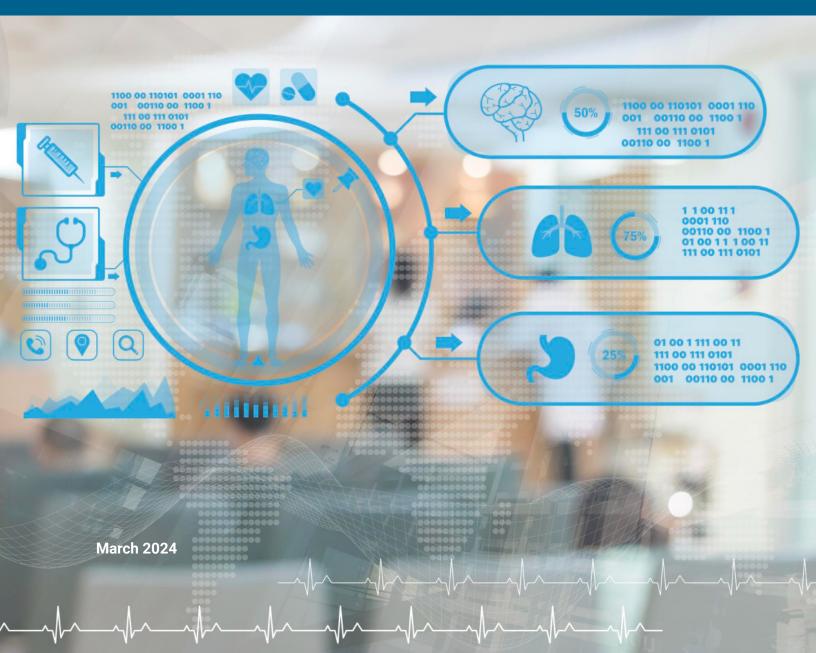


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# Fulfilling the Promise of Equity in Value-Based Care: A Focus on Data and Methods in Health Technology Assessment



# ACKNOWLEDGEMENTS

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# Introduction

Evidence emerging from the implementation of value-based care in the U.S. underscores that there is, "No Value Without Equity." The U.S. is experiencing significantly increased costs of healthcare alongside declines in health outcomes. Indeed, the U.S. has the worst outcomes of any high-income nation while spending more per person.<sup>1</sup> Despite this out-sized healthcare spending, life expectancy decreased in the U.S. for the first time in 2020 due to the COVID-19 pandemic. At the same time, health outcomes data reveal significant health disparities. The recent decline in life expectancy was greater for Hispanic and non-Hispanic Black populations than for White populations.<sup>2</sup> Evaluations have also shown significant unnecessary spending on low-cost, low-value care.<sup>3</sup> New approaches to understanding value are required.

### What Value and Whose Value?

Determining value in healthcare is complex. Value is a concept that encompasses multiple dimensions, including (but not limited to) cost, quality, outcomes, and impacts on patients' and families' experiences of health conditions. There are different perspectives on the value of a given healthcare technology (such as medication, surgical intervention, or digital health interventions) depending on who is making the judgment, the specific context for decision-making, Far better an approximate answer t o the right question, which is often vague, than the exact answer to the wrong question, which can always be made precise.

- John W. Tukey, Ann. Math. Stat. 33 (1962)

and the methods and data inputs used to assess value. Ultimately, efforts to assess the value of healthcare technology require answering questions of: Value to whom? The patient? The payer? Society?

Health technology assessment (HTA) is a method of systematically assessing the value of healthcare technology by using available evidence to model its expected benefits, risks, and costs. HTA plays an increasingly important role in informing healthcare resource allocation, decisions that ultimately impact access. Such decisions include designing formularies that outline coverage for treatments and developing guidelines and pathways that inform clinical practice. How healthcare decision-makers design formularies or make decisions about spending impacts patients' access to treatments. Health systems have the difficult job of needing to balance cost considerations with patients' ability to access necessary care. Traditional approaches to HTA adopt a health system perspective and prioritize efficiency over equity in resource allocation.<sup>4</sup> By efficiency, we mean a focus on how to use a limited set of healthcare resources. These approaches evaluate clinical outcomes and cost considerations of interest to payers, such as employers and commercial or public insurers. Cost-effectiveness analysis (CEA) is the most commonly used HTA method to inform priorities for healthcare decision-making. Traditional CEA aims to inform decisions to improve overall health for a population based on the estimated impact of a particular healthcare technology for an average patient. As a method for decision analysis, CEA is well-suited to inform decisions about maximizing health gains in the context of cost, leading to gains in efficiency. But, in its current form, CEA offers limited insight into the potential for healthcare technology to improve (or make worse) existing health disparities.<sup>5</sup> When evaluating health technology, decisionmakers today often need to balance efficiency in achieving health gains across an entire population with equity in fairly distributing health gains across subgroups of patients.6,7

Health equity impacts have not traditionally been incorporated into HTA. Both the scientific research community<sup>8</sup> and the patient advocacy community<sup>9, 10</sup> have raised and explored limitations of current HTA approaches to inform decisions about value. Equitycentered HTA is needed to generate useful information for decision-makers, particularly as payers and purchasers confront the growing imperative to address existing disparities in healthcare access, quality, and health outcomes.<sup>11</sup> However, there is a lack of consensus on the methods best suited for equitycentered HTA.<sup>12</sup>

Intentionally accounting for health equity in HTA requires exploring questions of perspective, context, and methods with the goal of reducing health disparities. Ultimately, HTA must be flexible enough to accommodate these diverse demands while also being both scientifically credible and relevant to all stakeholders.

### **Advancing Equity through HTA**

The Innovation and Value Initiative's (IVI) <u>Health Equity Initiative</u> has been working to identify and advance action in how HTA accounts for health equity. In partnership with a <u>Health Equity Initiative</u>

HTA advances equity when it reduces health disparities by aligning access and affordability of healthcare technologies and services with differing needs and values of diverse patient populations, especially those who are most marginalized. Steering Committee, and through dialogue with over 40 stakeholders representing patients and caregivers, researchers, policymakers, clinicians, industry, payers and purchasers, IVI has developed a framework for centering equity in HTA (Appendix 1). This framework includes four essential domains of HTA practice where fundamental shifts are necessary to ensure that HTA advances equity: Power, People, and Processes; Data and Inputs; Methods; and Communications and Use. In Fulfilling the Promise of Equity in Value-Based Care: A Focus on Power, People, and Processes in Health Technology Assessment, IVI explored the first domain of its Health Equity Framework to identify actions that stakeholders can take to address power structures, which may include addressing implicit bias and co-design of HTA studies with patients and caregivers.

In this document – the second of a series of publications highlighting each domain in greater detail – IVI delves into the **Data and Inputs** and **Methods** domains to discuss opportunities and imperatives for key players in HTA practice in use. **To remain relevant, HTA data and methods must incorporate an equity focus.** 

> Equity is not a method or procedure, it's a way of thinking and acting.

> > - Key Informant

To help readers identify steps they can take today, we have identified action steps for stakeholders who shape HTA through many different mechanisms, from funding to research, publication, and use. These action steps are based on learning from a systematic review of peer-reviewed literature focused on economic analyses and health equity, and engaging patients and other stakeholders through a series of key informant interviews, two roundtable discussions, and public discourse during the 2023 IVI Methods Summit. IVI deeply appreciates the contributions of our patient and stakeholder partners and steering committee in the development of this initiative.

With an eye toward accountability and lasting practice change, we focus on six key stakeholder roles: **Researchers**, **Patients and Caregivers**, **Professional Association Leaders**, **Journal Editors**, **Research Sponsors**, and **Payers and Purchasers**. For detailed descriptions of each stakeholder role, see Appendix 2. Recognizing these diverse audiences, we include a glossary of key terms in Appendix 3.

