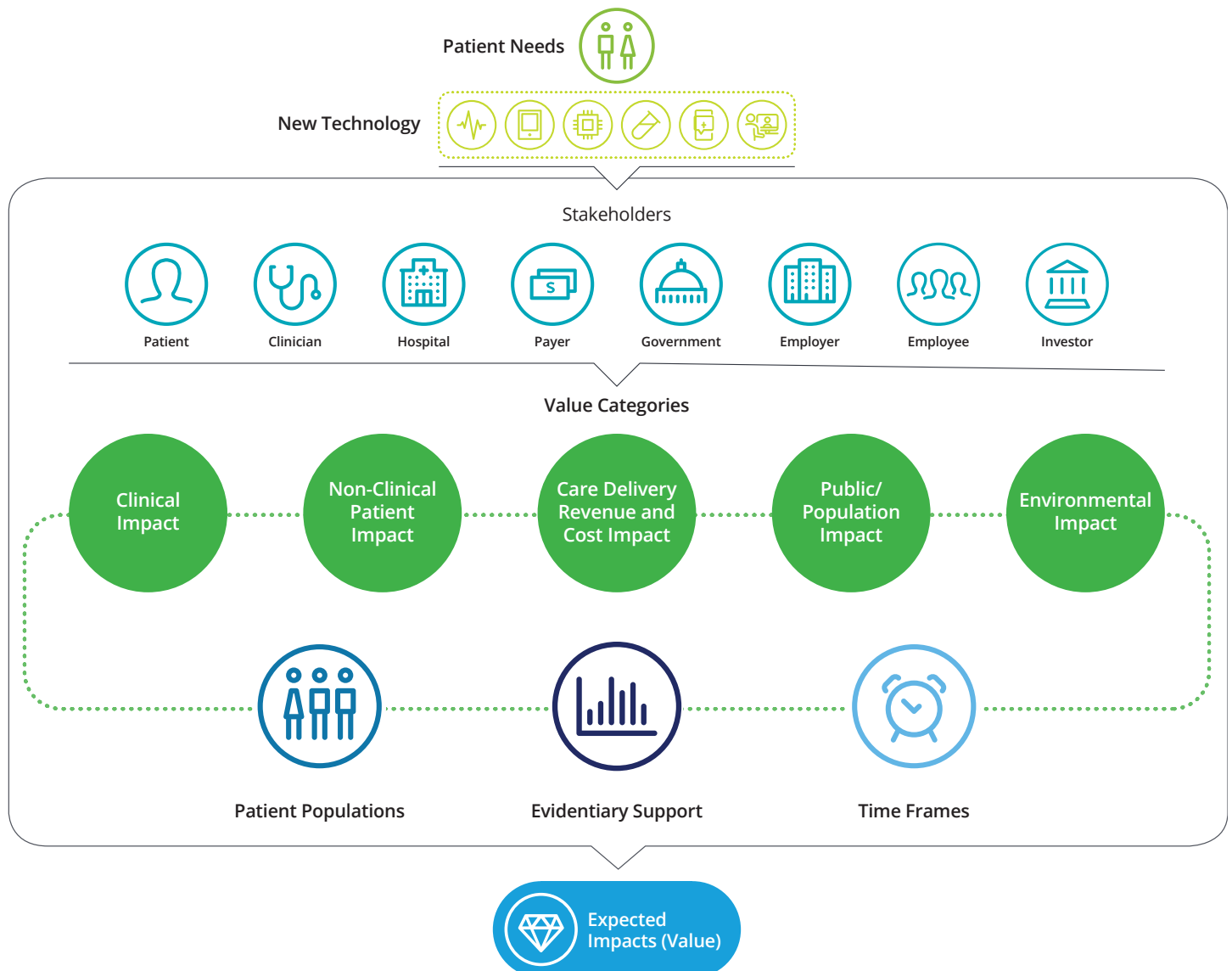
- Details the ways a medical technology will deliver an impact, together with scenarios describing the cumulative impact (measured against both quantitative and qualitative metrics, where appropriate). Economic effects of adoption include the cost of acquiring the technology and other costs (such

as changes to existing care protocols which require staff training prior to implementation) as well as offsetting savings, or reduction in environmental impact from waste generated in packaging or sterilizing;

- Considers the range of relevant time-frames over which the impact is expected to occur; and
- Acknowledges relevant patient sub-populations if impacts are likely to be significantly higher or lower than those for patients included in the baseline assessment.

