

A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem

In Brief
May 2017



Valuing Medical Technologies in Health Care's New Value-Based Ecosystem

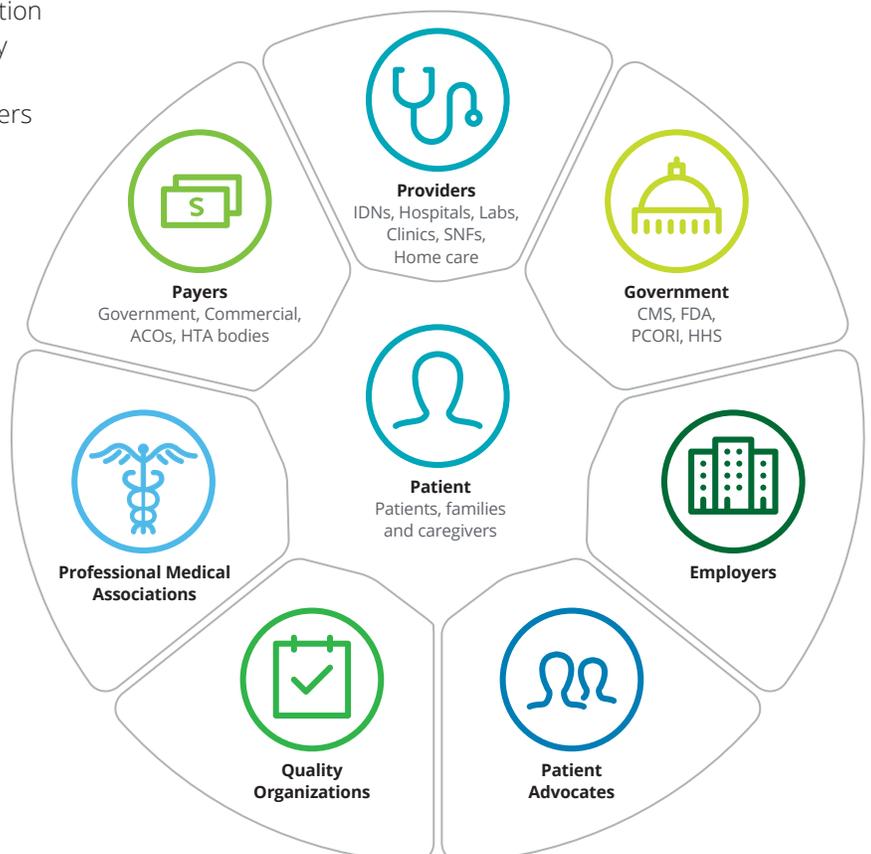
The health care ecosystem is in the midst of a major shift from volume-based, fee-for-service (FFS) systems to value-based care (VBC) models. These payment reforms shift risk from payers to providers, with the dual goals of reducing the per-capita cost of health care and improving the patient experience,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

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.

Stakeholders Assessing Value



This document summarizes AdvaMed's Strategic Value Initiative, with the principles and approach for assessing the value of medical technologies. The full report, "A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem" is available on AdvaMed's website at www.advamed.org.

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.

Multiple frameworks¹ already exist to assess the value of a life sciences product. While many of these frameworks were specifically developed to assess biopharma drugs, some have been used for medical technology product assessments. 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 sufficiently consider and reliably measure the breadth of ways that a medical technology can create value since some of these – beyond a product's traditional clinical and safety outcomes – have either been ignored or not been given appropriate weight in existing frameworks.

AdvaMed launched a Strategic Value Initiative, 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.

Guiding Principles for Effectively Assessing the Value of A Medical Technology

AdvaMed's recommended approach begins with a set of core principles that guide an effective process for 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 medtech 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 time-frames for patient impact.

¹ 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>

- **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.

These principles cover both specific aspects of determining expected impacts (e.g., what types of value and costs to include) as well as the nature of the assessment process itself (e.g., the degree of transparency into how the assessment is conducted). They can serve as a foundation for determining how to effectively and equitably assess the value of a medical technology.

Translating The Principles into Effective Value-Based Decisions

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 used in combination with a technology to improve health and economic outcomes. This approach

identifies four 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 care giver): 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.