To help readers begin taking action, this document is organized into two main sections. Foundational Changes focus on steps necessary to put the Data and Inputs and Methods domains into practice. Case Studies offer real-world examples of these steps in practice. We also include links to Action Guides with steps and resources customized for each of the six key stakeholder roles.

# Foundational Changes in HTA in Data and Methods

Ensuring equity in HTA requires that practitioners in the field re-examine what data and evidence they use to assess the value of health technologies, and what methods they use to conduct those assessments. Foundational changes in HTA in data and methods are identified in Figure 1.

For each of these foundational changes, we present a set of practice changes and accountability actions. **Practice changes** represent long term shifts in practice that must take place over many years. **Accountability actions** are near-term actions, possible over the next 1-2 years, that incentivize the longer-term practice changes. Figure 1. Foundational Changes in HTA in Data and Methods

Equity in HTA **Data and Methods** means that:



HTA explores questions about how healthcare technology may **impact** health disparities.



HTA practitioners **use existing methods that account for equity** to assess the value and impact of healthcare technology.

<u> </u>	

HTA prioritizes data that are representative of and reflect what is important to impacted populations.



HTA practitioners, users, and impacted populations **collectively define and address data gaps** that currently block equity-centered HTA.



HTA reports **consistently acknowledge data and methods limitations** that may impact or impede an equity analysis.



HTA practitioners test and adopt **new methodological approaches** to account for equity.

#### **Key Questions**

How do the data and methods used in HTA impact its use in real-world decisions?

Does data used in HTA adequately represent the diversity of populations most likely to be impacted by HTA?

Do the methods used in HTA address equity-focused questions?





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### HTA Explores Questions About How Healthcare Technology May Impact Health Disparities

A wealth of academic literature documents persistent health inequities in the U.S.: long-standing patterns of health disparities due to unjust differences in social, economic, environmental, and health care resources.<sup>13, 14, 15</sup> Rather than solely examining general population impacts, equity-centered HTA prioritizes understanding how healthcare technology might impact or mitigate health disparities. Key to this understanding is examining how an intervention's outcomes may vary across different groups of patients, especially among communities experiencing persistent health inequities.

Health disparities are differences in health outcomes and status between population groups characterized by social, demographic, environmental, and geographic attributes.

**Health inequities** are longstanding patterns of health disparities due to unjust differences in social, economic, environmental and healthcare resources.



HTA research must begin with questions that intentionally explore existing and potential health disparities. This requires framing relevant, equityfocused questions by collaborating from the beginning with impacted stakeholders, especially people with lived experience of the conditions or technology of focus, and individuals from communities experiencing health inequities. Engaging individuals who bring a diversity of lived experience ensures HTA practitioners have a thorough understanding of underlying factors driving health disparities. This in turn provides insight into questions about the potential impact of healthcare technology. The IVI report, Fulfilling the Promise of Equity in Value-Based Care: A Focus on Power, People, and Processes in Health Technology Assessment, explores in depth approaches to engage patients and caregivers in HTA.

Key questions equity-centered HTA strives to answer include:

- What are the sources of inequity?
- How can healthcare technologies address these?

Disparities in health-related outcomes may result from a complex web of factors, including: differences in clinical effectiveness of treatments among subgroups, differences in access to healthcare, differences in quality of care delivered, and impacts of social determinants of health (e.g., access to food or housing). When considering these factors, HTA practitioners will need to identify additional value components beyond clinical effectiveness to answer whether and how interventions may change the status quo. Equally important is examining potential impacts of healthcare technology by patient subgroups and considering how decisions based on HTA findings may lead to greater or less access to treatment for different groups of patients.



### Figure 2. Accountability Actions and Practice Changes for HTA to Explore Questions About How Healthcare Technology May Impact Health Disparities

#### **Foundational Change**

#### **Accountability Actions**

#### **Professional Association Leaders**

• Establish standards for conducting and reporting subgroup analyses, including choice of data to account for population and condition heterogeneity.

#### **Journal Editors**

- Require all HTA publications to:
  - Include information on existing health disparities as part of background information on burden of disease and the distribution of clinical effectiveness among relevant patient subgroups.
  - Provide rationale when subgroup analyses are not conducted.
  - Discuss how the technology of focus may impact overall population health as well as its impact on closing or widening health disparities.

#### **Research Sponsors**

• Require that HTA studies include an equity analysis informed by patient and stakeholder engagement.

#### **Payers and Purchasers**

- Consider equity impacts, including differential access to healthcare technology, as part of decision-making processes.
- Use HTAs that examine differential impacts of technology by race, ethnicity, gender, and other relevant patient characteristics. When HTAs do not include this information, ask for additional analyses or implications of data gaps.

HTA explores questions about how healthcare technology may impact health disparities

#### **Necessary Practice Changes**

#### Researchers

- Before beginning HTA, partner with a diverse group of patients to frame key questions about the burden of disease, barriers to access for underserved populations, and equity consideration for the technology of focus.
- Explore differential impacts of healthcare technology for patient subgroups.

#### **Patient Organizations**

- Speak up when HTA research does not address questions that matter to patients, especially those from communities experiencing persistent health inequities.
- Collaborate with HTA practitioners to help frame key questions that matter to patients, especially those from communities experiencing persistent health inequities.



HTA Practitioners Use Existing Methods that Account for Equity to Assess the Value and Impact of Healthcare Technology

There is growing interest in equitycentered HTA methods.<sup>16</sup> Recent reviews of HTA research literature offer insight into the use of equity-centered methods in analyses and decision-making.<sup>17, 18</sup> However, HTA practitioners have not yet consistently adopted these methods, especially in the U.S. It is vital to assess the appropriateness of HTA methods with the goal of minimizing the potential for perpetuating or exacerbating existing health disparities. To understand the impacts and potential harm resulting from analytic and methodological decisions, it is important to partner with patients from communities experiencing health inequities throughout the HTA process,

from the early scoping and design phase throughout analyses and interpretation. In choosing methods, prioritize those with evidence showing they are appropriate for equity-centered HTA.

> Checklists can guide decisions around data and methods selection, and help to limit the potential impact of implicit bias in HTA studies.<sup>19</sup>



#### Table 1. Specific Equity-Centered HTA Methods

Method	Accounts for Equity by	
Distributional Cost- Effectiveness Analysis	Examines differences in cost and clinical effectiveness across equity- relevant patient subgroups. Represents equity considerations through social welfare functions. For example, incorporating equity metrics such as the Relative Risk Index or Disparity Index helps to systematically assess and quantify disparities in access to healthcare interventions, particularly within communities already experiencing health inequities. <sup>1</sup>	
Equity-Based Weighting	Applies weights to mortality and/or quality-of-life measures or adjustments in incremental cost-effectiveness ratios or thresholds. Requires patient engagement to inform weighting approaches that center patient priorities. For example, traditional CEA approaches may be altered to account for additional elements of value, as in adoption of a higher cost-effectiveness threshold for rare disease treatments by the U.K. National Institute for Health and Care Excellence. Equity weighting methods allow decision-makers to vary the value of health gains depending on who benefits. <sup>III</sup>	
Equity-Constrained Mathematical Programming	Adjust incremental cost-effectiveness ratios to consider both equity and efficiency when assessing the value of healthcare technology. For example, this method could consider equity across geographic regions when allocating resources for HIV treatment.	
Extended Cost- Effectiveness Analysis	Models non-health consequences such as financial risk protection or other distributional outcomes. Requires engaging patients and other stakeholders to identify relevant non-health outcomes and policies for consideration.	
Multi-Criteria Decision Analysis	A framework for supporting complex decision-making with multiple and often conflicting criteria that stakeholder groups and/or decision-makers value differently. Engages stakeholders and uses mixed (qualitative and quantitative) methods with scoring or ranking systems to represent equity considerations.	

i Annie E. Casey Foundation (2015). Measuring Disparity: The Need to Adjust for Relative Risk. Available at: https://assets.aecf. org/m/resourcedoc/aecf-10practices2-appendix4-2015.pdf.

ii Avanceña A.L.V., Prosser L.A. Examining equity effects of health interventions in cost-effectiveness analysis: a systematic review. Value Health. 2021; 24: 136-143

Figure 3. Accountability Actions and Practice Changes for HTA Practitioners to Use Existing Methods that Account for Equity to Assess the Value and Impact of Healthcare Technology

# Foundational Change Accountability Actions

#### **Professional Association Leaders**

- Create forums to identify guiding principles and best practices for how how HTA practitioners can account for equity.
- Establish guidelines and offer training on equity-centered HTA methods.
- Offer training on implicit bias, cultural competency, and ethical issues that support equity-centered HTA practice.