A schematic of this is shown in Figure 4.

Figure 4. Comprehensive approach for assessing MedTech value



This expected value proposition should be explicitly tied to available, credible, evidence that supports the estimated impacts. The type of evidence that is appropriate and available will vary by value driver and the specific purpose of the assessment.

The timeframes over which a technology provides impact are important to consider and document. For medical technologies, impact should be assessed beyond traditionally relevant health system timeframes (e.g., an acute care episode or 90-day bundled episodes of care). In many cases, the value of a technology to the patient accumulates over a much longer period of time, and this should be considered in the value assessment. This is particularly relevant in today's value-based care models, in which payers and providers take on more risk, serve populations for longer time periods, and are given incentives linked to longer-term outcomes.

As noted earlier, the results of an effective value assessment include quantified estimates but do not assign higher values to one value driver category over another, and do not sum impacts across categories of value. Analyses may include sources of impact that cannot be easily (or usefully) quantified; but, nevertheless, are worthy of consideration when analyzing potential choices. In developing the assessment, choices on how best to summarize impact across different components of value (i.e., what to aggregate into financial quantifications and when to keep original metrics distinct) will depend on the technology and its unique value profile.

With the intensifying scrutiny on value, for many decisions it will be of increased importance to call out the core assumptions that are being made during decision-making – about the medical technology, alternative technologies and therapies, specific situation (for example, a provider health system's operations), and patient populations. Not only should these assumptions be clear, but the procedures followed in creating these assumptions, tying them to available evidence, and discussing sensitivities and scenarios should be articulated and well-understood.

3. Aligning on how to define and measure value drivers

AdvaMed's approach uses the five categories of value drivers to define the ways that technology can create value and includes sample questions and metrics to consider in building or assessing the value proposition of a specific medical technology offering. These questions and metrics indicate how multiple factors can be combined to capture the unique value profile of a particular offering. It is expected that any one technology will not have impact across all factors. The following five charts summarize sample questions and metrics.



Clinical impact

The clinical impact assessment captures three subcategories of unique value drivers: sources of value created by clinical

efficacy and effectiveness, patient safety and tolerability, and quality of life.

