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Executive Summary

The U.S. 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 diagnostic technologies¹ 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 diagnostics in improving the effectiveness of care delivery and their critical role in providing objective information to clinicians to determine appropriate medical interventions.

Diagnostics face a unique challenge compared to other medical devices and technologies in that the value of a diagnostic test or technology lies in enabling improved clinical decision-making and therapy selection, which is often distinct from the value of the underlying therapy or intervention itself. Additionally, recent years have witnessed growth in the availability and advancements of new digital diagnostic devices, e.g., incorporation of artificial or augmented intelligence (AI) and machine learning (ML) into diagnostic tests. This trend, along with a paradigm shift in industry towards Environmental, Social, and Governance (ESG) considerations, require stakeholders to assess the value of a diagnostic technology with these market changes in mind.

In this changing environment, it is a business imperative for diagnostic manufacturers to understand, demonstrate, and clearly articulate how their offerings can lead not only to improved patient outcomes but also create value for a variety of key stakeholders. There are many ways that diagnostic technologies can impact the quality and cost of care. In this paper, these are referred to as "value drivers." Different stakeholders care about and prioritize different but overlapping sets of value drivers against which they judge the benefits of a diagnostic test.

Diagnostic manufacturers must understand and speak effectively to each stakeholder's unique set of value drivers.

This may require new insights into how diagnostic testing can improve the effectiveness and efficiency of care delivery for providers or payers, and how tests go beyond improving clinical outcomes for a patient population to deliver non-clinical patient benefits, such as the patient experience during testing and patient economic considerations.

AdvaMedDx launched a Strategic Value Initiative in 2017, in collaboration with Deloitte Consulting LLP, to develop principles and an approach for assessing the value of diagnostics that can be adopted by diagnostic manufacturers, health systems, payers, and other stakeholders. The viewpoints of multiple stakeholders 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 diagnostics landscape has witnessed significant changes and advancements, especially with the advancements in digital diagnostic devices and a paradigm shift in industry towards Environmental, Social, and Governance priorities. Due to these recent market changes, the Diagnostics Value Framework has been refined and refreshed, incorporating important stakeholder viewpoints and feedback.

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

¹ The use of diagnostics tests and technologies refers to in vitro diagnostics as defined by the FDA in 21 CFR 809.3: "Those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body." This includes imaging technologies used to interrogate and analyze samples and includes in vivo imaging or testing.

- **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 test type and the potential risks and benefits to patients.
- **The Cost Principle:** Value assessments should consider and report costs incurred and costs avoided over timeframes appropriate for the test or 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 tests or 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 AdvaMedDx approach starts by capturing the full spectrum of value that a diagnostic may contribute (“value drivers”). This approach considers that the full value of a diagnostic may go beyond the traditional measure of clinical efficacy to capture additional newer patient-focused and environment-focused considerations. The value drivers also encompass the impact on the effectiveness and efficiency of care delivered under new value-based performance metrics and reimbursement models.

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

- **Clinical impact:** The extent of clinical utility and health outcomes associated with the diagnostic/imaging technology
- **Non-clinical patient impact:** The impact of diagnostic/imaging technology on non-clinical benefits for the patient (or caregiver), patient experience and patient economics (e.g., out-of-pocket costs)
- **Care delivery revenue and cost impact:** The impact of diagnostic/imaging technology on revenue and costs via bonuses or penalties associated with care quality metrics, impact on the care pathway, and other sources of operating efficiencies to payers, providers, or other risk-bearing entities
- **Public and population impact:** The impact of diagnostic/imaging technology to the health care system at-large, employers, or society as a whole
- **Environmental impact:** The impact of the diagnostic/imaging technology due to environmental initiatives, on an organization’s perception or differentiation and monetary value of a diagnostic (e.g., cost reduction in supply chain, device longevity)

Ultimately, these categories directly align value assessments with health reform initiative goals to improve the patient experience of care, improve the health of populations, and reduce the per capita cost of health care under new value-based performance systems for laboratories, providers, payers, provider-sponsored plans, and accountable care organizations.

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

- Details the ways a diagnostic test will deliver an impact, together with scenarios to describe the magnitude of the impact (against both quantitative and qualitative metrics where appropriate) and costs (such as the cost of the test, changes to existing care practice or management, training and implementation by providers, or reduction in unnecessary use of other services in the bundle, or reduction in waste generated in packaging or sterilizing)
- Reflects the unique characteristics that should be considered based on the type of diagnostic test being assessed
- Considers the range of relevant timeframes associated with testing or impact of a test, and
- Acknowledges relevant patient sub-populations that may experience significantly greater or lesser impacts than the general (intended use) population.

The flexibility of AdvaMedDx’s value assessment approach allows its use for a broad range of diagnostic test applications such as screening, detection, prognostic, theranostic, monitoring, and recurrence tests. While each of these testing applications presents unique challenges in demonstrating value in a systematic manner, the holistic nature of the value framework helps ensure continued access to all types of diagnostic innovations.

The expected value proposition should be explicitly tied to available, credible evidence that supports the estimated impacts. There are multiple types of evidence that, independently or collectively, can serve as appropriate evidentiary support for effective assessment analyses of diagnostic technologies. Over-reliance on randomized controlled trials (RCTs) limits the types of value impact that can be effectively investigated. Many diagnostics are evaluated in observational studies of comparable performance rather than RCTs, so consideration of a variety of appropriate evidence is necessary. AdvaMedDx identified multiple approaches to developing evidence that may be considered appropriate in addition to, or in place of, RCTs. A set of guidelines has been developed as a supplement to further describe this approach to the appropriate types of evidence and their relevance for different value assessments.