#### **Journal Editors**

- Prioritize for publication HTAs that use equity-centered methods. Require justification when equity-centered HTA methods are not used.
- Create focused collections that demonstrate best practices in conducting equity-centered HTA.

#### **Research Sponsors**

- Require use of equity-centered HTA methods or justification of why these methods were not used.
- Invest in training for researchers and patients to engage in equity-centered HTA.

#### **Payers and Purchasers**

- Prioritize HTA studies that use equitycentered methods.
- Build internal capacity to conduct equitycentered HTA.

HTA practitioners use existing methods that account for equity to assess the value and impact of healthcare technology

#### Necessary Practice Changes

#### **Researchers**

- Use existing checklists to guide equity considerations in HTA.
- Test equity-centered HTA methods and share learning to build consensus around best practices.
- Partner with patients throughout the HTA process to understand equity implications of methods choices.

#### **Patient Organizations**

- Partner with researchers throughout the HTA process to explore equity implications of methods choices.
- Build knowledge and capacity within patient groups to engage with HTA researchers.

# HTA Prioritizes Data that are Representative of and Reflect What Is Important to Impacted Populations

To gain a full understanding of the potential for healthcare technologies to reinforce, expand, or reduce health disparities, HTA practitioners must incorporate into their analyses data that are representative of the specific populations impacted by those analyses. This requires first partnering with patients and caregivers to define impacted populations for an HTA study. Impacted populations are the communities of patients and caregivers whose health and access to treatment are likely to be influenced by decisions informed by a **particular HTA.** Some of the communities most likely to be impacted are those that experience persistent health inequities, making their representation within the HTA process and data inputs essential.

After defining impacted populations, HTA practitioners must collaborate with diverse representatives of these populations to identify data suited to a specific analysis. In choosing data for HTA, prioritize data sources that:

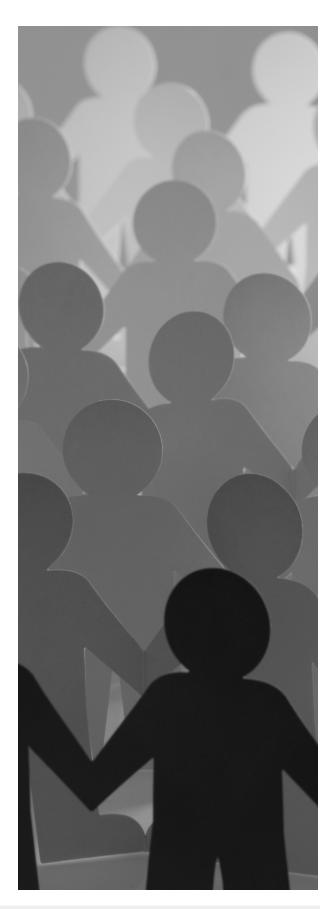
 Reflect the diversity of impacted populations by race, ethnicity, gender, and other relevant patient factors. Designing an HTA using data that do not reflect the diversity of impacted populations impairs the validity of any assessment of that technology's value. The more closely data used in HTA reflect the demographic, health status, and cultural profile of impacted populations, the more accurately HTA can assess the potential impact of healthcare technology for those populations.

- Include outcomes that matter to patients and their caregivers, including patient-reported economic impact measures. Choice of outcomes reflects the perspective of an analysis. Focusing HTA on outcomes prioritized by impacted populations ensures that the value of technology is assessed relative to the experience and preferences of patients and caregivers.
- Enable examination of distributional effects by race, ethnicity, gender, and other relevant patient characteristics. Understanding the full value of healthcare technology requires examining how the technology impacts groups of patients in different ways. Patient characteristics relevant to a particular HTA will vary, but at a minimum examining impacts by race, ethnicity, and gender provides insight into how access to and

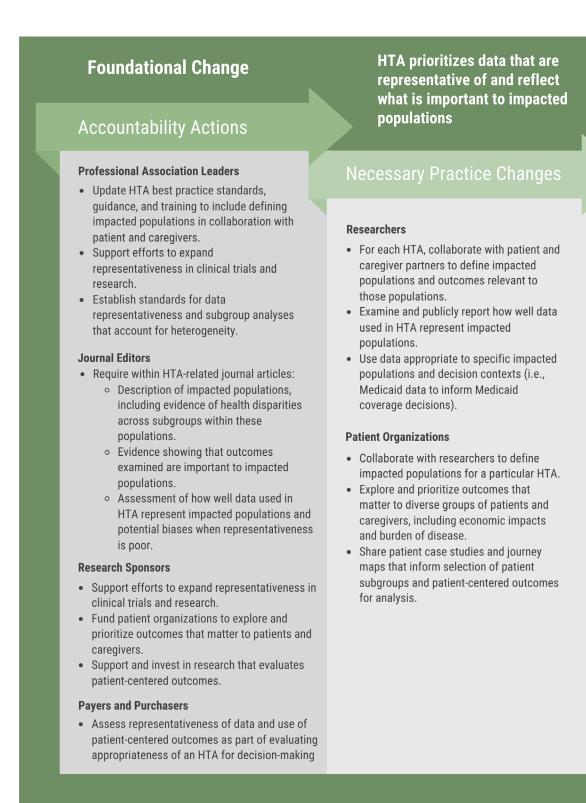
use of healthcare technology may impact existing health disparities. This requires using data sets that include relevant patient characteristics.

 Address all relevant opportunity costs to inform decision-making processes that must weigh improving population health overall with closing health disparities gaps. Opportunity costs relate to the resources, such as time, money, or effort, that are allocated to one healthcare intervention or technology instead of another.

As a primary source of data for use in HTA, randomized controlled trials' well-documented lack of diversity is especially problematic, as is failure to systematically report information about patients' race, ethnicity, and health-related social needs.<sup>20</sup> A recent analysis found only 22.9% of all clinical trials reported race<sup>21</sup> and only 25% of individuals who participated in U.S. drug trials in 2020 were from racial and ethnic minority groups, even though these groups make up approximately 30-40% of the U.S. population.<sup>22</sup> Rather than limiting HTA inputs to only RCT data, using a combination of data, including from real-world sources such as claims data, disease registries, and electronic health records, will help improve the representativeness and relevance of HTA analyses.



### Figure 4. Accountability Actions and Practice Changes for HTA to Prioritize Data that are Representative of and Reflect What is Important to Impacted Populations



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# HTA Practitioners, Users, and Impacted Populations Collectively Define and Address Data Gaps that Currently Block Equity-Centered HTA

Data gaps are often cited as reasons of omitting equity-centered analyses in HTA studies. The kinds of data important for equity-centered HTA include:

- Distribution of life expectancy across population subgroups (by race and ethnicity, socio-economic status, gender, age, etc.). In order to understand what different health gains a health technology might achieve for patient subgroups, we must first understand how life expectancy differs across these populations (i.e., baseline life expectancy).
- Health disparities for the healthcare condition of focus. Identifying existing health disparities<sup>23</sup> is necessary to understand differential treatment impacts between subgroups.
- Distribution of treatment effects across population subgroups (by race and ethnicity, socio-economic status, gender, age, etc.). Clinical effectiveness research, including results from RCTs, often do not report health outcomes by equityrelevant subgroups, limiting analysis of how differences in response to a treatment may impact its value.

