

2023 IVI Methods Summit Resources

- Page 2** **Agenda.** 4th Annual IVI Methods Summit: Rewriting the Playbook on Health Technology Assessment: Equity and Economic Impacts on Patients and Families
- Page 6** **A Synthesis of Cross-Stakeholder Insights.** No Value Without Equity: Transforming Practice and Accountability for Equity in Health Technology Assessment
- Page 28** **Value Blueprint.** No Value Without Equity: Action Opportunities Emerging from the IVI Health Equity Initiative
- Page 42** **Summary.** HEI Key Informant Interviews
- Page 64** **Brief.** Principles for Health Technology Assessment

2023 IVI 4th ANNUAL METHODS SUMMIT

March 13 – 14, 2023 | Washington DC & Virtual Event

Rewriting the Playbook on Health Technology Assessment: Action for Equity and Measuring Economic Impact

*Movement in policy, research and dialogue continue to emphasize that the U.S. health system cannot realize its value-based goals without measurable action on health equity and economic impacts on patients and families. Health Technology Assessment (HTA) is increasingly seen as a resource to guide decision-making about benefit design, price, and overall resource allocation, and yet the methods and inputs historically used for such work are both outdated and insufficient to reflect significant differences in patient disease and experience. Moreover, data is often missing on subgroup demographics, patient-identified outcomes, and economic impacts. The Innovation and Value Initiative has cultivated ideas and solutions to activate change through two key multistakeholder initiatives: the Health Equity Initiative, and the Economic Impacts Framework project. The 4th Annual IVI Methods Summit is a two-day forum highlighting key learning from both efforts, and exploring the immediate actions, roles, and accountability metrics needed for real and sustainable change.**

AGENDA

Monday, March 13, 2023

(In-person with livestream component)

Day 1: Changing Accountability and Practice of HTA for Health Equity

Time	Agenda Description Purpose:	Presenters / Panelists
10:00 am	Introduction and Welcome Objectives of the 4th Annual IVI Methods Summit Review of Program	Jason Spangler, MD, MPH, FACPM, Chief Executive Officer, IVI Jennifer Bright, MPA, Chief Strategy and Engagement Officer, IVI Ilisa Halpern Paul, MPP, Senior Policy Advisor, Venable LLP
10:20 am	Fireside Chat - Patient Driven Value – The Key Ingredient for Equity, Economic Impact and Quality <i>This fireside chat will emphasize the essential role for patient insight and collaboration and highlight system-wide learning and challenges that remain for all actors.</i>	Moderator: Jason Spangler, CEO, IVI Keynote: Dora Hughes, MD, MPH, Chief Medical Officer, CMS Innovation Center, Centers for Medicare & Medicaid Services
10:50 am	Keynote: Patient Driven Value – Seeds of Change <i>This keynote presentation will frame patient and family perspectives on why and how HTA needs to change – in</i>	Keynote: Donna Cryer, JD, CEO, Global Liver Institute

* The 2023 IVI 4th Annual Methods Summit is supported by contributions from PhRMA and Alexion Pharmaceuticals, and is partially funded through a Patient-Centered Outcomes Research Institute® (PCORI®) Eugene Washington PCORI Engagement Award (EASCS-24274). IVI general funds, which represent dues from diverse membership, also support this work.

	<i>mindset, methods, and practice – to achieve and uphold health equity.</i>	Moderated Q&A: Ilisa Halpern Paul, Venable LLP
11:20 am	Panel Dialogue: IVI Equity Initiative Key Findings and Recommendations <i>This panel discussion brings steering committee, key informant and roundtable participants in the IVI Health Equity Initiative to review key findings and call to action. Panelists will highlight priority actions for accountability and meaningful change in all dimensions of the Equity Framework</i>	Moderator: Ilisa Halpern Paul <u>Panelists:</u> Jennifer Bright, Chief Strategy & Engagement Officer, IVI Kistein Monkhouse, CEO & Founder of Patient Orator Karam Diaby, PhD., Director Health Economics & Value Evidence Partnership, Otsuka Pharmaceutical Companies Jacquelyn McRae, PharmD., MS., Director of Policy, Research, and Membership, PhRMA
12:05 pm	Question & Answer Session	
12:15 pm	LUNCH	
1:00 pm	Panel Dialogue: What Actions Can Researchers and HTA Practitioners Take to Improve Equity in HTA? <i>This panel will consider priority actions for change in research methods, data generation, and reporting/communication of HTA to promote and sustain a focus on equity in HTA.</i>	<u>Moderator:</u> Eberechukwu (Ebere) Onukwugha, MS, PhD, Professor, University of Maryland <u>Panelists:</u> Nicole Boschi, PhD., MS., Director of Regulatory Affairs, National Multiple Sclerosis Society Leticia Moczygemba, PharmD, PhD, FAACP, FAPhA, Associate Professor in the Health Outcomes Division and Associate Director of the Texas Center for Health Outcomes Research and Education, The University of Texas College of Pharmacy (UTCOP) Stacey Kowal, MSc., Principal Researcher, Health Policy and Systems Research, Genentech Daniel Touchette, PharmD, Professor, University of Illinois, Chicago
1:50 pm	BREAK	
2:00 pm	Panel Dialogue: What Actions Can Users of HTA Take to Improve Equity?	<u>Moderator:</u> Ashley Valentine, Co-founder, Sick Cells