AdvaMedDx’s Strategic Value Initiative is an iterative process. AdvaMedDx and its members will continue to engage in ongoing dialogue with laboratories, 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, including diagnostics. As the US health care system increasingly shifts towards value-based payment models, AdvaMedDx 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 diagnostic innovations.

Background

Medical diagnostic tests and technologies are at the forefront of health care and personalized medicine. These technologies increasingly are a key component in ensuring that the right treatment gets to the right patient at the right time. Advances in life sciences and in test technologies are making diagnostics ever more central in the delivery of effective health care. It is well understood by health care stakeholders that diagnostics significantly affect clinical decision-making. Nevertheless, it is critical for diagnostic test developers to be able to demonstrate the value of their tests to a variety of stakeholders in the face of growing scrutiny and cost pressure directed at almost every health care sector.

“The core challenge is that the value of a diagnostic test or technology lies in the value of the information generated by the test, which is dependent on whether and how that information is used in a multitude of decision pathways to inform and influence care.”

Diagnostic tests are an integral part of modern medical care and can be used in a variety of settings, including clinician offices, hospitals, clinics, laboratories, urgent care facilities, and at the home of the patient. Diagnostic tests take place within a patient (in vivo) and in health care settings (in vitro) beginning as early as preconception and stretching across a patient’s lifespan. Diagnostics are unique in that they deliver objective information about a person’s health status. Some tests, for example, are used for screening purposes to determine the likelihood that a medical condition exists or will become present at some point in a patient’s life, including detecting diseases in early stages before symptoms appear.

Other tests are used to screen for, confirm, or rule out a specific diagnosis, monitor the course of a disease, or assess a patient’s eligibility for or response to specific treatments. Tests can also be used to guide the selection of further evaluations and interventions. By combining the test results with patient history and other medical information, clinicians can better work with patients to improve standards of care and treat diseases appropriately. Technological advances, miniaturization, automation, artificial or augmented intelligence (AI) and machine learning (ML), mobile health applications (mHealth), wearables, data interoperability and analytics, have made tests both easier to use and more accurate, leading to more precise, more reliable, and more timely treatment, which saves lives.

In addition to individualized, patient-level care, diagnostics can also be used to assess information at a broader population level. Examples include tests that are used to identify emerging infections, antibiotic resistance, exposure to toxic substances, and detection of chemical and biological threats. Diagnostic tests can be used during public health emergencies – often at the point of care – to provide rapid information needed to triage patients and to confirm the presence of communicable disease.

In this emerging value-based world, diagnostics continue to have an important role to play in delivering critical information that can enable more effective care delivery and improve patients’ lives. However, they present new challenges for all stakeholders – patients, providers, and payers as well as diagnostic test manufacturers – in ensuring their appropriate use and adoption and continued investment in developing and bringing valuable innovations to clinicians and patients. While evolving policies tend to drive reimbursement and national payers seem inclined toward paying for digital solutions, including diagnostics, 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.

Assessing the value of diagnostic tests and technologies presents challenges that are distinct from the value assessment of other medical devices and technologies. The core challenge is that the value of a diagnostic test or technology lies in the value of the information generated by the test, which is dependent on whether and how that information is used in a multitude of decision pathways to inform and influence care. The value of a particular test, and to whom it is valuable, will vary depending on context and actual use. The value of a diagnostic may be in enabling improved clinical decision-making and therapy selection, often distinct from the value of the underlying therapy intervention itself. Appropriate diagnostic testing not only informs patients and clinicians but can guide them toward, or away from, specific treatment options. Equipped with this knowledge, patients and their clinicians are able to make better and more informed medical decisions that are in accordance with a patient's own values, interests, and preferences. In some situations, diagnosing a condition may not change treatment choices or drive improved clinical outcomes but still provide personal or clinical utility gained from the "value of knowing."²

Diagnostics can add both clinical and societal value by reducing the amount of uncertainty around a patient's health and prognosis and increasing the transparency and expectation of care. The diagnostic industry's future success and ability to develop new innovations under the new value-based paradigm of care will rely on demonstrating the ways in which diagnostic testing delivers value for patients, clinicians, the health care system, and society at large. Some diagnostic manufacturers are exploring new ways to partner with providers and payers and offer services and solutions - beyond the traditional product manufacturer model - in order to improve health care quality at a lower system cost. These kinds of services include data analytics, improved clinical guidelines, and long-term registries to monitor that patients are receiving the appropriate care.

Today, it is a business imperative for diagnostic test developers - and in fact, for all Life Sciences manufacturers - to understand, demonstrate, and clearly articulate how their offerings can help health systems and payers create value and improve outcomes for patients.

This requires new insight into how a technology can improve the effectiveness and efficiency of care delivery for providers or payers or have impact for a patient population that goes beyond clinical outcomes, such as ease of recovery. In this paper, the breadth of different ways a diagnostic test or technology can affect the quality and cost of care are referred to as "value drivers."

While diagnostic companies are adapting, health systems, payers, and health technology assessment (HTA) groups also should move toward value assessment practices that account for and give adequate weight to a diagnostic technology's full set of potential value drivers, including those captured by patient-centric measures. This requires defining the value of a diagnostic test more broadly than by clinical and safety metrics alone. Decisions should factor in metrics and incentives associated with new reimbursement and care

"In this paper, the breadth of different ways a diagnostic test or technology can affect the quality and cost of care are referred to as 'value drivers'."

delivery models as well as the increasing emphasis on both individual patients and on the health of populations. To do this, value assessors will have to go beyond traditional health economics and outcomes research (HEOR) methodologies to estimate expected impacts using a range of types of evidence, including qualitative as well as quantitative metrics.