| Value Category | Value Subcategories | Value Drivers | Sample Questions to Consider | Sample Value Metrics |
|-----------------|-------------------------------------|---|---|---|
| Clinical Impact | Clinical Efficacy and Effectiveness | Improvement in clinical outcomes (disease-specific morbidity measures, reduction in mortality, reduction in rate of disease progression, and reduction in the burden of follow-up care) | <ul style="list-style-type: none"> How does the technology affect clinical outcomes compared to other treatment options (whether vs. direct competitive offerings or vs. alternative treatments or care plans)? How does the technology impact the rate of disease progression? How does the technology impact the burden of follow-up care (short- and long-term), function, activities of daily living (ADLs)? How does the technology change patient recovery time and/or post-surgical care (e.g., number of follow-ups, intensity, site of care, rehabilitation)? How does the technology ensure care gaps are closed (e.g., via data-driven personalized care, preciseness of care delivery)? How does the technology improve clinical decision-making (e.g., with access to patient data, interoperability)? How does the technology provide real-world economic and clinical value in various settings (e.g., acute sites)? How does the technology ensure that needs of different sub-populations including under-represented population, are accounted for? | <ul style="list-style-type: none"> Survival rate (e.g., overall survival, progression-free survival) Morbidity endpoints based on disease progression (e.g., disability/mobility ratings like Framingham score, Kaplan Meier score) Length of time to reach key recovery milestones (e.g., ADL milestones) Degree of invasiveness Number/severity of post-care complications Readmission rates; Hospital Compare scores Hospital-acquired infection rates Number of follow-ups Number of repeat procedures (e.g., revision surgeries) Utilization of various categories of services (e.g., post-acute care) Incremental Clinical Effectiveness Ratio (ICER) Time to serve patient (e.g., 4 min response for stroke) Number of visits to correct diagnosis Number of ED visits Reduction in patient transfers |
| | | Improvement in compliance with plan of care | <ul style="list-style-type: none"> How does the technology influence patient compliance or engagement in their plan of care? | |
| | Patient Safety and Tolerability | Improved patient safety and tolerability vs. alternative treatments | <ul style="list-style-type: none"> How does the technology impact patient safety (lower/higher risk of complications, less/more invasive, etc.) relative to available alternatives? What is the effect on patient risk tradeoffs? | <ul style="list-style-type: none"> Incidence or rate of adverse events Severity of adverse events and side effects Usability |
| | | Effect on patient risk tradeoffs based on safety profile and outcomes | | |
| | | Impact on security and privacy (technology and data) | <ul style="list-style-type: none"> How does data security and privacy compare to other available alternatives? | <ul style="list-style-type: none"> Frequency of data breaches Compliance to data security and privacy standards (e.g., HIPAA rule) |
| | Quality of Life | Improvement in quality of life (physical and social well-being) | <ul style="list-style-type: none"> How does the technology address regaining function, including mobility, re-integration into daily life, improvement in activities of daily life, etc.? How does the technology impact quality of life (physical and social well-being) in the short and/or long term? | <ul style="list-style-type: none"> Quality-adjusted life years (QALY)# Disability-adjusted life years (DALY) # Health-adjusted life expectancy# Quality-adjusted life expectancy# Patient perceived/reported outcomes (PROs) – across physical, mental (emotional), and social health measures (e.g., SF12, SF36, EQ5D) Caregiver-perceived outcomes (caregiver ratings of patient QOL using utility indexes such as the European Quality of Life-5 Dimensions Scale – a global QOL visual analogue scale) # Commonly accepted clinical impact metrics |

Non-clinical patient impact

The assessment of non-clinical patient impact aligns two subcategories of value drivers: 1) Sources of value stemming from patient experience and 2) Patient economics. These can be specific to the patient population being treated as well as inclusive of value to family members or caregivers. Some of these patient-centric or

patient-reported value drivers are tracked and measured using qualitative versus quantitative sources (e.g., patient satisfaction scores, case studies). While the metrics are not always easily or robustly quantifiable, they are measurable and important, and should be accounted for in impact assessments.