 Patient-centered and patientreported outcomes data reflecting clinical endpoints, quality of life outcomes (e.g., functioning, fatigue), patient preferences, patient experience, patient-centered economic outcomes, and other outcomes that matter most to patients in their health journey or health care.

Over time, ongoing efforts to improve the representativeness of research data – especially increasing diversity in clinical trials, modernizing clinical trials, and focusing research on patient-centered outcomes and economic impacts – will improve availability of data for equity-centered HTA. But the increasing focus on equity in policymaking and system transformation efforts means that waiting for upstream changes to address data gaps that currently limit equity-centered HTA is no longer an option.

Using mixed methods to combine data from a variety of sources, including rigorous qualitative data, will help fill data gaps and balance the limitations of any one data set. It is worth noting that while quantitative data may capture many aspects of outcomes, qualitative data can provide valuable patient insights to contextualize analyses, especially when representative data from under-served populations are not available.

In addition, HTA practitioners may overcome data gaps by using statistical methods to **impute missing values** from a variety of sources, rather than eliminating cases with missing data.<sup>23</sup>

HTA practitioners also may need to **collect additional data** for an equity-centered assessment. It is essential to

collaborate with patient organizations to collect data on patient experiences, goals, preferences, and priorities around treatment for specific health conditions.

**Quantitative data** is information that can be counted or measured numerically.

**Qualitative data** is information in the form of text, words, stories, or descriptions.



Figure 5. Accountability Actions and Practice Changes for HTA Practitioners, Users, and Impacted Populations to Collectively Define and Address Data Gaps that Currently Block Equity-Centered HTA

#### HTA practitioners, users, and **Foundational Change** impacted populations collectively define and address data gaps that currently block equity-centered HTA Accountability Actions Professional Association Leaders • Advocate for open access to data, including integrating data from disparate **Researchers** sources (e.g., care delivery, industry, • Partner with patients to identify data gaps research). and collect additional data when needed, • Support national efforts to standardize especially data on patient treatment data necessary for equity-centered HTA, including patient-centered outcomes. preferences, patient-centered outcomes, and economic impacts on patients and • Offer training on mixed methods approaches, including ways to strengthen caregivers. • Use mixed methods and multiple data HTA analyses by combining different sources, including real-world evidence and types of data. qualitative data, to address data gaps. • Conduct secondary analyses where **Journal Editors** needed to derive the inputs necessary for Create pathways to open access publishing to improve accessibility of data

### for equity-centered HTA.

#### **Research Sponsors**

- Fund research to identify and address data gaps limiting equity-centered HTA.
- Encourage mixed methods approaches for examining burden of disease (including health disparities) and patient priorities.
- · Fund patient organizations to collect data on treatment goals and preferences among diverse samples of patients.

#### **Payers and Purchasers**

- Increase access to de-identified claims data and other real-world evidence for use in HTA research.
- Invest in initiatives to collect data on patients' health-related social needs and share de-identified data to inform HTA.

equity-centered HTA.

#### **Patient Organizations**

- Partner with researchers to explore use of registries, patient surveys, patient-reported outcomes, and other patient-centered data for use in HTA.
- Collaborate with researchers to collect data on treatment goals and preferences among diverse samples of patients.



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HTA Reports Consistently Acknowledge Data and Methods Limitations that May Impact or Impede an Equity Analysis

All data and methods have limitations, and the impact of these limitations on HTA conduct and use may vary for different patients and communities. Clarity around data and methods limitations is necessary to move the field away from building HTA models to fit available data, and instead toward using those data and methods best suited to answer questions important to patients and decision-makers. Some limitations are inherent to a particular data source or method and may be mitigated by using multiple sources or methods to answer one question (a process sometimes called triangulation). Other limitations result from gaps in available data or methods. In particular, HTA research is often limited by availability of data to explore differential impacts for patient subgroups, such as lack of data on race or ethnicity or disability status.

Questions to Consider when Acknowledging Data and Methods Limitations		
<ul> <li>Are we measuring relevant outcomes?</li> <li>Unclear what we should be measuring</li> <li>Unclear whose priorities are reflected by the outcomes measured</li> <li>Unclear who should be measuring outcomes</li> </ul>	<ul> <li>Are necessary data available for use?</li> <li>Data on relevant patient impacts exist, but</li> <li>There are barriers to accessing, sharing, and using the data</li> </ul>	
<ul> <li>Are we able to collect necessary data using current measures?</li> <li>Uniform data not available</li> <li>Unclear who can or should standardize and collect uniform data</li> </ul>	<ul> <li>Are we able to evaluate the data using current methods?</li> <li>Clear and valid data are collected and accessible, but</li> <li>Methods for incorporating the data into HTA are not well-formed.</li> </ul>	



Beyond simply acknowledging limitations (as is standard practice in all research publications), HTA practitioners must specifically discuss how data and methods limitations may bias HTA findings in ways that harm marginalized communities. For example, while quality-adjusted-life-years (QALY) and costs from the payers' perspective have been the most widely considered outcomes in cost-effectiveness analyses, HTA practitioners must acknowledge criticisms<sup>24</sup> (particularly from patient communities<sup>25</sup>) and the ethical implications of using QALYs.<sup>26</sup> It is important to work with individuals from communities experiencing persistent health inequities to understand potential harms. For example, IVI's report, Finding Equity in Value: Racial and Health Equity Implications of U.S. HTA Processes, draws on the experience of the Sick Cells organization to discuss the potential implications for marginalized communities relying on incomplete analyses when conducting HTA.

Figure 6. Accountability Actions and Practice Changes for HTA to Reports to Consistently Acknowledge Data and Methods Limitations that May Impact or Impede an Equity Analysis

### Foundational Change

#### Accountability Actions

#### **Professional Association Leaders**

 Establish standards for discussing and reporting equity implications of data gaps and methods limitations, including the potential for exacerbating health disparities.

#### **Journal Editors**

- Require that all HTA publications:
  - Justify how the data and methods used account for equity (or do not) when assessing the value of healthcare technology.
  - Discuss equity implications of data gaps and methods limitations, including the potential for exacerbating health disparities.

#### **Research Sponsors**

 Require all HTA reports or publications to discuss equity implications of data and methods gaps, including the potential for exacerbating health disparities.

#### **Payers and Purchasers**

 Raise questions about data and methods limitations during HTA review and decisionmaking processes. HTA reports consistently acknowledge data and methods limitations that may impact or impede an equity analysis

#### Necessary Practice Changes

#### Researchers

- Transparently acknowledge uncertainty, including uncertainty in data, measures of uncertainty for each subgroup, and data gaps, including un- or under-represented subgroups.
- When reporting HTA findings, discuss how data and methods limitations may bias HTA findings in ways that harm marginalized communities.

#### **Patient Organizations**

- When engaged in HTA:
  - Share patient case studies and journey maps to inform selection of patient subgroups for analyses.
  - Raise questions about how data and methods choices could obscure or exacerbate health disparities.
  - Call out data gaps, such as omitting relevant outcomes or aggregating data in ways that overlook communities experiencing health inequities.



## HTA Practitioners Test and Adopt New Methodological Approaches to Account for Equity

Developing new equity-centered HTA methods to accompany existing approaches will further strengthen the role of HTA in advancing equity. Drawing on frameworks and adapting methods from other fields, such as public health, epidemiology, and bioethics, could inform methods that are suitable for tackling broader value elements not yet widely adopted in current HTA practice. Adapting approaches from HTA practice in other countries can also enhance and inform HTA practice in the U.S. context.