March 13-14, 2023

	<i>This panel will focus on actions that key users of HTA can take to promote accountability and practice change in the conduct and communication of HTA to promote and sustain focus on equity.</i>	<p><u>Panelists:</u> Nelly Ganesan, MPH, Executive Director Health Equity, JPMorgan Chase & Co., Morgan Health</p> <p>Greg Baker, RPh., Co-founder and CEO, EmsanaRx</p> <p>Yasmeen Long, MS, Director, FasterCures, Milken Institute</p>
2:50 pm	<p>Keynote: Compass for Change: Future Action on Equity in HTA</p> <p><i>This closing session will highlight remarks about the role of philanthropy and research funding in shaping change for health equity in HTA.</i></p>	<p>Moderator: Jennifer Bright, IVI</p> <p>Keynote: Nakela L. Cook, MD, MPH Executive Director, PCORI</p>
3:20-3:30 pm	<p>Next Steps and Adjourn</p> <p><i>This session will culminate in reflections about the day's dialogue, and the vision for IVI's future dissemination and implementation of recommendations from the Health Equity Initiative</i></p>	<p>Ilisa Halpern Paul, Venable LLP</p> <p>Jason Spangler, IVI</p>

Tuesday, March 14, 2023

Day 2: Creating our Framework for Measuring Economic Impacts on Patients & Families (Virtual)

Time	Agenda Description	Presenters / Panelists
Purpose:		
10:00 am Public Virtual	Opening Welcome and Reflections on Previous Day	Jason Spangler, CEO, IVI
10:10 am Public Virtual	<p>Fireside Chat: Collaborating to Challenge and Change How Economic Impacts are Measured</p> <p>This keynote discussion will highlight the opportunities to improve our research approach and some of the common challenges that researchers, advocates, and decisionmakers are seeking to address.</p>	<p>Moderator: Jennifer Bright, IVI</p> <p>Gwen Darien, Executive Vice President for Advocacy, Patient Advocate Foundation</p> <p>Gretchen Wartman, Vice President for Policy, National Minority Quality Forum</p>
10:30 Public Virtual	Developing a Research Framework to Capture the Full Range of Economic Impacts on People living with Serious Health Conditions	Moderator: Erica deFur Malik, IVI

March 13-14, 2023

	IVI and AcademyHealth are collaborating to develop a guide for researchers and decisionmakers to capture the full range of economic impacts on people living with serious health conditions. Panelists during this session will reflect on the process of developing the framework.	<p>Panelists:</p> <p>Annie Kennedy, Chief of Policy, Advocacy, and Patient Engagement, Everylife Foundation for Rare Diseases</p> <p>Mary Reed, DrPH, Research Scientist, Kaiser Permanente</p> <p>Juan Marcos Gonzalez Sepulveda, Ph.D, Associate Professor, Duke University Population Health</p>
11:30	Break (Remainder of Day 2 is Invitation-Only)	

Invitation-Only:

Finding Common Ground and Applications of a Research Framework to Measure Economic Impacts on Patients and Caregivers

11:45 am – 2:30 pm Virtual Session

For more information, please contact Erica Malik at erica.malik@thevalueinitiative.org.

Thank you to our sponsors!



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Health Equity Initiative

IVI  INNOVATION AND
VALUE INITIATIVE

NO VALUE WITHOUT EQUITY

Transforming Practice and
Accountability for Equity in Health
Technology Assessment

March 2023

Innovation and Value Initiative

www.thevalueinitiative.org | info@thevalueinitiative.org

Innovations in HTA to Advance Equity

The health technology assessment (HTA) field acknowledges that status quo methods and processes often fail to assess and account for health equity^{2,3,4}. Efforts to integrate equity into HTA practice have thus far been exploratory, yielding recommendations, frameworks, and checklists, but inconsistent adoption^{5,6,7}. A common limitation cited by practitioners of HTA to account for this lack of focus on equity relates to the quality, representativeness, and availability of data⁸. While inclusion and representativeness in research is garnering significant attention, we are only seeing the beginnings of fundamental changes to improve such inputs.

Among Innovation and Value Initiative's (IVI) core principles is a commitment that HTA account for and uphold equity⁹. Building on a series of webinars in 2020-2021, IVI initiated a multi-stakeholder-driven process to explore necessary changes to HTA practice¹⁰. IVI's [Health Equity Initiative](#) aims to identify actionable changes to HTA processes, methods, and communication that acknowledge and resolve existing health disparities in research and healthcare decision-making¹¹. By incorporating representative leadership, methods, and data, HTA can evolve to uphold health equity and prevent further perpetuation of disparities.

After publishing early findings from key informant interviews¹², IVI hosted two roundtable dialogues to identify and prioritize action steps. Primary findings from these conversations include:

- **Fundamental change to the conduct of HTA is necessary to advance health equity.** Incremental or small adjustments “around the edges” will not reduce existing disparities or prevent further inequities in healthcare access or outcomes for patients. This means truly centering HTA on patients’ values and preferences in order to achieve better outcomes for patients, their families, and the broader healthcare system.
- **Stakeholders in positions of power must be accountable for leading change. Further, there is collective responsibility for allyship that includes, and responds to, the perspectives of patients and caregivers.** Funders and payers with financial resources control the prioritization and activation of research. Government payers, regulators, and foundations set expectations for the quality and execution of research, as well as for its use in decision-making¹³. Professional societies and scientific journals set parameters for research quality and influence the pace of change for new methods and the emergence of new research actors, including patients and patient communities. Leaders and implementers within these institutions have an opportunity – and a responsibility – to hold HTA practitioners, researchers, and implementers accountable for integrating equity into all aspects of HTA.
- **All actors must meaningfully engage patients and caregivers in HTA from the start.** New approaches for patient and caregiver engagement are needed when conducting HTA, to meaningfully include these partners in co-creating the questions being asked and designing value assessments that center patients’ lived experiences, goals, unmet needs, and patient-important impacts.

“Health technology assessment advances health equity¹ when it reduces health disparities by aligning access and affordability of healthcare technologies and services with the differing needs and values of diverse patient populations, especially those who are most marginalized.”

IVI's multi-year Health Equity Initiative is guided with the partnership of a cross-sector steering committee. The committee established the definition above to guide the work of developing best practices and new methods to ensure health technology assessment advances health equity.