These categories go beyond traditional clinical efficacy to capture newer patient-focused considerations and the 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 four categories are intended to reflect the perspectives of many different stakeholders although priorities may vary by organization.

Further details and additional examples of questions and metrics for assessing the unique value proposition of a specific medical technology are included in the full report, *“A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem,”* available on AdvaMed’s website at www.advamed.org.

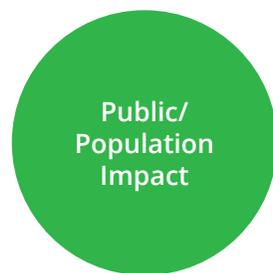
The AdvaMed approach seeks to ensure that appropriate analyses underpin value assessment. Stakeholders are interested in assessing the value of a specific medical technology, looking at the benefits to patients, providers and others, and considering the economic effects of adoption (including the cost 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:

- Details each of the ways the medical technology will deliver an impact, together with scenarios describing 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);

- 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 the scenario included in the baseline assessment.

Sample Key Questions for the Four Value Drivers



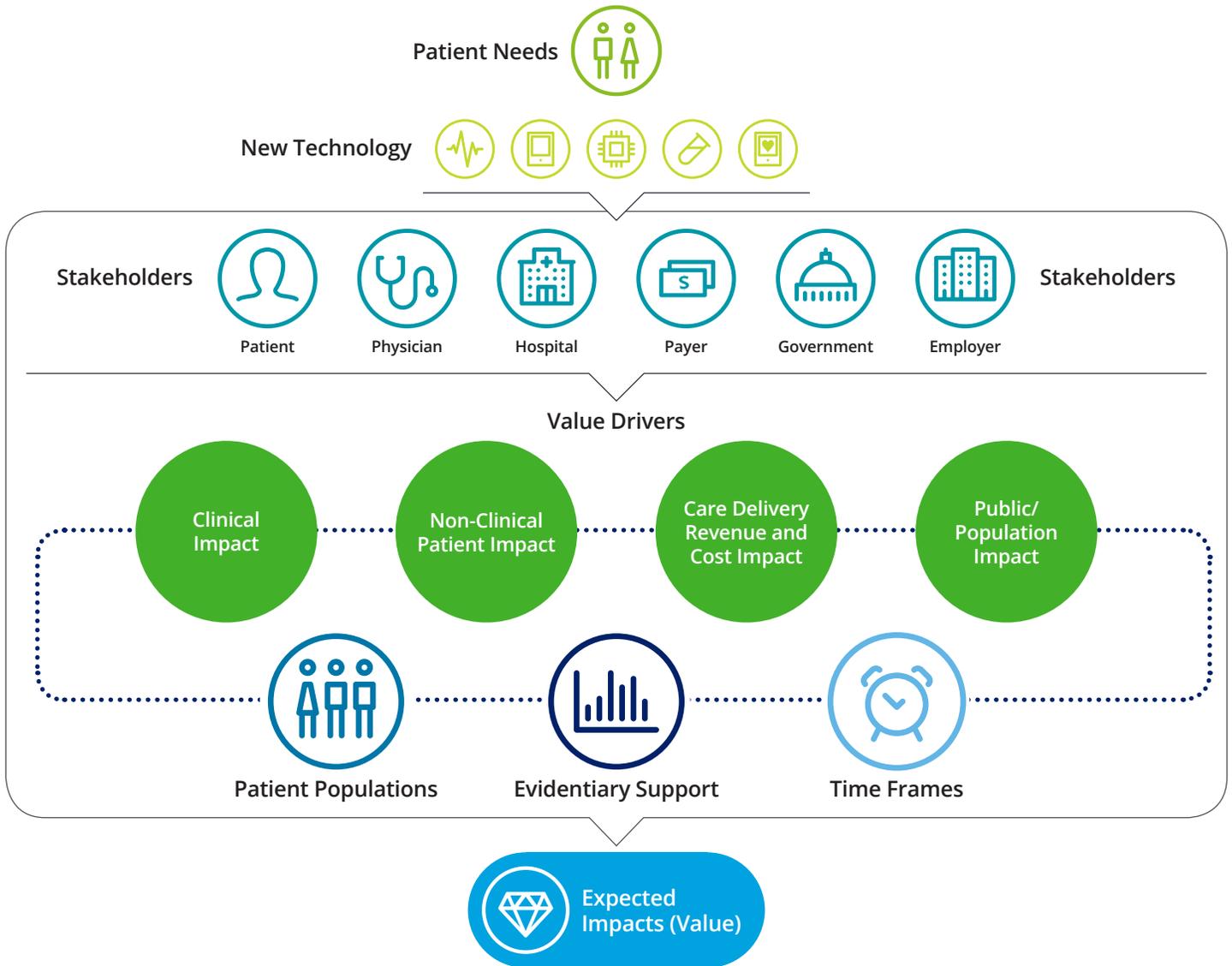
- How does the technology affect clinical outcomes, compared to other treatment options (whether with direct competitive offerings or versus alternative treatments)?
- How does the technology impact patient safety (lower/higher risk of complications, less/more invasive, etc.) relative to available alternatives?
- How does the technology impact quality of life in the short and/or long-term? (physical and social wellbeing)?