# Emerging approaches with potential to account for equity in HTA:

- **Generalized Risk-Adjusted Cost-**• Effectiveness (GRACE). The GRACE<sup>27</sup> approach distinguishes itself from traditional CEA analysis using QALY by incorporating the effects of diminishing returns to health improvements as severity of illness decreases. It also provides a rationale for valuing quality-of-life gains for persons with disabilities more than for comparable nondisabled persons. HTA practitioners may consider using the GRACE method to counter criticisms against the QALY measure for its potential to discriminate against people with disabilities or chronic conditions.
- Social Return of Investment
  (SROI). HTA studies from other countries have used social return of investment,<sup>28</sup> an approach that assesses a broad range of economic, social, and environmental impacts of interventions. SROI focuses on an inclusive process of stakeholder engagement to provide a comprehensive view of value, making it one potential approach to account for equity.
- Agent-Based Modeling (ABM). ABM<sup>29</sup> can examine a wide range of health outcomes and also incorporate a variety of factors, including individual-level characteristics, social networks, and environmental factors, to simulate long-term population-level outcomes. Originally emerging from studies in epidemiology, the model simulates the spread of infectious diseases considering factors such as transmission dynamics, contact patterns, and intervention strategies. Using ABM to study complex health systems may aid in decision-making processes for public health interventions and policy formulations that are difficult to model otherwise.



Distillation Method. The distillation method<sup>30</sup> offers a valuable complementary analysis to intent-to-treat results, particularly in trials where factors like inconsistent participation, engagement, or variations in dose or fidelity exist within the treatment arm. This approach becomes especially relevant in addressing ongoing efforts to enhance representativeness and diversity in RCTs.

Exploring and developing new methods is important to deepen the practice of equity-centered HTA.

#### Figure 7. Accountability Actions and Practice Changes for HTA Practitioners to Test and Adopt New Methodological Approaches to Account for Equity

#### HTA practitioners test and **Foundational Change** adopt new methodological approaches to account for equity **Accountability Actions Professional Association Leaders** Promote interest groups and practical application initiatives to encourage Researchers development and use of new equity- Collaborate with researchers from other centered HTA methods. fields and countries to adapt equity-• Facilitate interdisciplinary discussions to encourage adapting equity-centered centered methods to the U.S. HTA context. methods form other fields and countries • Test new equity-centered HTA methods in into the U.S. context. current projects and studies. **Patient Organizations Journal Editors** • Encourage manuscript submissions • When current HTA practice does not serve proposing and testing out new equitypatients well: centered methods. • Ask researchers: What can you do differently to address questions important to patients? **Research Sponsors** • Ask payers and purchasers: How can · Invest in studies that develop new equityyou include patients' priorities in your centered HTA methods. assessment of value?

#### **Payers and Purchasers**

· Provide ongoing training as new equitycentered HTA methods emerge.

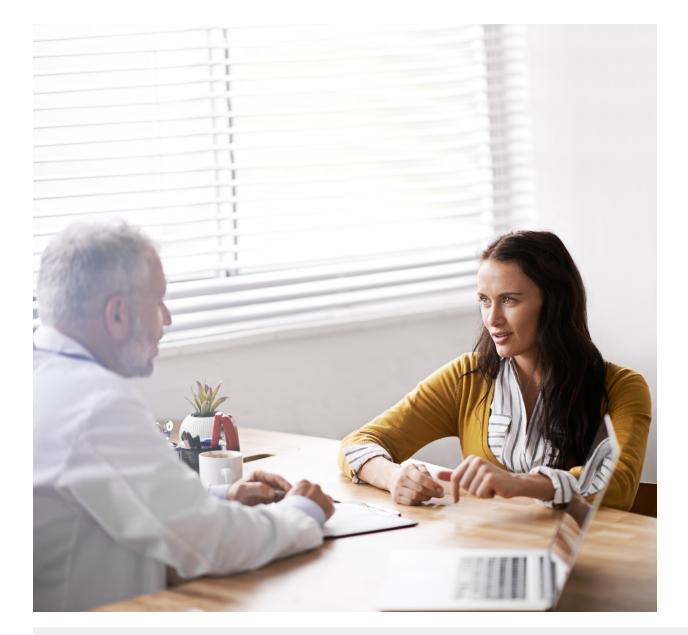
A Focus on Data and Methods in Health Technology Assessment



# **Case Studies**

The case studies highlighted in this section illustrate foundational changes in practice. Though the approaches and context differ for each case, together these examples show how small steps can add up to big changes that center equity throughout HTA practice and research. The two case studies that follow include:

- How Conducting Distributional Cost-Effectiveness Analysis (DCEA) Leads to Equity Insights
- Integrating Equity Into Value-Based Purchasing Contracts



### Case Study: How Conducting Distributional Cost-Effectiveness Analysis (DCEA) Leads to Equity Insights

A team of five researchers conducted a distributional cost-effectiveness analysis (DCEA) in 2022 to explore the health equity impacts of Medicare coverage of inpatient COVID-19 interventions in the U.S.<sup>31</sup>

#### About Distributional Cost-Effectiveness Analysis (DCEA)

Cost-effectiveness analysis (CEA) is a method to compare the costs and benefits of one or more interventions. It is usually expressed as incremental cost divided by incremental effectiveness. Cost-effectiveness is usually assessed relative to a comparator, such as the current standard of care. *Distributional* CEA looks at the distribution of these costs and effects across different groups of people within the total population to answer questions about equity impacts or overall impacts on social welfare. This can support understanding how interventions affect total costs and health within different groups based on their social determinants of health, access to care, and differential treatment effects. DCEA also examines costs and effects based on trade-offs in paying for one treatment at the expense of other health investments, known as opportunity costs.<sup>31, 32</sup>

#### DCEA as an Approach for Centering Equity in HTA

The research team conducted a targeted literature review to understand disparities in hospitalizations and deaths in the hospital from COVID-19. Based on this review, the team included in its analysis two primary, equity-relevant factors: race and ethnicity, and social vulnerability. For race and ethnicity, the team used three groups for which adequate public data were available: Hispanic, non-Hispanic black, and non-Hispanic white. For social vulnerability, the team used a Centers for Disease Control and Prevention (CDC) measure that estimates community vulnerability during public health emergencies based on a mix of social and demographic factors. These data are available at the census tract level and estimate social vulnerability in five levels, from least vulnerable to most vulnerable. Combining the three race and ethnicity groups with the five social vulnerability groups generated 15 equity-relevant subgroups, each with unique estimated risks for COVID-19 outcomes based on these factors and with their own unique impacts for opportunity costs.

In conducting the DCEA, the research team modeled estimates for differences in COVID-19 outcomes stratified by these equity-relevant factors across the population. For each of the 15 population subgroups, the team used available data to estimate information about baseline health status, the effectiveness of COVID-19 treatment, and health opportunity costs. These estimates helped the team answer questions such as: What disparities exist today in COVID-19 hospitalization and death? Would COVID-19 treatments work differently for different groups of patients? Who might have to give up resources to pay for COVID-19 treatment? What is the impact of resources forgone to fund cost-increasing interventions?

#### **Strategies to Address Data Gaps**

To conduct their analysis, the team had to work around several types of data gaps. Because data on county-level life expectancy at birth for different race and ethnicity groups was limited, the team combined data from several different data sets to estimate values for each population subgroup. Clinical trial data on COVID-19 treatment effectiveness was not reported separately for the specific race and ethnicity and social vulnerability subgroups the team was using. To address this gap, the team assumed that the treatment was equally effective in all subgroups and used published data to estimate differences in each subgroup's underlying risk for hospitalization or death due to COVID-19. To address lack of data on the distribution of opportunity costs across subgroups, the team made reasonable assumptions based on the available evidence and tested out different assumptions to understand how that changed their findings. Similarly, to estimate how much people in the U.S. value avoiding inequalities (that is, how much of a trade-off in opportunity costs is acceptable in order to reduce health disparities), the team used data from the U.K. and tested different assumptions.