- **HTA practitioners can no longer wait for better data.** We must begin using the learning laboratory approach – the HTA field can use modeling to shine a light on where there is missing data, where there is a need for research investment, and lead from a platform of improving decision-making through better data.
- **Mixed methods approaches are necessary.** Qualitative and quantitative methods are necessary to guide the direction of HTA and inform the outcomes used to assess healthcare value. Qualitative methods can provide insight into experiences of different subpopulations, highlight impacts not measured in clinical research, and reflect patients' preferences.

IVI Health Equity Initiative

40 Stakeholders*

*Note: Some have two sectors.



13 Patients & Caregivers



19 Researchers



3 Government/Policy makers



4 Clinicians



6 Payer/Purchasers



8 Industry



12

Steering Committee
Members



10

Key Informant
Interviews



2

Roundtables



30+

Hours of Dialogue



100+

Action Ideas

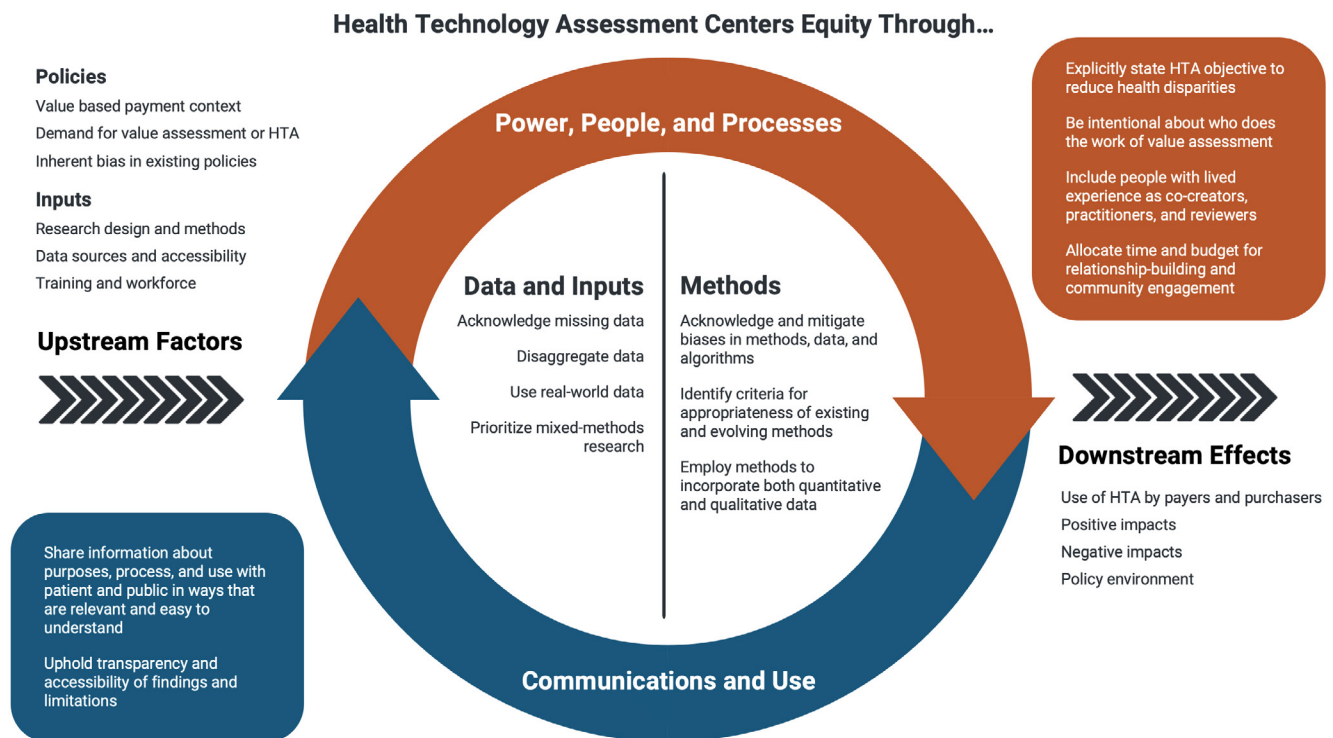
Ensuring that HTA advances health equity is a journey, rather than a destination. Like many entities prioritizing health equity, IVI believes it is vital to acknowledge incremental progress and learning, call out unanswered questions, and tackle complex challenges through collaboration¹⁴. This report documents our journey to date, and provides a vision for the next phase of collaborative effort. IVI will refine and release in-depth recommendations over the next several months, culminating in a capstone whitepaper and public dissemination later in 2023.

Framework

Based on the many hours of dialogue with patients, caregivers, and other stakeholders, IVI developed a framework (Figure 1) that guides our understanding of how HTA and health equity are connected through the ecosystem of research on value in healthcare. This framework highlights the interdependence of action by all stakeholders and clarifies where work must occur to fundamentally reorient HTA toward equity.

IVI developed this framework in partnership with our [Health Equity Initiative Steering Committee](#) to identify key domains necessary to center equity in HTA. This helped concentrate consensus-building roundtable discussions about action steps to change status quo processes, methods, communications, and use of HTA that both reflects and upholds equity in decision-making. The framework, and the action recommendations emerging from this work, uphold IVI's core principles of: **patient-centricity, transparency, and equity**.

Figure 1. Health Equity Initiative Value Framework



Notes: External (“upstream” and “downstream”) factors all outside of the HTA field and represent forces that can influence both inertia and transformative action. Such factors include HTA inputs (data availability and quality), fiscal constraints, research funding and publication requirements, and healthcare policy.

Health Equity Initiative Framework Domains

Power, People, and Processes: This domain is foundational to ensuring equity in health technology assessment (HTA). Rebalancing power emphasizes the importance of patient and lived-experience perspectives and leadership in the conduct of such research. To ensure that HTA accounts for underrepresented populations, and spotlights resource gaps, practitioners in the field must shift their mindset and their processes. Establishing, documenting, and reporting the impact of patient engagement¹⁵ is an example of early action for continuous improvement, transparency, and trust.