² Several recent publications have discussed the concept of the value of "knowing" with respect to diagnostic information, i.e., the concept that there is value in diagnostic information, such as reduced uncertainty and improved patient well-being or hopefulness, or improved health care decision-making. See Garrison L, Mestre-Ferrandiz J, Zamora B., "The Value of Knowing and Knowing the Value: Improving the Health Technology Assessment of Complementary Diagnostics," European Personalised Medicine Association (EPEMED) and Office of Health Economics (London), White Paper, June 2016; and "The Spectrum of Clinical Utilities in Molecular Pathology Testing Procedures for Inherited Conditions and Cancer," *The Journal of Molecular Diagnostics*, September 2016, Volume 18, Issue 5, pp. 605-619.

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 diagnostic tests or 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.

Widespread implementation of these value frameworks “as is” would not lead to consistently appropriate decisions on the adoption of diagnostic tests that improve patient lives. Value assessment practices must begin to account for and give adequate weight to a diagnostic test’s comprehensive set of potential value drivers, including those captured by patient-centric measures. Indeed, many constituencies outside the diagnostics 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

AdvaMedDx and its members saw a need for assessment processes to sufficiently consider and reliably measure the breadth of ways that a diagnostic test or 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, AdvaMedDx 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, laboratories, and diagnostic 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, AdvaMedDx’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 associated with the use of the test, differences in available supporting evidence), attempting to distill the expected impacts of a test or technology down to a single estimate makes the assessment insufficiently transparent and prevents the full scope of a test’s impacts from being reflected.

AdvaMedDx Approach: Guiding Principles for Effectively Assessing Value of a Diagnostic

AdvaMedDx believes that an effective process for assessing the value of a diagnostic test 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, laboratories, and diagnostic companies. AdvaMedDx 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 serve as a foundation for determining how to assess effectively and equitably the value of a diagnostic test. Individual organizations may elect to design their specific value assessment process to meet these overarching principles while still differentiating in their assessment processes and supporting methodologies.

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>

⁵ For examples see ICER’s recent national call for comments (<https://icer-review.org/announcements/improvements-value-framework/>) or ISPOR’s call for papers and stakeholder conference to gather input as part of its Initiative on US Value Assessment Frameworks (http://www.ispor.org/ViH/Call_for_Papers_value-assessment-frameworks.pdf)

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 test or 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 test type and the potential risks and benefits 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 test or technology's overall risk, product approval pathway, special payment provisions, claims, 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 test or 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 test or technology (including, where available, costs incurred and avoided outside the healthcare system).	<ul style="list-style-type: none"> The assessment cost analysis should 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 reduction in duplicate or repeat testing, elimination of unnecessary treatment, etc. Incurred and avoided costs should cover all of the healthcare delivery system costs for payers, providers, and patients. These include general healthcare costs and savings, as well as other types of costs and savings outside the healthcare system, such as lost time at work, personal care costs, etc. The cost impact of adopting a new test or 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 test or technology over a timeframe that is appropriate to capture the extent of the benefit to a patient beyond the immediate episode of care. The value analyses should capture not only the impact, but also how that impact provides immediate value (e.g., rapid results) or accrues value over time. The assessment should consider how value drivers can vary for different patient populations (e.g., how to define at-risk populations in order to limit unnecessary testing in the broader population).
The Flexibility Principle	Value assessments should be flexible to account for different types of tests or 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 test 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. Centers for Medicare & Medicaid Services [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 that are characteristic of the diagnostics industry. These changes usually take the forms of newly available tests or technologies, as well as developments in alternative testing or treatment choices and standards of care.

AdvaMedDx Approach: Translating the Guiding Principles into Effective Decision-Making

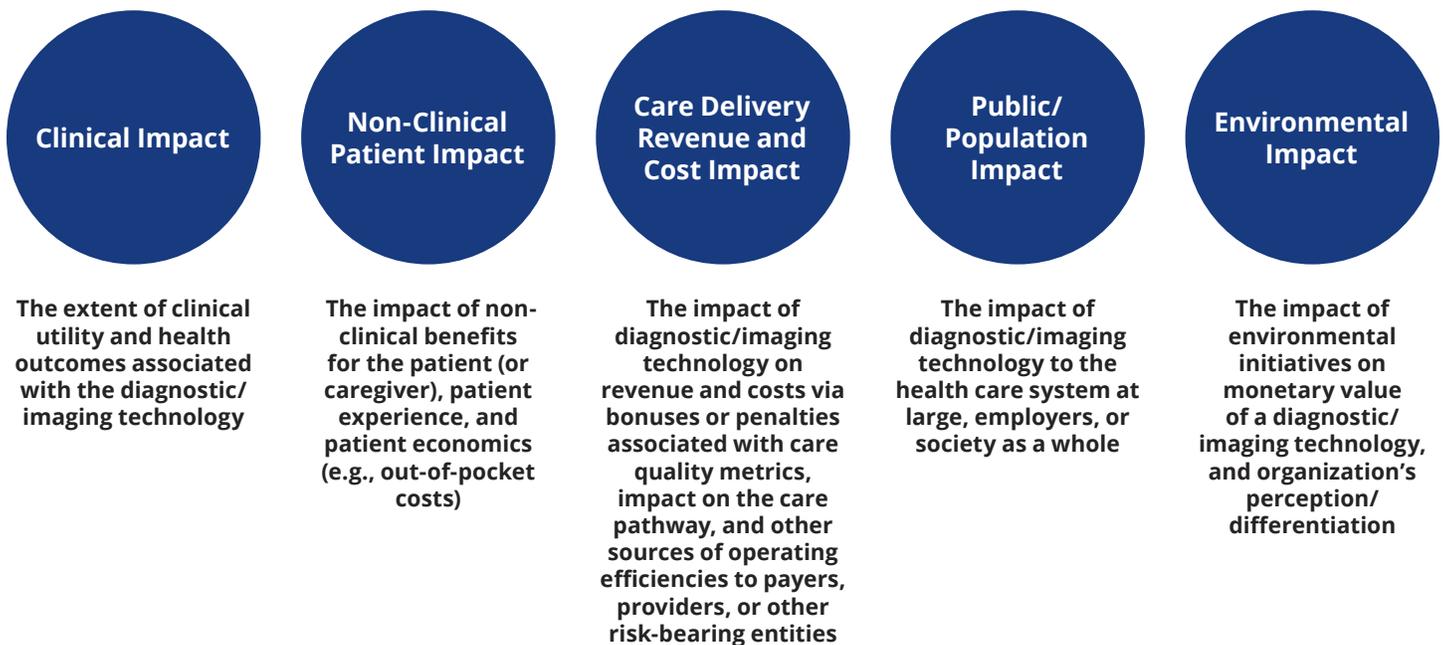
1. Capturing the full spectrum of the value that a diagnostic test contributes