The study found that Medicare funding of COVID-19 treatments would not only increase the health of the population overall, it would also decrease the gap in health between more vulnerable and less vulnerable subgroups. This finding suggested that Medicare coverage for COVID-19 treatments would contribute to reduced health disparities.

#### **Lessons Learned**

**Start with the data that are available now.** The team utilized what life-expectancy data was available and identified critical data gaps. Data collated by the research team through a follow-on study on baseline estimates of health inequalities is available for use in other DCEA studies.<sup>23</sup> This data will need to be remeasured once the impact of COVID-19 morbidity and mortality becomes available through U.S. public health data.

**Identify and work around data gaps.** The team used several estimation methods to address data gaps. In addition, data on inequality aversion was not available for the U.S., so they used data from the U.K. to address this gap.

There is consensus in the U.S. on value in addressing health inequities. The team is conducting a study to estimate inequity aversion for the U.S.; however, estimates from the U.K. can be used for now.

We need to do a better job of understanding opportunity costs. Better tools are needed to inform decision-making about healthcare resource allocation in the U.S. It is especially important that these tools help decision-makers understand what groups are more or less likely to bear consequences from those decisions when healthcare budgets are constrained.

# Case Study: Integrating Equity into Value-Based Purchasing Contracts

Blue Cross Blue Shield of Massachusetts (BCBSMA) is acting on its equity commitments by establishing pay-for-equity contracts that incentivize health systems to address health disparities.

#### **Strategies for Centering Equity**

BCBSMA established pay-for-equity value-based care contracts with five large health systems already participating in its Alternative Quality Contract (AQC) program. The participating providers will receive financial rewards for reducing racial and ethnic disparities in quality metrics. A key part of the insurer's approach is to **build data infrastructure** for examining health disparities by:

- Expanding data collection and imputing missing data: BCBSMA first took stock
  of what data it already had on its members' race and ethnicity and explored
  additional data sets from government, employer, and academic sources. It
  decided to use an approach that combines these data sets and imputes missing
  race and ethnicity values. Imputation is a statistical method for calculating the
  probabilities that a member would self-identify in each race and ethnicity based
  on other available information. BCBSMA uses data on race and ethnicity that
  members self-report directly to the plan as the gold standard, then combines this
  data with information from other data sets to impute missing data.
- Reporting quality metrics by race and ethnicity: BCBSMA uses this data to publicly report quality metrics by race and ethnicity for its 1.4 million commercial members. It also provides health systems participating in AQC with confidential reports showing their performance on equity compared to peer institutions. The five health systems now participating in pay-for-equity contracts receive financial incentives for reducing health disparities on key metrics.
- Investing in technical assistance and financial support for health systems: In 2021 Blue Cross established an equity action community with the Institute for Healthcare Improvement to provide technical assistance and foster cooperative learning among all AQC participants. It also provided <u>\$25M in grants</u> for action community participants to support infrastructure, staff time, and capacity building for addressing inequities.

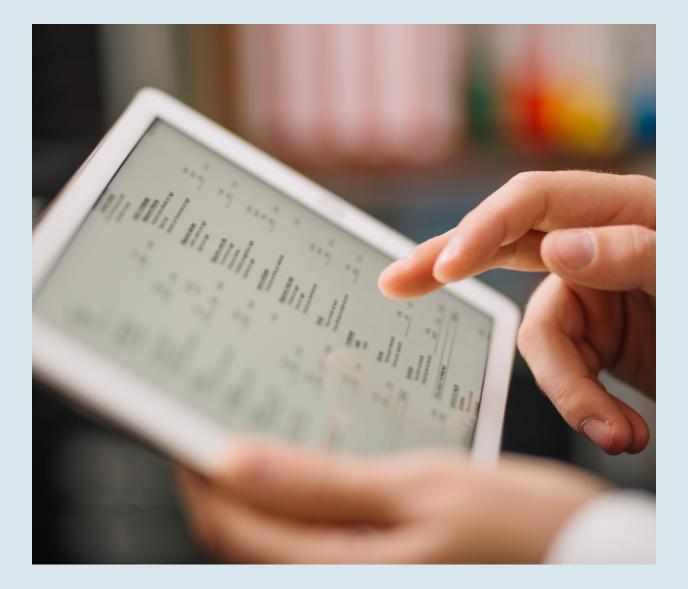
#### Lessons Learned

In reflecting on the important role of equity-driven data and methods to its value-based purchasing, BCBSMA Senior VP of Performance Measurement and Improvement Mark Friedberg shared:

• It is better to act now using imputed data than to let inequities go unaddressed while waiting for self-reported data. Analyzing only those cases with self-

reported race and ethnicity data and ignoring the rest (known as a complete-case analysis) introduces bias because data are rarely missing at random. This is especially true for race and ethnicity. Failing to act until 100% self-reported data area available ignores the urgent needs of individuals experiencing inequities.

- Implementing federal data standards made combining data sources easier.
   Following the Fast Healthcare Interoperability Resources data standards, known as FHIR, helped the insurer work through differences in how race and ethnicity information is recorded across different data sets. This made it easier to combine data, improving reliability of imputation methods.
- Examining disparities supports equity efforts across the health system. In addition to supporting its own equity commitments, reporting metrics by race and ethnicity highlighted quality gaps health systems were previously unaware of, enabling focused improvement efforts. Employers working toward their own equity goals are also increasingly asking payers, including BCBSMA, for data on how they are addressing health disparities.



# **Action Guides**

Readers can find all of the action steps from this report, organized by stakeholder role, within the brief, 2-page action guides linked below. These action guides are meant to provide ideas on where to begin taking action to foster change in the practice of HTA. Each stakeholder guide includes links to best-in-class resources and tools to help readers create impact. These action guides will continue to grow and evolve over time as new actions and resources are identified by partners. Click below to download the guide that aligns with your role or explore the <u>full set of action guides</u>.

To fulfill the promise of value-based care, integrate equity throughout HTA by taking the actions highlighted in these guides.



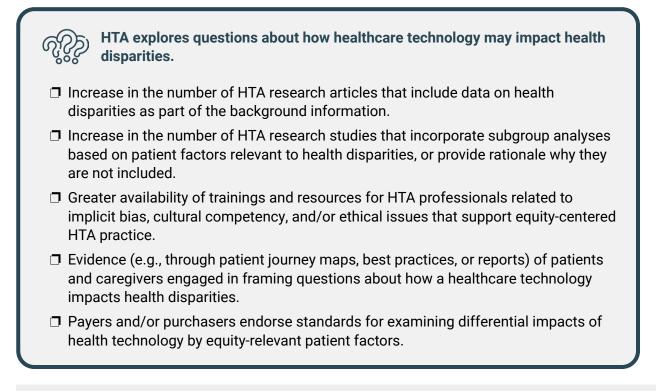
# Making Progress Toward Equity in HTA

Accountability is an essential part of the change process. In this section, we discuss how IVI and other stakeholders can gauge progress in centering equity in HTA within the **Data and Inputs** and **Methods** domains. In this discussion we focus on signs of near-term progress over the next 12 to 18 months (through mid-2025). By progress, we mean interim steps toward larger changes. For the **Data and Inputs** and **Methods** domains, that means including in HTA exploration of

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how healthcare technology may impact health disparities, and being mindful of equity implications when choosing and reporting data and methods for those assessments. For now, we focus on signs of progress, rather than formal metrics, recognizing the early stage of equity integration in HTA. Over time, tracking these signs of progress will help develop more robust accountability mechanisms, including more formal measures of success.