Data, Inputs, and Infrastructure: While upstream factors, including infrastructure (interoperability, data accessibility, data sharing), have impact on HTA, this domain acknowledges the prioritization and selection of data sources to inform models and cost-effectiveness analyses that are primary outputs of HTA. There are many related initiatives¹⁶, which will improve the quality and type of data available to researchers. More work is needed, focusing on identifying representative sources of data, developing and using real-world evidence, and transparency about both data limitations and potential for selection bias as essential elements in the analyses.





Methods: While debates about modification and exploration of novel methods are ongoing (and have recently increased), the methods used in HTA model development and analyses have been slow to change¹⁷. Of note, papers published over a decade ago regarding health equity in HTA focused on many of these same process, transparency and methodological factors, but have yielded little change in practice¹⁸. This domain speaks to both immediate practices and tools that should be prioritized to elevate equity considerations in HTA, as well as longer-term areas for investment and collaboration through all organizations acting in this research field.

Communications and Use: Equally important is how the results and limitations of HTA are communicated to both impacted communities (i.e., patients and caregivers), as well as decision-makers (e.g., payers, purchasers, and clinicians). Transparency and inclusion are key principles that must be guideposts for action. Essential actions for HTA practitioners and researchers (that contribute inputs to HTA) include full process transparency, consistent inclusion and delineation of data sources, subgroup analysis or explanation as to why such analysis is omitted, plain language communication about potential implications for both represented and underrepresented subgroups, and identification of research and data gaps that must be prioritized to improve future assessments.

Accountability for Equity in HTA

Building on the IVI HTA Equity Framework, key informants and roundtable discussants articulated necessary action steps and roles for specific actors sharing responsibility for change. The overarching call for a culture of accountability was a consistent theme of discussions among all stakeholders. Table 1 depicts high-priority action steps for stakeholders. This blueprint offers a reference point for further discussion within and among stakeholder groups. In the following pages, we address each of the four domains with a focus on emerging actions.

Table 1. Blueprint: Accountability for Equity in HTA

DOMAINS					
		Power, People, Processes	Data, Inputs, and Infrastructure	Methods	Communications and Use
		HTA is co-created with patient experts, whose contributions are documented and compensated	HTA uses representative, quantitative and qualitative data that reflects outcomes and impacts relevant to patients and caregivers	HTA uses mixed methods to identify relevant data; researchers employ existing equity-focused methods and test emerging methods	Transparent, plain language communication of HTA findings, including equity impact and subgroup analyses, and identification of data gaps
STAKEHOLDER OPPORTUNITIES	HTA Assessors/ Researchers	Prioritize early and consistent partnership with diverse patient communities to define HTA objectives, research strategies, data availability, and implications for health disparities. Establish consistent checklists for data and methods choices and document the impact of patient partnership on analysis. Communicate limitations, data uncertainty, and study findings in plain language.			
	Life Science Companies	Prioritize early and consistent partnership with diverse patient communities to define HTA objectives, research strategies, data development, and methods used. Support post-market research to define impacts of an intervention on subpopulations.			
	Payers/ Purchasers	Require HTA developers to disclose patient engagement strategy informing an HTA and impact on choice of objectives, metrics, data used and methods of analysis. Require subgroup population analyses and clear delineation of gaps in data that have implications for decision-making that affect the unrepresented and underrepresented groups. Invest in patient community with capacity to partner with HTA researchers.			
	Policymakers	Set expectation that study leadership, data used, methods chosen, and communication strategies reflect patient populations affected by HTA. Require transparency related to data and methods limitations, and report on research priorities to support future equity-focused analysis.			
	Publishers & Professional Societies	Create review criteria related to equity in HTA, including clear documentation of engagement with patients and patient communities, use of equity-focused methods, equity impact analysis, and delineation of data gaps, methods limitations, and uncertainty. Require open access in HTA publications. Set reporting and other standards guiding professional practice. Host dialogue, training and professional scientific exchange to test processes and methods to improve equity in HTA.			
	Patient Communities	Collaborate across disease communities to identify common data elements fit for HTA purpose and to develop centralized resources for use in engagement with assessors and researchers. Identify representative leaders that can partner with HTA bodies. Emphasize accountability for action by other actors to uphold equity in HTA. Evaluate HTA activities against equity framework outlined in IVI Equity Initiative.			
	Research Funders	Increase investment for research teams that represent communities most affected by disparities, researchers that elevate and compensate patient co-research relationships, and projects that identify and address data gaps to promote understanding of need and impact on marginalized communities. Set expectations for HTA research transparency, communication and dissemination that are understandable to multiple audiences. Support patient researchers and capacity building for patient communities to expand technical ability to engage in HTA, and patient-led efforts to build data inputs fit for purpose for HTA.			



Power, People, and Processes

“How can HTA be considered reliable and valid if it is not representative?”

- Key Informant

KEY QUESTIONS

Who is doing the HTA work?

What is the impact of lived experiences expertise on HTA processes?

Envisioned Change: Development and conduct of HTA emphasizes power-sharing and co-leadership between researchers, decision-makers, and patient/family/caregiver communities impacted by such research. Research questions are defined collaboratively and modeling and analyses reflect insights and context from people with lived experience, to ensure research questions, inputs, methods, and analyses are relevant for real-world implementation. Processes, analytic methods and limitations of such work are fully transparent. HTA drives prioritization of research and data investments that help all actors understand differences based on heterogeneity, as well as disparities in access and use of resources.



Changes Needed to Achieve Equity in HTA*

- Engage patients, caregivers, and their communities BEFORE research begins. Focus on establishing TRUST and ALLYSHIP partnership first.
- Include people with lived experience as co-creators, practitioners, and reviewers.
- Report demographic composition of committees (i.e., leadership, reviewers, etc.) transparently.
- Fairly compensate patient, caregiver, and community research partners for their contributions.
- Require equity skills and training for HEOR researchers¹⁹.
- Provide capacity and training on HTA processes and engagement for patients and patient organizations.
- Define value based on what is most important to those affected – consider most marginalized groups. Engage those affected directly to understand how they define value²⁰.
- Document patient, caregiver, and community research partner contributions on HTA and their role throughout the HTA process²¹.