| Value Category | Value Subcategories | Value Drivers | Sample Questions to Consider | Sample Value Metrics |
|-----------------------------|---------------------|--|---|--|
| Non-clinical Patient Impact | Patient Experience | Preferable site or channel of care (ease of access) | <ul style="list-style-type: none"> Does this technology create more/less preferable options for the patient (e.g., more accessible care settings, less intensive care settings)? Does this technology increase convenience (both short and long term) to patients and allow faster and easier access to care (e.g., reduced waiting or commute time)? | <ul style="list-style-type: none"> Patient preferences (e.g., preference for care settings) Median travel time for patient Wait time for patient Time invested in follow-up care by patient |
| | | Effect on patient's active engagement in self-care journey | <ul style="list-style-type: none"> How does the technology improve patient's access to easy-to-comprehend data and actionable insights to enable them to stay informed of their health? How does the technology help improve patient adherence to the treatment (e.g., via patient assistance mHealth apps)? | <ul style="list-style-type: none"> Medical adherence (self-reported, proportion of days covered, etc.) Daily Active Users Customer Experience Score Task Completion Rate (for patient) Net Promoter Score⁶ |
| | | Predictability of care/ experiences vs. expectations | <ul style="list-style-type: none"> How does the technology impact the patient experience? How does the technology contribute to the patient, family, and caregiver experience of care related to quality, safety, and access across settings? How does the technology enable patients and their families and caregivers to navigate, coordinate, and manage their care appropriately and effectively? How does the technology address predictability of care? | <ul style="list-style-type: none"> Number, intrusiveness of follow-ups Number of repeated procedures Patient experience evaluation metrics (e.g., Hospital Compare ratings, CAHPS) |
| | | Reintegration/ reengagement of patient into society | <ul style="list-style-type: none"> How does the technology affect ADLs, mobility, returning to work, etc.? | <ul style="list-style-type: none"> SF 36 Caregiver quality of life (physical, social, financial, etc., as contained in the Zarit Burden interview and other indices) |
| | | Reduced burden on caregivers due to better patient experience and outcomes | <ul style="list-style-type: none"> How does the technology reduce the burden on caregivers and improve ease of use/adoption of technology? | <ul style="list-style-type: none"> Time invested by caregivers |
| | Patient Economics | Impact on out-of-pocket (OOP) patient expenses | <ul style="list-style-type: none"> How does the technology impact affordability of treatment/OOP expense for different patients? Does the technology enable early intervention and provide more efficient or precise care, reducing overall cost? Does the technology have price transparency⁷ allowing patients to make an informed provider choice? | <ul style="list-style-type: none"> OOP cost to patient/family over the course of disease progression and treatment |
| | | Reduced time to return to ADLs | <ul style="list-style-type: none"> Does the technology help the patient return to ADLs and, therefore, the workforce faster? Does the technology require less one-to-one care and patient monitoring, which will decrease caregiver/nursing expenses? | <ul style="list-style-type: none"> Patient recovery milestones (e.g., ADLs, walking, time to return to work) |

⁶ [Net promoter score \(NPS\)](#) is a widely used market research metric for the measurement of customer loyalty and satisfaction that is based on a single survey question asking respondents to rate the likelihood that they would recommend a company, product, or a service to a friend or colleague.

⁷ [Transparency in Coverage Final rule by CMS, effective 2022](#), requires insurers to disclose the rates they have negotiated with participating providers for all covered services and items, as well as the allowed and billed amounts for out-of-network providers.

Care delivery revenue and cost impact

Care delivery revenues and cost impact consider the economic impact to the health system of both the immediate episode of care and long-term disease progression. These measures can include impacts on system efficiencies, comparisons of 30- 60- and 90-day episodes (instead of single

procedure cost), and impacts to operational factors such as length of stay (LOS) and readmissions. Two subcategories of this value driver include sources of value resulting from improving quality of care economics and care efficiency.

| Value Category | Value Subcategories | Value Drivers | Sample Questions to Consider | Sample Value Metrics |
|---------------------------------------|--------------------------------|--|--|---|
| Care Delivery Revenue and Cost Impact | Quality of Care Economics | Economic impact of performance-based reimbursement metrics (e.g., hospital-acquired infections, readmissions, LOS, cost efficiency) | <ul style="list-style-type: none"> How does the technology enable the right choice of treatment, for the right patient, at the right time, at the right place? How does the technology impact the economics associated with the quality of care provided? What are the direct and indirect cost benefits of improved quality of care? | Costs related to: <ul style="list-style-type: none"> Incidence/severity of post-care complications Rate of readmissions, especially unplanned/preventable; Hospital Compare scores Incidence/rate of hospital-acquired infections and pressure ulcers Number of follow-ups Number of repeat procedures (revision surgeries) Reduced harm from inappropriate or unnecessary care LOS Use of post-acute care and other categories of services Patient satisfaction scores (e.g., based on expectations met, comfort) Errors in triage |
| | Care Efficiency and Experience | Economic impact of improved system throughput and workflow/ efficient time and resource utilization (clinician's time and effort, automation, disposable utilization, site of care, staff utilization, OR utilization, service / maintenance, LOS, time in ICU/ED) | <ul style="list-style-type: none"> How does the technology affect costs related to system throughput, workflows, device/ technology setup and maintenance, and care efficiency (site of care, staff)? What are the meaningful reductions in time and resource utilization for the system in the short term and long term? How does the technology affect costs based on the reduction of patient no-shows, elimination of waste and unnecessary procedures? How does the technology affect the administrative efforts and staff utilization in managing data (e.g., duplication, documentation)? How does the technology impact care productivity and capacity to grow revenue by new patient acquisition and improved retention? | Costs related to: <ul style="list-style-type: none"> Number and types of services used Utilization of less-expensive services Patient flow (i.e., overall impact on system efficiency) Procedure times Consumption of materials Human resource and staff/OR utilization Length of recovery time Patient no-shows Average late visits by patient Set-up and operational cost of technology Time and resources in administrative tasks (e.g., documentation, coordination) Technological issues, such as service outages, etc. |
| | | Impact of costs associated with clinical outcomes variance | <ul style="list-style-type: none"> How does the technology help reduce costs associated with variance in clinical outcomes across individual clinicians/sites of care? | <ul style="list-style-type: none"> Costs associated with clinical outcomes variance |
| | | Economic impact of improved adoption of new care practices (due to easier/more effective training/ education or easier access/usage of data and technology) | <ul style="list-style-type: none"> How does the technology affect costs based on the improvement in adoption of new care practices due to improved ease of use? How does the technology impact the economics associated with clinician engagement and satisfaction (e.g., easier data access, improved workflow visibility and management, etc.)? | <ul style="list-style-type: none"> Training and education time (hours) and costs Clinician turnover Clinician engagement with work Perceived effectiveness of technology Perceived ease of use of technology |