# Signs that the HTA field is making progress toward integrating equity through shifts in the data and methods of HTA include:





HTA practitioners use existing methods that account for equity to assess the value and impact of healthcare technology.

- **G** Greater availability of training on equity-centered methods for HTA researchers.
- Increase in the number of HTA research studies that use equity-centered methods or that include a justification of why equity-centered methods are not used.
- Increase in the number of HTA research studies that include the use of decision analysis (e.g., MCDA) to incorporate equity-relevant factors in HTA.
- Increase in the number of HTA research articles that incorporate equity metrics (e.g., disparities index) to assess equity impact.



HTA prioritizes data that are representative of and reflect what is important to impacted populations.

- **I** Standards published to guide conduct of equity analyses as part of HTA.
- Increase in the number of HTA research articles that report how the outcomes examined are important to impacted populations.
- Increase in the number of HTA research articles that discuss limitations due to gaps in data representativeness.

HTA practitioners, users, and impacted populations collectively define and address data gaps that currently block equity-centered HTA.

- Increase in HTA practitioner engagement in national initiatives to standardize data necessary for equity-centered HTA.
- Increase in HTA practitioner engagement in initiatives to standardize patientcentered outcomes measures (e.g., IVI's Economic Impacts project).
- Increase in funding opportunities for patient and caregiver groups to partner in HTA conduct, especially collecting data on patient goals, preferences, and outcomes.
- Increase in number of courses within Health Economics and graduate programs on qualitative research methods to address data gaps impeding equity-centered HTA.

HTA reports consistently acknowledge data and methods limitations that may impact or impede equity analysis.

- □ Standards published to guide reporting HTA sub-group analyses based on equityrelevant patient factors.
- Increase in number of HTA research articles that discuss any data and methods limitations that impacted the ability to account for equity.
- Increase in HTA research articles that acknowledge uncertainty in analyses or findings as a result of data gaps or lack of representativeness in the data.
- Evidence that payers and/or purchasers are engaging patients and caregivers to understand data and/or methods gaps in HTA assessments.

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HTA practitioners test and adopt new methodological approaches to account for equity.

- Increase in the number of forums or public dialogues about testing new approaches to account for equity in HTA.
- Increase in funding opportunities for HTA research that incorporates novel methods to account for equity.
- Evidence that HTA practitioners are engaging patients and caregivers in HTA research develop and test new methods that account for equity.

In keeping with its mission to advance the science, practice, and use of patient-centered HTA, IVI calls on its peer institutions to join in a commitment to equity-centered HTA practice. This report, and IVI's ongoing Health Equity Initiative, represent initial steps toward fulfilling this commitment.

#### In its patient-centered HTA research, IVI commits to:

- Collaborate with patients and caregivers to define impacted populations and identify outcome and impact data and measures relevant to these populations.
- Use a mix of clinical trial and real-world data sources (e.g., claims, EHR, registry, and quality and social care measures) in HTA models.
- Follow existing checklists and other resources that guide equity-centered HTA practices.
- Explore implementation of equity-centered HTA methods that have been established in other countries and contexts.
- Consistently and transparently acknowledge gaps and limitations in data and methods.
- Transparently share findings and lessons learned from applying equitycentered data and methods practices.
- Support national efforts to standardize data necessary for equitycentered HTA, especially standards around data on race, ethnicity, and social determinants of health.

We call on researchers, patients and caregivers, professional association leaders, journal editors, research sponsors, and payers and purchasers to join IVI in taking action now to ensure equity is a driving force in HTA.

# **Appendix 1: Health Equity Initiative Value Framework**

Value-based care promises to deliver better healthcare experiences, better population health outcomes, and lower healthcare costs by directing resources toward the most effective treatments.

A decade of experience implementing value-based care makes clear: there is no value without equity. The increasing focus on equity in <u>policymaking</u> and <u>system</u>. <u>transformation efforts</u> reflects this learning. Institutions and decision-makers across the healthcare sector have committed to ensuring that everyone has a fair and just opportunity to be as healthy as possible.

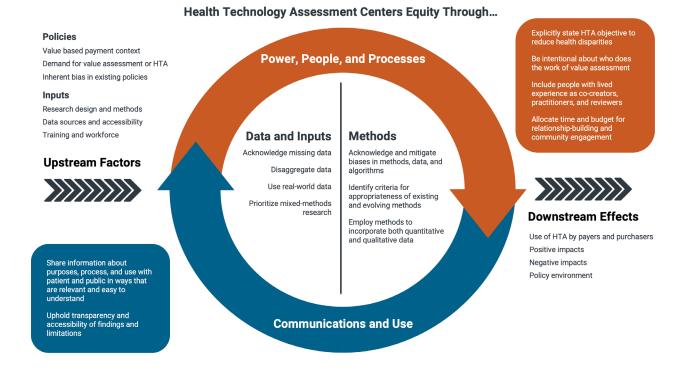
Health technology assessment (HTA), too, must commit to and integrate equity. HTA advances equity when it reduces health disparities by aligning access and affordability to healthcare technologies and services with differing needs and values of diverse patient populations, especially those who are most marginalized.

Researchers, patients and caregivers, professional association leaders, journal editors, research sponsors, and payers and purchasers must act now – and act together – to ensure that HTA practice is grounded in equity. To fulfill the promise of value-based care, stakeholders must integrate equity throughout HTA by taking the actions outlined in this report.

#### Integrating Equity throughout HTA Practice

The Innovation and Value Initiative's (IVI) <u>Health Equity Initiative</u> aims to identify actionable changes to HTA processes, methods, and communication that acknowledge and contribute to progress in addressing existing health disparities through more informed healthcare decision-making. In partnership with a <u>Health Equity Initiative</u> <u>Steering Committee</u>, and through dialogue with over 40 stakeholders representing patients and caregivers, researchers, policymakers, clinicians, industry, payers, and purchasers, IVI has developed a framework for centering equity in HTA (Figure A1).

#### Figure A1. Health Equity Initiative Value Framework



IVI's framework for centering equity in HTA includes four essential domains of HTA practice where fundamental shifts are necessary to ensure that HTA advances equity:

- **Power, People, and Processes:** This domain is foundational to rebalancing power throughout HTA processes, with an emphasis on grounding HTA in lived experience through co-creation and leadership by patients, caregivers, and community members, particularly those from marginalized communities.
- Data and Inputs: The domain focuses on prioritizing equity when selecting data sources to inform the models and cost-effectiveness analyses that are primary outputs of HTA. Key strategies for equitable data use include using representative data, developing and using real-world evidence, and transparently acknowledging data limitations and biases.
- **Methods:** This domain speaks to immediate practices and tools necessary to integrate equity considerations into HTA, as well as longer-term areas for investment and collaboration among all organizations acting in this research field.
- **Communications and Use:** This domain focuses on full process transparency in the design and assumptions of HTA models, how the results and limitations of HTA are communicated to both impacted communities (i.e., patients and caregivers), and decision-makers (e.g., payers, purchasers, and clinicians), and clarity about the impact of those limitations on the use of HTA for decision-making.

### **Appendix 2: Stakeholder Roles**

To identify action steps to integrate equity throughout HTA, we focused on six key stakeholder roles (below). We recognize that these stakeholder roles are not mutually exclusive, that roles differ by organization, and that we have not called out every role important to HTA. For example, payers often act as both sponsors and users of HTA-related research and policymakers are important in shaping the context of HTA conduct and use. Our goal in organizing around these six stakeholder roles is to highlight near-term action steps and opportunities for synergy as the actions of each stakeholder build on one another to catalyze fundamental changes in the practice of HTA.