*As reported by Roundtable participants

First Steps for Stakeholder Action

Expanding on the roundtable recommendations, here are some examples of action steps stakeholders can take to advance health equity in HTA.

When HTA Centers Equity, Researchers²²:

- Co-develop research questions, objectives, and analysis plan from the outset with individuals and organizations who bring lived experience
- Compensate and support co-researchers and participants who bring lived experience
- Engage those affected, especially the most marginalized groups, to define elements of value.
- Document patient, caregiver, and community research partner contributions to HTA and their role throughout the HTA process²³.

When HTA Centers Equity, Patients and Patient Advocates²⁴:

- Set standards for research partnership that stipulate community engagement must happen first, before defining research question(s)
- Advocate for accountability with policymakers, funders, and regulators regarding inclusive processes, transparency, impact analysis, and data representativeness
- Collaborate with other organizations in disease space to identify key data and resources (e.g., patient diversity data, natural history, preferences, patient-reported outcomes) that are relevant to HTA research
- Expand efforts to diversity the community of patients and caregivers who are available and prepared to partner in research and HTA; emphasize representation of communities most impacted by health disparities

When HTA Centers Equity, Funders and Payers²⁵:

- Make evidence of early engagement and partnership with patient and patient organizations at a community level a prerequisite for funding approval
- Set expectations for co-investigator and leadership roles for patient, family, and caregiver experts in HTA research
- Fund workforce capacity and training of researchers in equity and methods; increase equity in researchers receiving funding²⁶
- Require reports and analysis from HTA to include equity and patient engagement details and implications for findings



Data, Inputs, and Infrastructure

“Equity is not a method or procedure, it’s a way of thinking and acting.”

- Key Informant

KEY QUESTIONS

Is the data used representative of marginalized groups and populations most likely to be impacted by HTA?

Where is data generation needed and who is responsible for doing the work?

Envisioned Change: All data collection endeavors, from pre-clinical to implementation and outcomes assessment, engage representative patient communities to define impacts of importance based on their lived experience. Such end-to-end improvement will support more accurate subgroup analyses and contribute to clearer dialogue and consensus around common measures essential to include in HTA. Policies for linking and sharing data empower patients, caregivers, and patient communities to share and learn from research endeavors. Greater transparency in use of data for decision-making increases accountability of payers, purchasers, and others to those impacted by such decisions, namely, the clinicians and patients and caregivers.



Changes Needed to Achieve Equity in HTA*

- Start collecting patient data earlier (e.g., pre-clinical; natural history); collaborate with patients to define population(s) of importance at inception of HTA process, and select and build data sources fit for purpose for HTA
- Create common lexicon of race and ethnicity; standardize data reporting by race/ethnicity; collect granular level race/ethnicity data²⁷
- Develop resources needed to prioritize patient insight and data inputs (e.g., capacity-building grants, explicit budgets within research proposals)
- Define patient-reported economic measures: costs from patient perspectives, including direct non-medical and indirect costs
- Acknowledge data uncertainty and address gaps through real-world evidence and qualitative data development
- Expect HTA and models to define data limitations and identify research questions that should be prioritized to improve data quality, representativeness, and use for equity analysis
- Establish minimum expected standards for HTA researchers addressing data sources, types, and collaboration with patients and caregivers to define studies and data collection that must occur
- Use data appropriate to specific populations and decisions (e.g., Medicaid data, not just commercial or Medicare)
- Use ALL relevant data (e.g., claims, EHR, clinical/RCT, registry, quality and social care measures²⁸, etc.) and explicitly report data gaps

*As reported by Roundtable participants

First Steps for Stakeholder Action

Expanding on the roundtable recommendations, here are some examples of action steps stakeholders can take to advance health equity in HTA.

When HTA Centers Equity, Researchers:

- Commit resources and staff time to patient engagement and collection of data on preferences, outcomes and impacts important to them^{29, 30}
- Include full range of personal and economic impacts (not just healthcare-related) in HTA analyses^{31, 32}
- Include prominent reporting on data limitations (including un- and under-represented patient subgroups) and priority research questions with every HTA analysis
- Use data appropriate to specific populations of importance and specific decision contexts

When HTA Centers Equity, Patients and Patient Advocates:

- Identify patient subgroups that may not be represented in data, and prioritize efforts to expand representativeness of patient participants in research
- Advocate for clear reporting of data selection processes and limitations in HTA
- Advocate for prioritization of research that addresses data gaps and accessibility
- Explore development of common patient data format or repository for data that outlines history, heterogeneity, core impacts, measures, and existing resources (PFDD, registries, surveys, etc.)

When HTA Centers Equity, Funders and Payers:

- Support research on non-medical and indirect costs to patient family and caregiver communities as a critical input to HTA
- Establish public engagement processes to advise agencies on patient roles in early data collection, including involvement in early-phase research design, data collection methods, and ability to collect patient-relevant impacts earlier (e.g., CTTI-FDA initiative)³³
- Support/underwrite public-use data repositories and common formats for data collection with input and co-governance of patient, family, and caregiver communities
- Establish expectation that HTA and models define data limitations and identify gaps and research questions that should be prioritized to improve data quality, representativeness, and fit for purpose for equity in HTA
- Consider mechanisms for making Medicare and Medicaid data sets more usable and accessible for research purposes



Methods

*“How does society value equity?
How do we handle variation in
valuing equity?”*

- Key Informant

KEY QUESTIONS

Are mixed methods (qualitative and quantitative) being used in HTA? Why or why not?

How does the inclusion or absence of subgroup analyses in HTA impact its use in real-world decisions? How does this impact marginalized and unrepresented populations?