Public and population impact

This category considers the impact of a technology's introduction for large segments of the patient population on overall population health, as well as health care systems' costs to society on a macro level. The assessment

focuses on two subcategories of value drivers: sources of value linked to population health and workforce productivity.

| Value Category | Value Subcategories | Value Drivers | Sample Questions to Consider | Sample Value Metrics |
|------------------------------|------------------------|---|--|---|
| Public and Population Impact | Population Health | Improved population health (burden of illness/ disease) | <ul style="list-style-type: none"> How does the technology impact overall public and population health measures (e.g., life expectancy free of disability)? | <ul style="list-style-type: none"> Quality-adjusted life years (QALY) (population) Disability-adjusted life years (DALY) (population) Health-adjusted life expectancy (population) Quality-adjusted life expectancy (population) Overall survival Child mortality |
| | | | <ul style="list-style-type: none"> How does the technology address any socioeconomic disparities in care? Does the technology address patient clinical outcomes, improve quality and safety due to health disparities? Does the technology help improve patient, family, caregiver, and clinician experience due to health disparities? How does the technology impact patient access to care (e.g., access across geographies, at home, due to socioeconomic barriers etc.), including equitable access to health technology and data? How does the technology help people re-engage in society? | <ul style="list-style-type: none"> Rate of utilization across socioeconomic categories Cost of serving underserved population Patient access (# of patients) Percentage of patients who delay care due to access barriers Time to return to work Function/ADLs |
| | | Impact to overall private and public health care cost | <ul style="list-style-type: none"> How does this technology impact overall health care costs, private and public? Does the technology impact overall health care costs and efficiency by addressing health inequities as one of the key drivers? | <ul style="list-style-type: none"> Overall health care cost (\$) per capita |
| | | More efficient private and public spending | <ul style="list-style-type: none"> How does the technology help lower unnecessary private and public spending? How does the technology help in targeted spending to meet population health goals via access to quality data/trends (ease of data interpretation, actionable insights, etc.)? How does the technology help manufacturers improve device based on data-driven insights? | <ul style="list-style-type: none"> Amount of public spending (\$) Reproducibility (same outcome when two different medical staff use the technology) Accuracy (same outcome if the technology is used more than once) |
| | Workforce Productivity | Increased employee productivity (reduced absenteeism, improved presenteeism) | <ul style="list-style-type: none"> How does this technology impact employee productivity and attendance? How does the technology impact employee's general health and wellness and provide a sense of purpose? Does the technology have an impact on the organization's ESG value proposition, which in turn positively affects employee's sense of purpose/belonging and attraction/retention towards the company? | <ul style="list-style-type: none"> Employee absences (#) Presenteeism Time to return to work |
| | | Increased caregiver productivity (reduced absenteeism, improved presenteeism) | <ul style="list-style-type: none"> How does the technology impact ability for caregiver to provide care, and address productivity and attendance? | <ul style="list-style-type: none"> Caregiver absences (#) Presenteeism |

Environmental Impact

The environmental impact category is a recent addition to the value framework. This category is added as ESG initiatives with a focus on environment are increasingly gaining momentum as it impacts various stakeholders.