- Does this technology create more/less preferable options for the patient (e.g., more accessible care settings, less intensive care 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 impact affordability of treatment/out of pocket expense for different patients?

- 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 affect costs related to system throughput, workflows, and care efficiency (site of care, staff)?
- How does the technology help reduce costs associated with variance in clinical outcomes across individual physicians / sites of care?

- How does the technology impact overall public and population health measures (e.g., life expectancy free of disability)?
- How does the technology help lower unnecessary private and public spending?
- How does the technology impact ability for caregiver to provide care, and address productivity and attendance?

Comprehensive Approach for Assessing Medtech Value



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 evidence [PRE]). For medical technologies, over-reliance on randomized controlled trials (RCTs) may limit the types of value impact that can be effectively investigated so 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 a range of observational studies as well as expert/KOL review/consensus statements and patient-reported evidence.

Evidence used in medical technology value assessment should reflect the diversity of technologies available for patient care, and how the technologies are seldom standalone solutions; rather, they are embedded in complex care processes that involve a variety of health care providers with differing 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 gain experience in using them. Evidence generation and analysis must accommodate this iterative product lifecycle.

Ultimately, 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.

A more detailed discussion of AdvaMed's view of appropriate evidence types and their relevance for different value assessments can be found in the supplemental paper ***“Understanding Evidence on the Value of Medical Technologies”***.

In contrast to some other medtech 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.

About AdvaMed's Strategic Value Initiative

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 use and 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.



The Advanced Medical Technology Association (AdvaMed), is a trade association that leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world. AdvaMed's membership has reached nearly 300 members and more than 80 employees with a global presence in countries including Europe, India, China, Brazil, and Japan. AdvaMed's member companies range from the largest to the smallest medical technology innovators and companies. The Association acts as the common voice for companies producing medical devices, diagnostic products and health information systems.

Deloitte.

This document contains advice and recommendations that were created by Deloitte Consulting LLP for the sole benefit of AdvaMed and is not intended to be relied upon by any other party. Any use or disclosure of, or acts or omissions based upon, this document by any other party shall be the sole responsibility of such party, and neither AdvaMed nor Deloitte Consulting LLP shall have any liability with respect thereto. This document is not intended to be used for purposes of, and AdvaMed and Deloitte Consulting LLP expressly disclaim, any assurance of sufficiency or compliance, including for any business, legal, or regulatory purposes. This document contains proprietary information of AdvaMed and Deloitte Consulting LLP, and cannot be reproduced or further disclosed to others without prior written permission from AdvaMed and/or Deloitte Consulting LLP unless reproduced or disclosed in its entirety without modification.

Deloitte Consulting is not, by means of this publication, rendering accounting, business, financial, investment, legal, tax, or other professional advice or services to any person. This publication is not a substitute for such professional advice or services, nor should it be used as a basis for any decision or action that may affect your business. Before making any decision or taking any action that may affect your business, you should consult a qualified professional advisor. Deloitte Consulting shall not be responsible for any loss sustained by any person who uses or relies on this publication.

As used in this document, "Deloitte" means Deloitte Consulting LLP, a subsidiary of Deloitte LLP. Please see www.deloitte.com/us/about for a detailed description of our legal structure. Certain services may not be available to attest clients under the rules and regulations of public accounting.