Envisioned Change: HTA employs a range of methods that account for equity and allow comparison of how method choice influences HTA results. Analysts recognize the need for varied metrics and mixed methods for equitable decision-making, as no one measure (e.g., QALYs) can capture all relevant impacts. Multiple perspectives, including societal perspective, are included as core analyses in HTA modeling. Subpopulation analysis is a routine component of HTA, and limitations and implications for decision-making about resource allocation and access are transparently and consistently communicated to users of HTA as well as communities impacted (i.e., patients and caregivers). Scientific dialogue, publication, and professional development emphasize advancing methods for equity in HTA.



Changes Needed to Achieve Equity in HTA*

- Use existing equity checklists and other resources for HTA and continue to develop and refine them^{34, 35}
- Use existing equity-related methods that are established and well-tested as tools to support rapid decision-making (e.g., equity impact analyses, QALY shortfall metrics); if not used, justify rationale^{36, 37}
- Incorporate formal deliberative processes³⁸ (e.g., MCDA) that can explicitly include equity-related attributes
- Operationalize alternative analyses that can illuminate potential equity implications of health care interventions (e.g., distributional cost-effectiveness analysis (DCEA), extended cost-effectiveness analysis (ECEA), and equity weighting)
- Establish transparency standards for analyses of subgroup impacts and data to account for population and condition heterogeneity; absence of relevant subgroup analyses and/or data must be clearly documented and acknowledged in reporting
- Use data-driven approaches to uncover other patient characteristics relevant to observed differences in patient outcomes and access
- Incorporate perspectives beyond healthcare payers (including society) in HTA to reveal important equity-related aspects
- Provide training for researchers in patient engagement methods and plain language communication methods
- Explore and utilize qualitative and mixed methods approaches in assessments
- Acknowledge root causes by incorporating patients' and communities' unique social, political, and historical contexts³⁹

*As reported by Roundtable participants

First Steps for Stakeholder Action

Expanding on the roundtable recommendations, here are some examples of action steps stakeholders can take to advance health equity in HTA.

When HTA Centers Equity, Researchers:

- Explicitly report their use of and results from equity-related checklists for HTA
- Use existing equity-related methods, including formal deliberative methods, that can support equitable decision-making; and justify rationale if not used
- Identify subpopulations of relevance to assessment questions, using literature and input from patient and clinician communities; identify data gaps or other barriers to subpopulation analysis and implications or potential impacts of omission
- Include societal and other perspectives in HTA assessments, as quantitative analyses (when data are available) or as qualitative assessments of likely equity impacts from those perspectives; use of mixed methods promotes advancement of improvement measurement

When HTA Centers Equity, Patients and Patient Advocates:

- Expect and call for relevant subpopulation analyses in all reviews
- Identify patient characteristics relevant to differences in outcomes
- Work with stakeholders to point out limitations of data collection or assessment plans, and encourage plans to fill data gaps
- Call out where assessments are omitting important equity-relevant impacts outside of healthcare

When HTA Centers Equity, Funders and Payers:

- Seek clear identification of which equity-related methods are used and rationale for their absence
- Require that projects include subgroup analyses and/or discussion of how data gaps impact results
- Probe limitations posed by data gaps in applying HTA to real-world decision contexts
- Fund research into new methods to include disparity impacts and other equity considerations in HTA



Communications and Use

“If you don’t see how race, income, gender, and other patient characteristics inherently drive value, then you are not assessing true value in healthcare.”

- Key Informant

KEY QUESTIONS

Do findings and limitations identify data gaps and assumptions made as a result?

Do results analyze potential impact on disparities and on subgroups?

Envisioned Change: All HTAs include clear delineation of patient engagement plans and impact on the analysis, identification of inputs, methods and outputs related to equity analysis for the population and sub-populations. HTA also includes discussion of gaps in data, methods, and evidence on outcomes that may prohibit decision-making with support for equity. Such an Equity Analysis Plan is required by research funders and publishers and is considered a standard as part of professional health economics and outcomes research practice.



Changes Needed to Achieve Equity in HTA*

- Provide clear and ongoing information about data collection efforts to communities involved, including plain language communication about why data is being collected and how it will be used
- Communicate HTA reports and models transparently, in plain language, and with detail about objectives, processes, methods, and data⁴⁰
- Develop collaboration opportunities between health services researchers and implementation scientists
- Emphasize knowledge exchange focus for HTA and clarify what insights are most important for patients, clinicians, and payers
- Look to public health for ideas and lessons learned about plain language communication, including accessible formats and messaging; improve clarity of messaging, consistently communicate health technology impacts and for whom, and state areas of uncertainty
- Explicitly define timing and process for patient engagement in HTA, including impact such input contributed to objectives, methods, and data
- Include transparent documentation of subpopulation analyses, including inability to do such analysis and limitations of data
- Provide technical assistance to patient communities on how to participate in and interpret HTA and associated methods
- Describe groups within a condition that could be marginalized as a result of lack of representation in studies
- Define criteria or standards for communication throughout the process of conducting clinical trials (e.g., data collection purpose, procedures, analyses, etc.)

*As reported by Roundtable participants

First Steps for Stakeholder Action

Expanding on the roundtable recommendations, here are some examples of action steps stakeholders can take to advance health equity in HTA.

When HTA Centers Equity, Researchers:

- Publish plain language summaries in partnership with patient communities to share findings, limitations and implications; in developing summaries, consider health literacy, linguistic, cultural, and disability accessibility factors important to impacted communities
- Collaborate with patients, caregivers, and patient organization to co-publish the importance for patients, messages to payers and research funders regarding impacts on disparities, need for research and data, and implications of HTA
- Clearly define limitations of methods and data, including remaining areas of uncertainty and rationale for using or not using specific methods or analytical tools
- Describe groups within a condition that could be marginalized as a result of lack of representation in studies (e.g., women, people with disabilities, racial and ethnic communities)

When HTA Centers Equity, Patients and Patient Advocates:

- Require full transparency of information, process, data, and findings as condition of engagement in HTA deliberations
- Across patient communities, develop key questions as a benchmarking tool for HTA that all communities can use to evaluate HTA process and communication
- Refer HTA bodies to resources for effective patient engagement⁴¹
- Clearly define subgroup populations of importance to patient community to emphasize purpose in HTA