Researchers and health economics and outcomes research (HEOR) professionals who conduct or produce HTA, regardless of institutional setting. This could include HTA practitioners working in academia; life sciences, pharmaceutical, device, or digital health industries; and other research institutions (e.g., <u>Institute</u> for Clinical and Economic Review, <u>University of Washington CHOICE Institute</u>, <u>Innovation and Value Initiative</u>). Lead researchers, such as principal investigators (PI), as well as others responsible for the oversight and conduct of HTA, and research institution leadership (e.g., directors, chief science officers) have important roles to play in shaping the conduct of HTA.

#### Journal Editors

Editors-in-chief, associate editors, and editorial board members of peer-reviewed journals that frequently publish HTA findings, methods, or related research (e.g., *Value in Health, PharmaceoEcnomics, Journal of Managed Care and Specialty Pharmacy, Journal of Comparative-Effectiveness Research*). Through editorial oversight and discretion, authorship guidelines, and facilitating the peer review process, journal editors play an important role in shaping what gets published about HTA, what details are included within those publications, and whose contributions are recognized through authorship.



Individuals who receive healthcare services and their caregivers, especially individuals who bring lived or caregiving experience with health conditions, diagnoses, or treatments relevant to a particular HTA. This group also includes individuals working or volunteering within organizations that represent, support, or advocate for patients and caregivers (e.g., National Health Council, American Cancer Society). While we group together patients, caregivers, and patient organizations for the purpose of this document, we recognize that caregiving is a distinct perspective from that of patients and that there is no universal patient or caregiver perspective. Patients, caregivers, and the organizations that seek to represent them are extremely diverse in experiences, values, preferences, and identities. We recognize that lived experience as patients and caregivers includes, and cannot be isolated from, intersecting cultural identities, socio-political context, and experiences of marginalization. Throughout this document, we refer to patients and caregivers as inclusive of both individuals bringing their own lived experience and organizations advocating on behalf of patients and caregivers. We also use the term 'patient' with the understanding that each patient is foremost a whole person and is not solely defined by their health condition(s).



Decision-makers within employer purchasers and commercial and public payers who use findings from HTA to inform market launch planning, plan design, coverage, reimbursement, or other decisions about payment for healthcare treatment (e.g., chief medical officers and other C-suite leaders, medical or pharmacy directors, members of pharmacy and therapeutics committees, leaders within pharmacy benefit managers).

#### esearch Sponsors See See Sponsors

Decision-makers within organizations sponsoring HTA-related work, whether supported through public or private grants, contracts, or other funding mechanisms. Specific research sponsor roles include directors, program officers, and leaders within entities that fund the conduct of patient-centered outcomes research, comparative effectiveness research, HTA, HEOR, or related research. Examples of sponsor organizations include the <u>National Institutes of Health</u>, <u>Patient-Centered Outcomes Research Institute</u>, philanthropies, and life science companies. We focus on the role of sponsors, rather than funders, recognizing that financial support for HTA comes from a variety of organizations and mechanisms, including those outside traditional research funders.

# Professional Association Leaders

Presidents, board and committee members, and other leaders of professional societies and trade associations focused on health economics and/or HTA practice. This includes membership organizations representing and providing oversight of professionals engaged in HTA, including health economists, researchers, and other HEOR professionals (e.g., ISPOR -The Professional Society for Health Economics and Outcomes Research, American Society of Health Economists, and AcademyHealth). This group also includes members of trade associations such as Advanced Medical Technology Association, Medical Device. Innovation Consortium, and the Pharmaceutical Research and Manufacturers of America that establish best practices and principles related to HTA conduct and use. By establishing best practices, guidelines, standards, and training, leaders and members within professional associations play a key role in ensuring high-quality, ethical HTA conduct.

# **Appendix 3: Glossary**

Term	Definition
Cost-Effectiveness Analysis (CEA)	Form of economic analysis that compares the relative costs and outcomes, or effects, of different options. Cost-effectiveness analysis is the most commonly used HTA method to inform priorities for healthcare decision-making. Traditional CEA aims to inform decisions to improve overall health for a population based on the estimated impact of a particular healthcare technology for an average patient.
Comparative Effectiveness Research (CER)	Studies that compare the benefits and harms of two or more treatments, clinical strategies, or other healthcare technologies.
Effectiveness	The ability of an intervention (drug, device, treatment, test, pathway) to provide the desired outcomes in the relevant patient population.
Efficiency	A focus on how to use a limited set of resources.
Health Disparities	Health disparities are differences in health outcomes and status between population groups characterized by social, demographic, environmental, and geographic attributes. <sup>33</sup>
Health Economics and Outcomes Research (HEOR)	A term that includes both outcomes research studies encompassing real-world evidence of treatment patterns among patients, health outcomes, resource utilization, and economic evaluation of the costs associated with treatment. Multiple disciplines contribute to this type of research including clinical research, clinical outcomes assessment, epidemiology, health economics, policy research, and health services research.
Health Equity	There are many definitions of health equity. At its most basic, health equity is when everyone has the opportunity to be as healthy as possible. This means that everyone has the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances. <sup>34</sup>
Health Inequities	Long-standing patterns of health disparities due to unjust differences in social, economic, environmental, and health care resources. <sup>35</sup>
Health Technology Assessment (HTA)	A method of systematically assessing the value of healthcare technology by using available evidence to model its expected benefits, risks, and costs.

Term	Definition
Impacted Population	Communities of patients and caregivers whose health and access to treatment are likely to be influenced by decisions based on a particular HTA.
Mixed Methods	Mixed methods strategically integrate or combine rigorous quantitative and qualitative research methods to draw on the strengths of each. <sup>36</sup>
Multi-Criteria Decision Analysis (MCDA)	A framework for supporting complex decision-making with multiple and often conflicting criteria that stakeholder groups and/ or decision-makers value differently. Through the use of MCDA, priorities and preferences of patients, insured individuals, and experts can be integrated systematically and transparently into the decision-making process.
Patient Reported Outcomes (PRO)	A health outcome directly reported by the patient who experienced it. This is in contrast from clinical or other outcomes reported by physicians, nurses, or other individuals.
Perspective	Refers to the point of view adopted when deciding which types of costs, health, and economic benefits are to be included in an economic model (e.g., healthcare sector vs. societal).
Qualitative Data	Information in the form of text, words, stories, or descriptions. Examples of qualitative data include transcripts from interviews or text in news articles. Qualitative data is not numerical, though researchers can count themes or ideas occurring within qualitative data through qualitative research methods.
Quality Adjusted Life-Year (QALY)	The fraction of a perfectly healthy life-year that remains after accounting for the damaging effects of an illness or condition.
Quantitative Data	Information that can be counted or measured numerically. Examples include measuring distance in miles, cost in dollars, or time in hours.
Randomized Controlled Clinical Trials (RCT)	A type of research study that assigns some individuals (or other entities being studied) to different groups by chance. In medical research, typically one group receives an intervention, such as a medication or treatment, while the other group does not. This approach allows researchers to measure the effect of the intervention, while accounting for differences between individuals across the two groups. Randomized control trials are considered the "gold standard" for determining whether and how well a treatment works.

Term	Definition
Real-World Data and Evidence	Data about patients' health status or delivery of health care that are routinely collected from a variety of sources. Sources may include electronic health records, insurance claims and billing data, product and disease registries, and data gathered through personal devices or health applications. Analyzing real-world data, such as through observational studies or pragmatic clinical trials, generates real-world evidence.
Social Determinants of Health (SDOH)	Conditions in which people are born, grow, live, work, and age. These circumstances are shaped by the distribution of money, power, and resources at global, national, and local levels. <sup>37</sup>

#### Endnotes

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The Innovation and Value Initiative (IVI) is a 501(c)(3) tax-exempt, non-profit research organization dedicated to advancing the science and improving the practice of health technology assessment through development of novel methods and the creation and application of enhanced health technology assessment models to support local decision-making needs in healthcare.

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