The path to an effective value assessment depends first on what the assessment includes in terms of the different ways a diagnostic test or technology can have impact (value drivers), and thereby benefit, the patient care pathway, as described in the Comprehensiveness Principle.

Five broad categories of “value drivers” – clinical impact, non-clinical patient impact, care delivery revenue and cost impact, public or population impact, and environmental impact – can be incorporated in the value assessment process to capture the full spectrum of ways a diagnostic test may create value as shown in Figure 2.

These assessment categories go beyond the traditional measure of clinical efficacy to capture additional 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. While health economics and outcomes research (HEOR) experts have historically analyzed societal impact in different ways, there is increased emphasis on improving the health of populations. Improving overall health and reducing morbidity are important considerations as providers assume (or share) increased financial risk for patients over longer timeframes and payers are incented in new ways for both

Figure 2. Assessment Categories to Capture the Full Spectrum of Value



their commercial and publicly insured populations. Disparities in health outcomes and related access to care across patient sub-populations are increasingly more evident, and as a result, there is increased emphasis on understanding and addressing the root cause of these disparities and identifying appropriate interventions. Moreover, environmental impact is also becoming a relevant consideration for various stakeholders for value assessment of a test or technology, although at a very nascent stage. Ultimately, these categories directly align value assessments with health reform initiatives to improve the patient experience of care, improve the health of populations, and reduce the per capita cost of health care.

It is important to recognize that these five categories are relevant across the health care ecosystem and 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.

Figure 3. Key Diagnostic Stakeholder Groups



All stakeholders value clinical impact. They also consider the drivers of value identified in this framework but 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 beginning to look at efficiency in new ways and across the care continuum. Stakeholders likely will continue to prioritize drivers in different ways, but there may be a greater push to emphasize these broader drivers of value – especially patient-centered measures – across stakeholder groups.

2. Ensuring that robust analyses underpin the value assessment

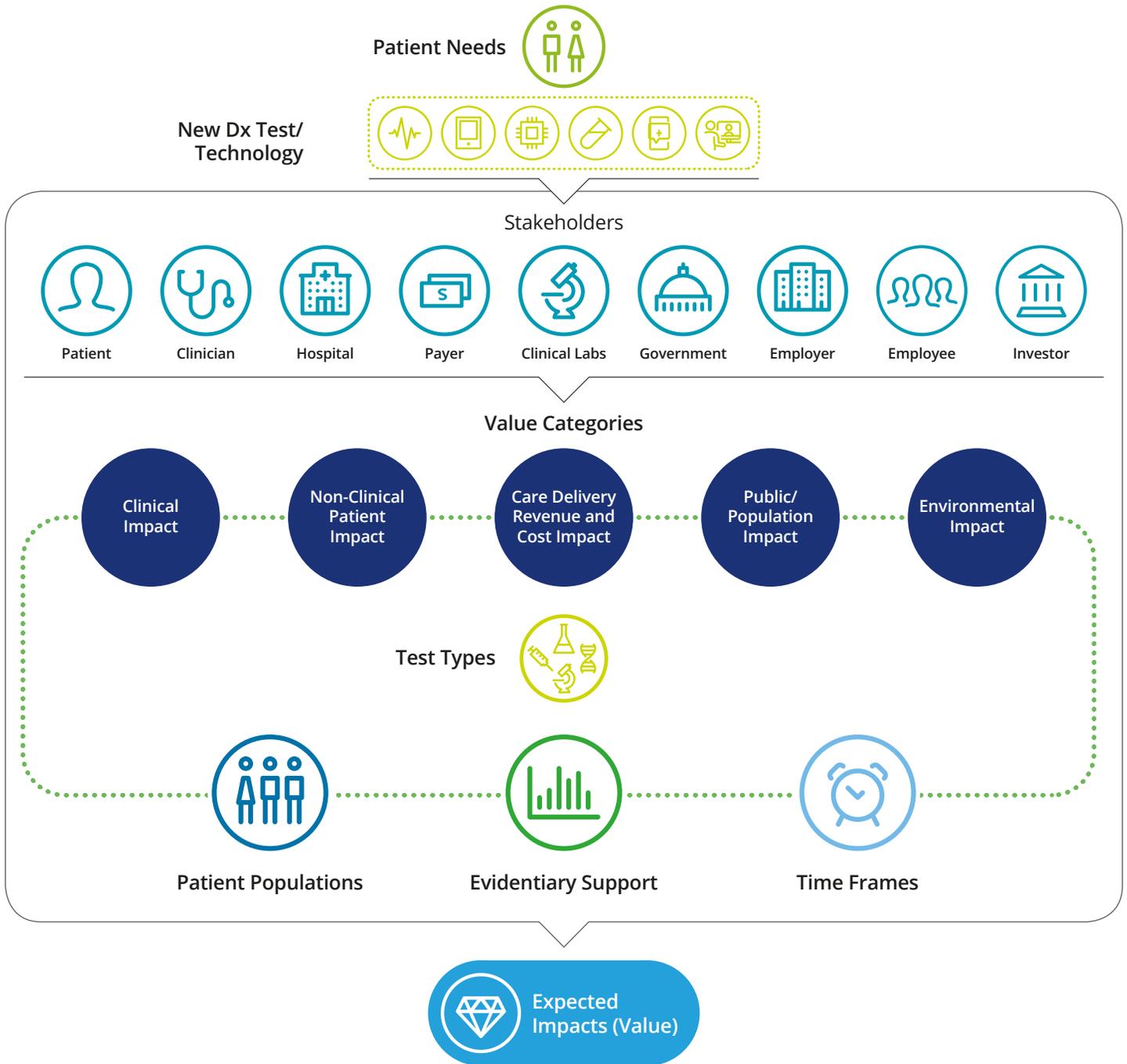
Each stakeholder is ultimately looking to generate a robust assessment of the value that a specific diagnostic test is expected to deliver; this occurs after considering the offsetting costs of adoption (including the cost of acquiring the diagnostic test system from the manufacturer) and calculating the costs of potential risks. In the traditional fee-for-service model of care delivery, many factors in an assessment may have been less relevant. In this new environment, stakeholders must optimize decisions on use of resources while considering new performance goals for the effectiveness and efficiency of care for different patient populations.