This value category measures the impact technology has on environment by analyzing the monetary impact, and impact on perception and differentiation.

| Value Category | Value Subcategories | Value Drivers | Sample Questions to Consider | Sample Value Metrics |
|----------------------|--------------------------------|---|--|--|
| Environmental Impact | Monetary Impact | Impact on cost due to environmental initiatives and execution | <ul style="list-style-type: none"> How does the technology impact cost reduction due to environment-friendly initiatives in manufacturing, packaging, use, and disposal of devices? | <ul style="list-style-type: none"> Single-use plastic usage Waste generated in packaging or sterilizing Waste generated in upstream and downstream process due to device use Energy reduced by using device over alternatives Total energy and percentage of renewable energy used in manufacturing |
| | | Increased asset optimization by capital allocation in sustainable devices | <ul style="list-style-type: none"> How does the technology enhance investment returns over a given period (e.g., extended life of a medical device)? | <ul style="list-style-type: none"> Device longevity Recyclability of device Availability of closed-loop recycling |
| | Perception and Differentiation | Impact of reduced net global emissions on company value proposition | <ul style="list-style-type: none"> How does the technology support sustainable practices which lead to reduced net global emissions, improving stakeholder perception, and value differentiation? | <ul style="list-style-type: none"> Green House Gas emissions Water usage Safety of materials and packaging |
| | | Reduction in regulatory, legal, and activist shareholder interventions | <ul style="list-style-type: none"> How does the technology help in compliance with environmental best practices, reporting environmental metrics, and price transparency? | <ul style="list-style-type: none"> Financial penalties Claims for compensation Legal costs |

4. Drawing on an appropriate body of evidence for effective assessment

As noted in the context section of this paper, medical technology companies recognize that payers and providers are intensifying their scrutiny of medical technology choices and are changing their expectations regarding the level and types of evidence used to demonstrate value. The desires to keep the patient “first” and to better incorporate the patient perspective in value assessment methodologies are gaining broader stakeholder acceptance and changing the dialogue on appropriate types of evidence to consider.

Much has been written about the range of unique challenges in developing and assessing the value of medical technologies.⁸ Evidence used in value assessment for medical technologies should reflect the diversity of medical technologies available for patient care, and how the technologies are seldom standalone solutions; rather, they are embedded in complex processes of care that involve a variety of different health care providers who have different levels of experience with the technology. In addition, medical technologies typically go through rapid innovation cycles that result in improvements to products once they come to market and providers acquire experience in using them. This iterative product lifecycle must be accommodated in evidence generation and analysis.

The Evidentiary guiding principle (shown earlier in Figure 1) summarizes AdvaMed’s assertion that there are multiple types of evidence which, independently or collectively, can serve as appropriate evidentiary support for effective assessment analyses of medical and diagnostic technologies. Over-reliance on randomized controlled trials (RCTs) may limit the types of value impact that can be effectively investigated, so consideration of a variety of appropriate evidence is necessary. AdvaMed identified multiple approaches to developing evidence that may be considered appropriate in addition to, or in place of, RCTs. These include a range of observational studies that generate “real-world” evidence as well as Expert/KOL Review/Consensus Statements, and patient-reported outcomes (PRO) – see page 20.

In the process of creating comprehensive frameworks for assessing the value of both medical technologies and diagnostic tests, AdvaMed developed a set of evidence guidelines, “**Understanding Evidence on the Value of Medical Technologies,**” as a supplement to these framework documents to further describe its approach to evidence development and use. These guidelines are especially important given the diversity of medical technologies and the different lifecycle stages where evidence may be used in assessment (from pre-approval to long-term patient usage after initial market adoption).