When HTA Centers Equity, Funders and Payers:

- Emphasize purpose of HTA as a tool to reduce disparities in access to and outcomes from health technology⁴²
- Require transparency, accessibility, and availability of processes, research design, data and dissemination (e.g., open access); require studies include action and investment to clearly and transparently communicate findings to patients and patient communities
- Require study deliverables to clearly outline priorities for further research investment, especially in data collection to improve equity
- Engage patient and patient communities in dialogue about HTA findings and implications for patient communities

IVI Health Equity Initiative: Where We Go From Here



Power, People, Processes

HTA is co-created with patient experts, whose contributions are documented and compensated



Data, Inputs, and Infrastructure

HTA uses representative, quantitative and qualitative data that reflects outcomes and impacts relevant to patients and caregivers



Methods

HTA uses mixed methods to identify relevant data; researchers employ existing equity-focused methods and test emerging methods



Communications and Use

Transparent, plain language communication of HTA findings, including equity impact and subgroup analyses, and identification of data gaps

IVI continues to engage stakeholders across the healthcare field to explore and implement changes necessary to achieve equity in the practice of HTA. As noted in this report, there are opportunities for action by every stakeholder. Our blueprint will guide our work with the steering committee and others in the coming months to outline specific action steps. In addition, IVI will define our own commitment to change, embedding these actions in our own engagement with patients and caregivers, model development, research, and communications. We remain committed to open and transparent communication of the learning emerging from the IVI Health Equity Initiative. Above all, we encourage your partnership and contribution to this crucial work.

“The only way to change the order, she thought, was not to do something differently, but to do a different thing.”

- Toni Morrison -

(Quoted by Roundtable Participant)

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Appendix A: List of Contributors and Phases of Work

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25 Funders and Payers for this report include, but are not limited to, health plans, insurers, integrated delivery networks, ACOs, employer/purchasers, ERISA plans, life sciences companies, federal agencies such as FDA, CMS, AHRQ, NIH, philanthropies and foundations, venture capital investors, and professional research organizations and societies.

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About the Innovation and Value Initiative

IVI is a 501(c)(3) nonprofit research organization committed to advancing the science, practice, and use of patient-centered health technology assessment to support decisions that make healthcare more meaningful and equitable.



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No Value Without Equity: Action Opportunities Emerging from the IVI Health Equity Initiative

January 2023

The [Innovation and Value Initiative's \(IVI\)](#) founding mission is to improve the science and the practice of health technology assessment to ensure it is equitable, represents multiple perspectives, and adapts to the ever-evolving knowledge derived from both clinical research and lived experience of patients and families. Through intentional engagement on the complex limitations of current methods and practice, IVI has demonstrated an impact and continues to spur practitioners to act with greater [transparency](#), to test flexibility in [methodological approaches](#), and to prioritize the complexity of diverse [patient perspectives](#). In addition to patient-centricity and transparency, a [hallmark principle](#) underpinning health technology assessment in the U.S. must be supporting health equity.

Introduction

Recent commentaries and research offer further evidence that there can be no meaningful discussion of value in health care without intentional focus on health equity. Across a wide range of organizations offering frameworks and recommendations (see "Resources/Further Reading" on page 5) to embed equity into our thinking and action, there are two common themes about needed change:

1. Power imbalances in design and decision-making must be intentionally addressed to give equal leadership to lived expertise from patients, families, and communities marginalized in research and care delivery; and
2. Data and research must reflect real-world diversity across multiple dimensions to be considered relevant and reliable for decision-making.

The Innovation and Value Initiative (IVI), as part of the [Health Equity Initiative \(HEI\)](#), recently conducted a series of key informant interviews with stakeholders that reinforced these themes and identified early learning opportunities applicable to the field of health economics research and health technology assessment¹. This research brief summarizes our work to date and reinforces our belief that without explicit attention to equity, health technology assessment risks reinforcing or exacerbating disparities in the U.S. healthcare system.

Background

Current methods used in health technology assessment in the U.S. generally evaluate clinical outcomes and cost considerations of interest to payer stakeholders. These methods are often deemed inadequate to evaluate and inform other dimensions of value, such as patient heterogeneity, economic impacts outside medical costs, disparate access to care or outcomes, and comprehensive impacts on quality of life.

“

If you don't see how race, income, gender, and other patient characteristics inherently drive value, then you are not assessing true value in healthcare.

Interview Participant

”

While some aspects of patient-defined value are commonly included in health technology assessments as qualitative information alongside quantitative estimates, there is little agreement on what factors are most important to include, or on how to capture and measure perspectives from diverse communities of patients. Patient data sources are increasingly available, due to significant contributions

¹ Health technology assessment and value assessment have been used interchangeably, although HTA is more commonly used in ex-U.S. contexts. Both terms refer to the evaluation of cost, benefit, and risk to determine resource use in health care. IVI uses the term to reflect the evolution in the U.S. from a focus on pharmaceuticals to a broader effort to assess clinical, real-world impact and cost-effectiveness across therapeutic interventions and technologies.

of patient organizations, but do not yet reflect the full breadth of patients' experiences and have not been utilized effectively for health technology assessment to date.

Building on a 2021 public dialogue series addressing the importance of health equity and the insufficiencies in current methods and practice, IVI initiated a multi-year collaborative learning effort to explore how health technology assessment must account for and uphold equity. Through dialogue with patient communities, researchers, foundations, clinician leaders, and others, IVI invited a multi-stakeholder Steering Committee to collaborate in this process. Leaders were invited based on expertise in health equity (e.g., demonstrated through publication, presentation, or professional action), lived experience, and representation of perspectives both closely tied to VA/health technology assessment (HTA) and to broader health care delivery and policy contexts. Contributors represent both existing members and non-members of IVI to ensure wide-ranging opinion and diversity across multiple dimensions, including disability, gender, age, race, language, health condition, and geographic location.