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

- Details the ways a diagnostic test will deliver an impact, together with scenarios to describe the magnitude of the impact (against both quantitative and qualitative metrics where appropriate) and offsetting costs (such as changes to existing care practice or management, training and implementation by providers, reduction in unnecessary use of other services in the bundle, or reduction in waste generated in packaging or sterilizing)
- Reflects the unique characteristics that should be considered based on the type of diagnostic test being assessed
- Considers the range of relevant timeframes associated with testing or impact of a test, and
- Acknowledges relevant patient sub-populations that may experience significantly greater or lesser impacts than the general (intended use) population

A schematic of this is shown in Figure 4.

Figure 4. AdvaMedDx’s Approach for Effective Value Assessment: A Schematic



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

The relevant time horizons for diagnostic tests may differ from those of traditional medicine. For example, a rapid test or test delivered at or near the point of patient care may provide rapid results that can be acted upon quickly. Alternatively, a test may be performed periodically to monitor a particular medical condition, such as the progression of cancer. Still other tests might be performed annually or on a periodic schedule as a screening tool. An effective value assessment must take into consideration relevant timeframes appropriate to the type and use of the test.

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 across categories of value. Analyses will be able to include sources of impact that cannot be easily (or usefully) quantified but nevertheless, are worthy of consideration when analyzing the choices to be made, such as patient-reported data, patient preference data, or the value of having information about a diagnosis or condition, even if no treatment is currently available. In developing the assessment, the choices on how best to summarize impact across different components of value (e.g., what to aggregate into financial quantifications and when to keep original metrics distinct) will depend on the specific technology and its unique value profile.

With the intensifying focus on value, for many decisions it will be important to call out the core assumptions that are being made – about the diagnostic test or technology, about alternative testing technologies, about the specific situation (for example a provider health system’s operations), and about the appropriate patient populations for the test. 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. Accounting for variation in diagnostic test types in value assessment methods

As the US health care system shifts further toward value-based payment models, diagnostic test developers increasingly will need to adopt a systematic approach to diagnostics value assessment. While there are benefits to such an approach, the broad range of diagnostic test applications present unique challenges in demonstrating value in a systematic manner. The distinctions between different types of tests must be accounted for in value assessment to help ensure access to all types of diagnostic innovations.

The major types of diagnostic tests include screening, detection, prognostic, theranostic, monitoring, and recurrence. Figure 5 highlights unique value considerations that test developers face for each type of test.