A set of recommendations that emerged during discussions with AdvaMed members and stakeholders is summarized below and expounded on in the evidentiary paper:

- There is a growing need and ability to incorporate patient perspectives in value assessment. Metrics for collecting patient-generated perception and preference data must be accounted for to achieve patient-centric impact, even if agreed-to methodologies are still emerging and data are measured using qualitative versus quantitative sources.
- Expectations for evidence should align with the goals for using the evidence that is generated. Risks to patients and the practical limitations of evaluating the technology in a study should align with the intended goals for using the evidence, regardless of the research methods used. Generally, the weight of evidence should be commensurate with the level of resources that are expected to be invested by payers, providers, and patients to successfully adopt the technology. Thus, if the medical technology company desires reimbursement for an innovative technology which has expected high impact for patients but requires significant changes to current standards of care or where increased reimbursement is sought, the burden of evidentiary support for the value of the technology will likely be higher.

⁸ “Challenges in Developing and Assessing Comparative Effectiveness for Medical Technologies,” Price, R., and Long, G.

- The assessment approach should allow a novel product with high expected value to be available for patient care while further evidence is generated, even if there is limited evidence at approval/launch. Historically low diffusion rates for new and breakthrough technologies result in limited clinician knowledge and can negatively impact use of the new technology-- creating challenges in conducting large-scale studies.
- New ways are required for medical technology and diagnostic companies, health care providers, and payers to work together to accumulate evidence and support adoption of the technology by appropriate patients. Some shared examples suggest that stakeholders are increasingly open to this, such as piloting a technology at a limited number of care sites to develop evidence and understand provider and patient education needs before introducing the technology for use across the full health system. In another example, a payer analyzes outcomes in early cohorts of members with access to a technology; this is followed by proactive screening to accelerate delivering that technology to other patients who would likely benefit based on the accumulating evidence.
- Evidentiary methodologies must take into consideration the increasing possibility that a medical technology may not be a standalone product; it may feature new types of services to drive improved health and economic outcomes. Capturing the impact of these new offerings may require developing or adapting assessment methodologies, which may be best informed by cross-stakeholder cooperation.

Medical technology companies and diagnostic test developers understand the importance to stakeholders of a credible track record of evidence generation and will continue to adopt appropriately robust approaches as standards evolve. Companies also will continue working with stakeholders to seek agreement on how to align the evidence-generation methodology with each type of value driver.

Types of Evidence

- **Prospective Cohort Study (Longitudinal with Comparator Group):** An observational study with two or more groups (cohorts) with similar characteristics. One group receives a treatment or technology, and the other group does not. The study follows their progress over time from the time they receive the intervention, and records are reviewed at multiple intervals.
- **Prospective Studies Using Patient Registries:** Another form of prospective cohort study, but these typically would not include a prospective comparator group since only the individuals [patients] receiving the technology are included in the registry. Registries can be used to establish the hypothesis and the data elements to include in the study and then collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure.
- **Retrospective Clinical Studies Using Medical Records:** Evidence about the clinical (or other) outcomes from medical interventions is retrospectively generated from information in patients' medical records after the intervention has been delivered.
- **Retrospective Observational Studies Using Cost Data:** Claims data can be used to retrospectively collect evidence about medical technologies that may capture a broader spectrum of information, including diagnostic information, treatments given, provider type, and financial measures such as billed amounts, reimbursed amounts, and patient cost-sharing
- **Case Studies:** Case studies retrospectively compare one or more patients (aka a "series") to either similar patients (controls) or to the known natural history of patients with the condition or clinical situation being evaluated.
- **Meta-Analyses:** A method that uses statistical techniques to combine results from different independent studies and obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome – i.e., it is a statistical process for pooling data from many clinical trials to produce a stronger conclusion than can be provided by any individual study.
- **Consensus Statements:** Synthesis of many types of information by experts in a specific field based upon both the available data and their collective experiential wisdom in the clinical or technical area, using processes where different types of evidence are weighted and individuals' expertise is collectively aggregated and reported in structured formats.
- **Patient-Reported Outcome (PRO):** Report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else. Unlike more structured methodologies for collecting evidence, PRE is usually qualitative information rather than easily quantified data.
- **Randomized Control Trial (RCT):** A study in which similar subjects are randomly assigned to two (or more) groups to test a specific treatment or technology with one group (treatment group) receiving the intervention being tested and the other group (comparison or control group) receiving an alternative intervention, placebo intervention, or no intervention at all. Participants and clinicians may be blinded to which group receives which intervention.