Figure 5. Considerations in Demonstrating Value by Diagnostic Test Type

Dx Test Type	Definition and Example Tests	Considerations When Assessing Value ⁶
Screening	Test that can detect early disease or risk factors for disease in apparently healthy individuals (e.g., BRCA for aggressive breast cancer; colorectal cancer screening; CT lung cancer screening, blood-based cancer screening)	<ul style="list-style-type: none"> • Can the test result be linked to an improved health outcome? • Does the test result lead to patient treatment decisions beyond standard practice? • How many patients must be screened in order to identify one with the disease (or risk factor) or condition? • Do the benefits justify the incremental costs of testing if large numbers of patients are screened to identify a small number of potential cases with the disease? • Are there potential harms associated with false positive test results?
Detection	Tests that establish the presence or absence of disease as a basis for treatment decisions in symptomatic individuals or provide confirmatory results where disease is suspected (test to identify cancers of unknown primary origin, at-home Covid test, Artificial Intelligence (AI) based lung cancer detection)	<ul style="list-style-type: none"> • Can the test result be linked to an improved health outcome? • Does it lead to patient treatment decisions beyond standard practice? • Does the test produce confirmatory or a negative/rule-out result?
Prognostic	Tests that make probabilistic predictions about clinically important outcomes or future medical events given a current medical condition (e.g., test to predict risk of contracting aggressive breast cancer)	<ul style="list-style-type: none"> • Can the test result be linked to an improved health outcome? • Does the test result lead to patient treatment decisions beyond standard practice? • Is the test result actionable, i.e., does it change clinical practice to reduce or eliminate ineffective treatment or change patient behavior? • Are there potential harms associated with false positive test results?
Theranostic	Tests that indicate a patient's response or non-response to a prescribed therapy (e.g., companion diagnostics which allow the prescription of targeted therapies)	<ul style="list-style-type: none"> • Is the test result actionable, i.e., does it change clinical practice to reduce or eliminate ineffective treatment or change patient behavior?
Monitoring	Tests that evaluate the effectiveness and appropriate dosing of a prescribed therapy or course of care (e.g., testing for warfarin sensitivity and HIV viral load testing, remote heart monitoring, wearable-based health monitoring, minimal residual disease testing to assess response to treatment over time)	<ul style="list-style-type: none"> • Can the monitoring test result add to, or result in, patient treatment decisions beyond the standard of care? • Can the test results be linked to an improved health outcome in patients with the condition by changing clinical practice or patient behavior? • Is a risk/benefit analysis needed (e.g., risk of additional or burdensome testing, compared with benefit of appropriate dosing, or early identification of disease relapse)? • Are there risks associated with false positive or false negative test results?
Recurrence	Tests that analyze the patient's risk for a recurrence of the disease (e.g., testing to determine risk of recurrence of bladder cancer)	<ul style="list-style-type: none"> • Is the test result actionable, i.e., does it change clinical practice to reduce or eliminate ineffective treatment or change patient behavior? • Do data on the effectiveness of testing, including data developed as part of a surveillance/registry program demonstrate better clinical outcomes than alternative options?

⁶ See Faulkner, E., Spinner, D., Ransom, J., "Developing Appropriate Evidence for Demonstrating the Value of Diagnostics: Where are We Now and What is Appropriate for the Future State?", Journal of Managed Care Medicine, Vol. 19, No. 4, <http://www.namcp.org>.

4. Aligning on how to define and measure value drivers

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

Value Driver: Clinical Impact

The clinical impact assessment captures subcategories of unique value drivers: sources of value created by traditional value subcategories (analytical validity, clinical validity, and clinical utility), as well as patient safety/tolerability/ compliance and patient response to diagnostic results.

Value Category	Value Subcategories	Value Drivers	Sample Questions to Consider	Sample Value Metrics
Clinical Impact	Analytical Validity	The ability of a test to measure accurately and reliably the analyte/biomarker of interest in a sample or specimen	<ul style="list-style-type: none"> What is the smallest quantity of substance in a sample that can be measured (analytical sensitivity)? What is the ability of the diagnostic to measure one particular organism or analyte, rather than others (analytical specificity)? How well does the diagnostic test measure the condition in a population of patients (accuracy)? How well does the diagnostic test measure the condition in different sub-populations including under-represented population? How reliably does the diagnostic test measure the analyte (precision)? How consistently will the diagnostic test results be under different environments and operators (reproducibility)? 	<ul style="list-style-type: none"> Analytical sensitivity (e.g., Limit of Detection—LoD, Limit of Quantitation—LoQ, Limit of Blank—LoB) Analytical specificity (i.e., false negative/ false positives amongst cross reactants/ interfering substances) Accuracy expressed as % of total true positives and true negatives vs. the entire population Precision expressed as % true positives as compared to all positives Reproducibility as % of agreement of test results Image quality
	Clinical Validity	The ability to check how consistently and accurately a test detects or predicts the outcomes of interest in a patient population	<ul style="list-style-type: none"> Is the target analyte/biomarker relevant to the health state or condition of interest? Does the diagnostic test result accurately inform decision-making based on the relationship of the target analyte/biomarker to the health state or condition of interest? How well does the diagnostic distinguish between patients who have disease and those who do not in the targeted population? 	<ul style="list-style-type: none"> Clinical specificity (% true negatives, false positives) Clinical sensitivity (% true positives, false negatives) Positive Predictive Value (PPV)/Negative Predictive Value (NPV) Adherence to clinical guidelines and appropriate use
	Clinical Utility	The ability of a test to inform an appropriate clinical treatment decision to improve patient outcomes	<ul style="list-style-type: none"> What clinical decision is the diagnostic supporting? How does the diagnostic impact the clinician’s treatment decision? (i.e., how useful is the diagnostic to making the clinical decision?) How does the diagnostic test direct downstream clinical decision-making? 	<ul style="list-style-type: none"> % Changed clinician decisions post implementation of diagnostic vs. prior The resulting difference in endpoints or outcomes from a changed clinical decision (i.e., reduced number of repeat procedures, response to treatment, or best treatment selected initially)
	Patient Safety, Tolerability, or Compliance	Improved patient safety, tolerability, and compliance vs. alternative diagnostic options	<ul style="list-style-type: none"> Are there differences in the diagnostic options (e.g., blood draw/urine sample versus invasive tissue specimen collection, or off-site radiology vs. on-site)? How does the diagnostic compare to alternative diagnostics in terms of patient follow-through? 	<ul style="list-style-type: none"> Adverse reactions or side effects of anesthesia in invasive specimen collection Patient follow-up for diagnostic result review and compliance to clinician guidance Radiation dose tracking per visit/per exam
	Patient Response to Diagnostic Results	Improved physical and psychological wellbeing	<ul style="list-style-type: none"> How does the diagnostic result affect physical and psychological well-being (value of “knowing”)? How does the diagnostic help avoid patient demand or clinician request for unnecessary procedures? 	<ul style="list-style-type: none"> Frequency/amount of retesting Number of additional/wasteful procedures

Value Driver: 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	More preferable site or channel of care (ease of access) and test delivery	<ul style="list-style-type: none"> Does the diagnostic enable patients to be tested at their preferred site of care (e.g., at-home diagnostics)? Is the diagnostic easier to use/administer (relative to other tests)? Does the diagnostic test allow faster and easier access (e.g., reduced waiting or commute time, point-of-care diagnostics, over the counter (OTC) diagnostics)? 	<ul style="list-style-type: none"> Patient preferences (e.g., preference for care setting, such as point-of-care diagnostics, clinician office/home) Proximity of testing laboratories/locations for patient Comfort during the exam Median travel time for patient Wait time for patient
		Effect on patient's active engagement in self-care journey	<ul style="list-style-type: none"> How does the diagnostic test improve patient's access to easy-to-comprehend data and actionable insights to enable them to stay informed of their health? 	<ul style="list-style-type: none"> Medical adherence (self-reported, proportion of days covered, etc.) Daily Active Users Customer Experience Score Net Promoter Score⁷
		Predictability of care/experience vs. expectations	<ul style="list-style-type: none"> How does the diagnostic test influence the patient experience? How does the diagnostic impact the predictability of the patient experience? How does the diagnostic affect patient understanding of or engagement in the plan of care? 	<ul style="list-style-type: none"> Number of follow-ups Number of repeat procedures (revision surgeries) Patient experience evaluation metrics (e.g., Hospital Compare ratings) Ease of administration Wait times
		Reduced burden on caregivers due to better patient experience and outcomes	<ul style="list-style-type: none"> How does the diagnostic affect burden on caregivers due to better patient experience and outcomes? How does the diagnostic test improve ease of use / adoption of technology? 	<ul style="list-style-type: none"> Caregiver quality of life (e.g., physical, social, financial, etc.) Time invested by caregivers
		Improvement in compliance with plan of care	<ul style="list-style-type: none"> How does the diagnostic help affect patient compliance or engagement in their plan of care? 	<ul style="list-style-type: none"> Number of follow-ups/compliances
	Patient Economics	Impact on out-of-pocket patient expenses	<ul style="list-style-type: none"> How does the diagnostic impact out-of-pocket expenses for different patients? Does the diagnostic test enable early intervention, reducing overall cost? Does the diagnostic test have price transparency⁸ allowing patients to make an informed choice? 	<ul style="list-style-type: none"> Out-of-pocket cost to patient over the course of disease progression

⁷ [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.

⁸ [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 & billed amounts for out-of-network providers.

Value Driver: Care Delivery Revenue and Cost Impact

Care delivery revenues and cost impact consider the economic effect on the health system of both the immediate episode of care and long-term disease progression. The care delivery driver recognizes that a new diagnostic test

can impact both the ability of health care providers to earn incremental revenue but also incur costs. 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, length of stay, cost efficiency)	<ul style="list-style-type: none"> How does the diagnostic enable the determination of right choice of treatment for the given patient? What are the direct and indirect economic benefits of the improved quality of care? How does the diagnostic impact performance-based reimbursement metrics (e.g., hospital-acquired infections, readmissions, length of stay)? Was the diagnostic test appropriate for the clinical indication? How does use of the diagnostic result in cost-offsets (averted complications or unnecessary procedures)? 	Costs related to: <ul style="list-style-type: none"> Use of toxic therapy Number of repeat procedures (revision surgeries/imaging procedures) Number of adverse events reported Number of readmissions; Hospital Compare scores Number of hospital-acquired infections Number of follow-ups Length of stay Variance in decision-making Patient satisfaction scores (e.g., based on expectations met, comfort) Compliance with follow-up diagnostic recommendations Errors in triage
	Care Efficiency	Economic impact of improved system throughput, workflow/ efficient time, and resource utilization	<ul style="list-style-type: none"> How does the diagnostic impact costs related to system throughput, diagnostic setup and maintenance, workflows, and care efficiency (e.g., degree of automation)? How does the diagnostic affect costs related to the elimination of waste and unnecessary procedures and costs? How does the diagnostic enable more efficient time, resource, and test utilization, both upstream and downstream? How does the diagnostic test affect administrative efforts and staff utilization in managing data (e.g., duplication, documentation)? How does the diagnostic test impact productivity and capacity to grow revenue by new patient acquisition and improved retention? 	Costs related to: <ul style="list-style-type: none"> Patient flow (i.e., overall impact on system efficiency) Time to effective treatment Human resource utilization Frequency/amount of retesting Number of additional/wasteful procedures Hours of operation Time from sample collection to result Wait times Uptime aligned to business hours, emergency service response, etc. 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 diagnostic affect 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 diagnostic affect costs related to improved adoption of new care practices due to easier/more effective training/education? How does the diagnostic affect lab or departmental workflow and lab integration, training, ease of maintenance, etc.? How does the diagnostic test 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