Note: observational studies are also conducted to determine impact on operations (for example, on the time and resources needed to conduct a certain procedure). These studies are important in demonstrating the value that a medical technology can bring in terms of the efficiency of care delivered, but they require special care given the high degree of variation in operations within and across different care settings and institutions. In considering how to address this and reach generalized conclusions (where appropriate), choices on economic modeling methodologies are critically important.

Conclusion

The recommendations outlined in this paper can be used to reach a common understanding of what enables effective assessment of the value of a medical technology. These overarching principles and approach for assessing value can be adopted by medical technology companies as well as by other stakeholders involved in value assessments, including health systems and providers, payers, HTA bodies, and patient advocates. This approach identifies five broad categories that capture the full spectrum of value that a medical technology may contribute and includes important patient- focused and ESG- focused considerations. These categories apply both to traditional medical technology products and to offerings that include new types of services in combination with the product to improve health and economic outcomes for patients.

AdvaMed is committed to the goal of ensuring that patients continue to have access to and benefit from medical innovations. We encourage others to use and incorporate the principles and supporting practices contained in this paper to existing frameworks and assessment models as they evolve over time. We will continue to engage in ongoing dialogue with payers, providers, and patient groups on value assessment and the need for a broad perspective on value drivers that apply to the evaluation of medical technologies.

If you would like to provide feedback or obtain more information, please email valueframework@advamed.org, a special email box we've created for this initiative.



Looking to assess and define your medtech product's value proposition? You can download and explore [Deloitte's Value Proposition Framework services](#) here.

About AdvaMed's Strategic Value Initiative

In response to the growing need to demonstrate how medical technologies fit in to the emerging value-based paradigm for providers, payers, and patients, AdvaMed approved a 2016 Strategic Value Initiative, in collaboration with Deloitte Consulting LLP, to develop an approach to value assessment for medical technologies that can be used by medical technology companies as well as by health systems, payers, and other stakeholders. In 2022, AdvaMed and Deloitte Consulting LLP collaborated again to refresh the value assessment framework in light of market shifts and changes since 2017, especially due to advent of new digital health technologies and increasing relevance of ESG (Environment, Social, and Governance) in company's strategic approach.

AdvaMed's approach is intended to enable discussion and foster greater alignment across stakeholders on the best approaches to assess value.

AdvaMed formed a working team that included task forces of members from MedTech companies, AdvaMed staff, and Deloitte Consulting LLP specialists from a range of disciplines. It was particularly important to develop recommendations in collaboration with key stakeholders and the process incorporated discussions with many different organizations, including patient groups, payers, providers, and clinical labs. These discussions resulted in constructive refinement of the proposals as well as general agreement on the importance of this topic.

While AdvaMed appreciates the involvement and high degree of engagement from all participants, AdvaMed would particularly like to thank the task force members who committed substantial personal time and contributed significantly throughout the process.

For questions about the Value Framework, please contact Glenn Snyder, Principal and MedTech Practice Leader, Deloitte Consulting LLP, at gsnyder@deloitte.com.



AdvaMed, the Advanced Medical Technology Association, is the world's largest trade organization representing the medical technology industry. The industry comprises the companies that develop, manufacture, and distribute the technologies, devices, equipment, diagnostic tests, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments.

Based in Washington, D.C., AdvaMed has 450 member companies, operating all over the United States and world. Members range from the smallest medical technology start-ups to the largest device and technology developers and manufacturers.



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