Value Driver: Public/Population Impact

This category considers the impact of a diagnostic test or 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/ Population Impact	Population Health	Improved population health (burden of illness/disease)	<ul style="list-style-type: none"> • How does the diagnostic affect overall population health (e.g., ensure appropriate treatment for a patient population)? • How does the diagnostic affect the socioeconomic disparities in care? • How does the diagnostic affect patient access to care? • How does the diagnostic help control pandemics? • How does the diagnostic test address patient clinical outcomes and improve quality and safety due to health disparities? • How does the diagnostic test help improve patient, family, caregiver, and clinician experience due to health disparities? • How does the diagnostic test impact patient access to care (e.g., access across geographies, at home, due to socioeconomic barriers, etc.), including access to health technology and data? 	<ul style="list-style-type: none"> • Health-adjusted life expectancy • Quality-adjusted life expectancy • Disability-adjusted life years (DALY) • Quality-adjusted life years (QALY) • Overall survival • Child mortality • Proportion of earlier diagnoses • Screening rates in target populations • Incremental cost-effectiveness ratio (ICER) • Percentage of patients who delay care due to access barriers
		Impact to overall private and public health care costs	<ul style="list-style-type: none"> • How does the diagnostic impact overall health care costs? • Does the diagnostic test 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 (\$)
		Increased efficiency of private and public spending	<ul style="list-style-type: none"> • How does the diagnostic test 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 diagnostic test help manufacturers improve the test based on data-driven insights? 	<ul style="list-style-type: none"> • Reproducibility (same result obtained when two different medical staff apply the test) • Accuracy (same result obtained if the diagnostic test is used more than once)
		Workforce Productivity	Increased employee productivity/reduced absenteeism, increased presenteeism	<ul style="list-style-type: none"> • How does the diagnostic test impact employee productivity and attendance (e.g., provide information that changes care patterns)? • How does the diagnostic test impact employee’s general health and wellness and provide a sense of purpose? • Does the diagnostic test 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?
	Increased caregiver productivity/reduced absenteeism, increased presenteeism		<ul style="list-style-type: none"> • How does the diagnostic technology impact caregiver productivity and attendance? 	<ul style="list-style-type: none"> • Caregiver productivity/absenteeism and presenteeism

Value Driver: Environmental Impact

This category considers the impact of ESG initiatives with a focus on environment, which are increasingly gaining momentum across various stakeholders.

This value category assesses the value of a diagnostic device taking into consideration the monetary impact of a diagnostic test and the impact on an organization’s perception and differentiation due to environment-focused initiatives.

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 diagnostic test 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 diagnostic test 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 diagnostic test 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 diagnostic test 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

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

As noted in the context section of this paper, diagnostic test developers recognize that payers and providers are intensifying their scrutiny of choices with respect to diagnostic tests and other technologies 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. For diagnostics, the patient perspective can be particularly challenging with respect to details about the test itself, access to testing, specimen collection, and the understanding of the test result, because most patients do not order tests directly nor do they interpret the test results themselves. However, patients will have important perspective on the choices available to them based on information provided by the diagnostic test. Therefore, it is increasingly important to include the patient in the dialogue.

Much has been written about the range of unique challenges in developing evidence for assessing the value of medical technologies, including diagnostics.⁹ For example, randomized controlled trials are not always the best or most practical study design for demonstrating diagnostic value to payers and other stakeholders.¹⁰ Evidence used in value assessment for these technologies should reflect the diversity of tests or technologies available for patient care. 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 diagnostic testing systems. In addition, the test systems and formats may 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.

Development of Evidence Guidelines

The Evidentiary guiding principle (shown earlier in Figure 1) summarizes the assertion that there are multiple types of evidence which, independently or collectively, can serve as appropriate evidentiary support for effective assessment analyses of diagnostic tests and technologies. Over-reliance on randomized controlled trials (RCTs) limits the types of

“There are multiple types of evidence which, independently or collectively, can serve as appropriate evidentiary support for effective assessment analyses of diagnostic tests and technologies. Over-reliance on randomized controlled trials (RCTs) limits the types of value impact that can be effectively investigated.”

value impact that can be effectively investigated. Many diagnostics are evaluated in observational studies of comparable performance rather than RCTs, so consideration of a variety of appropriate evidence is necessary. AdvaMed¹¹ 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). Please refer to table on the ‘Types of Evidence’ (Page 23).

⁹ See Faulkner, et al., supra note 5. See also, Price, R., and Long, G., “Challenges in Developing and Assessing Comparative Effectiveness for Medical Technologies,”

¹⁰ See Faulkner, et al., supra note 5.

¹¹ For purposes of this section, references to AdvaMed include AdvaMed and AdvaMedDx.

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, entitled “**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. This section summarizes these evidence guidelines and their application to both medical technologies and to diagnostic tests. These guidelines are especially important given the diversity of medical and diagnostic 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 or diagnostic test developer desires reimbursement for an innovative technology that 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.

- 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 influence 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 or diagnostic 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, including 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 Outcomes (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, time and resources needed to conduct a certain procedure). These studies are important in demonstrating the value that a medical technology or diagnostic test 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 diagnostic test or technology. These overarching principles and the approach for assessing value can be adopted by diagnostic companies and diagnostic test developers, 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 diagnostic test or technology may contribute and can include important patient-focused and ESG-focused considerations. These categories apply both to traditional products and to offerings that include new types of services, e.g., digital diagnostic tests, in combination with the product to improve health and economic outcomes for patients

AdvaMedDx is committed to ensuring that patients continue to have access to and benefit from diagnostic innovations. The association encourages 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. The association 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 diagnostic tests or technologies.

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



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.



AdvaMedDx, a division of the Advanced Medical Technology Association (AdvaMed), represents over 70 manufacturers of innovative in vitro diagnostic (IVD) tests in the U.S. and abroad. AdvaMedDx advances policies that promote innovation and expand access to quality testing to enable improved clinical decision-making and therapy selection for patients.

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