Shared Leadership Yields a Common Vision

The IVI Health Equity Initiative Steering Committee established early on the importance of clarifying the definition of health equity and its intersection with the unique focus on health technology assessment. Based on collaborative dialogue in group and individual discussions, as well as consideration of definitions used by other organizations, the Committee formed the following definition of the initiative's focus on equity:

Health technology assessment advances health equity when it reduces health disparities by aligning access and affordability of healthcare technologies and services with the differing needs and values of diverse patient populations, especially those who are most marginalized.

The initiative seeks to further refine the specific parameters of how health technology assessment advances health equity through a series of key informant interviews, subsequent roundtable discussions, and a capstone consensus meeting (in Spring 2023) to define promising practices and opportunities for change.

Key Informant Interviews

In September and November 2022, IVI conducted a series of ten interviews with key informants representing a cross-section of health care stakeholders (see Appendix 1). Key informants were identified through a process that included review and publications and presentations, recommendations from members of the IVI Foundation Board and Patient Advisory Council, Equity Initiative Steering Committee recommendations, and referrals from those invited but unable to participate. Invitees were reviewed for balance of sector perspectives, areas of expertise, diversity, and opportunity to explore linkages with equity initiatives in other organizations, with emphasis on ensuring representation of all stakeholder sectors in the key informant interviews.

The one-hour discussions were preceded by sharing of a pre-read document and interview guide co-developed with the Equity Initiative Steering Committee. Interviews were conducted virtually with recording for transcription accuracy. The key informant interviews explored views on value, health equity, and important elements of equity-centered health technology assessment practice (i.e., framework domains) (see Figure 1 for original framework, see Appendix 2 for Interview Discussion Guide). To identify common themes and expected characteristics, questions also explored which criteria key informants used to evaluate whether research or data appropriately accounts for equity concerns.

IVI staff mapped key informant input using online whiteboards to identify common themes, key perspectives and feedback on the working equity framework. The mapping was then used to summarize themes, which were shared during a Steering Committee discussion for feedback and clarification. A summary narrative was also shared with all key informant participants to ensure transparency, shared learning, and ongoing feedback with the overall initiative.

In Figure 1, we acknowledge the presence and impact that upstream factors such as policy trends (e.g., value-based reimbursement and external demand from payers for the conduct of HTA) and factors related to traditional inputs (e.g., research design, data sources, and methods training) have on how equity is viewed and incorporated into HTA. We also acknowledge the downstream impacts that equity-

Figure 1. Visual Representation: Original Framework for Equitable Health Technology Assessment

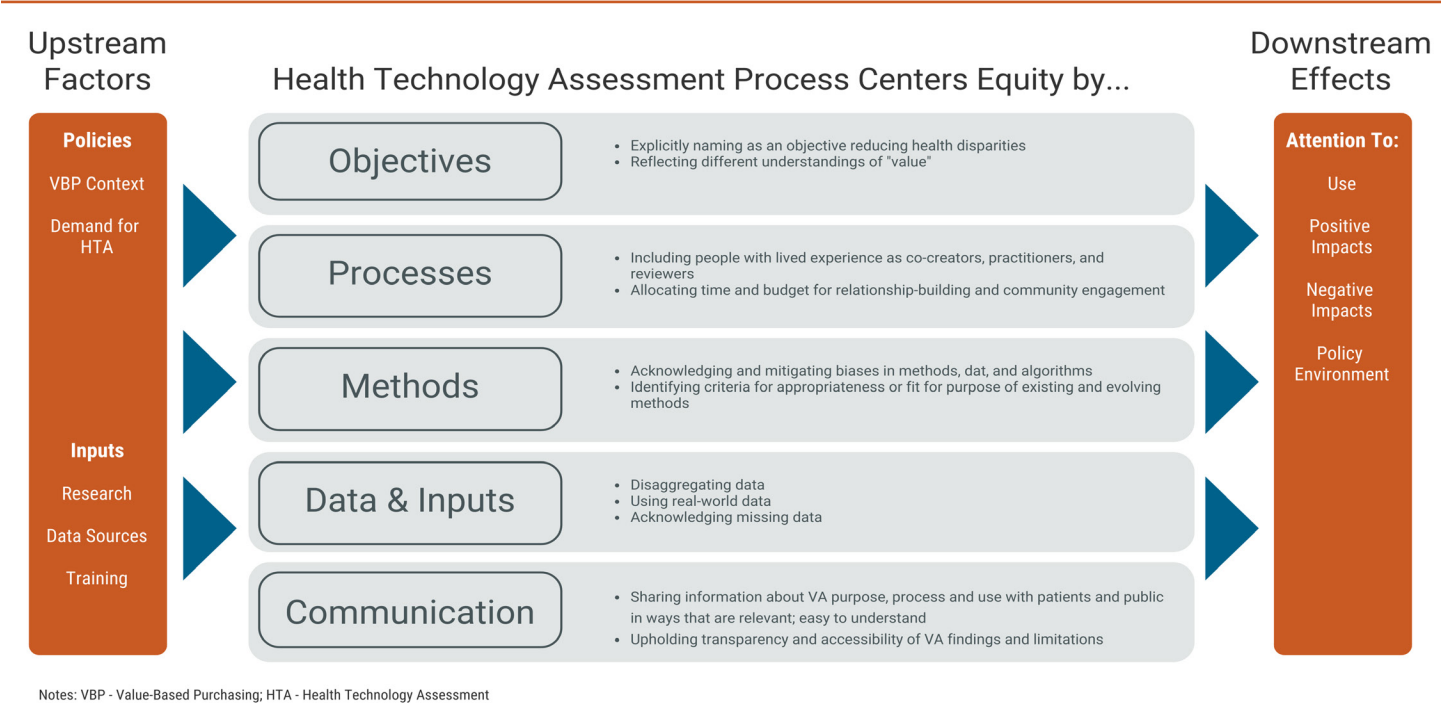
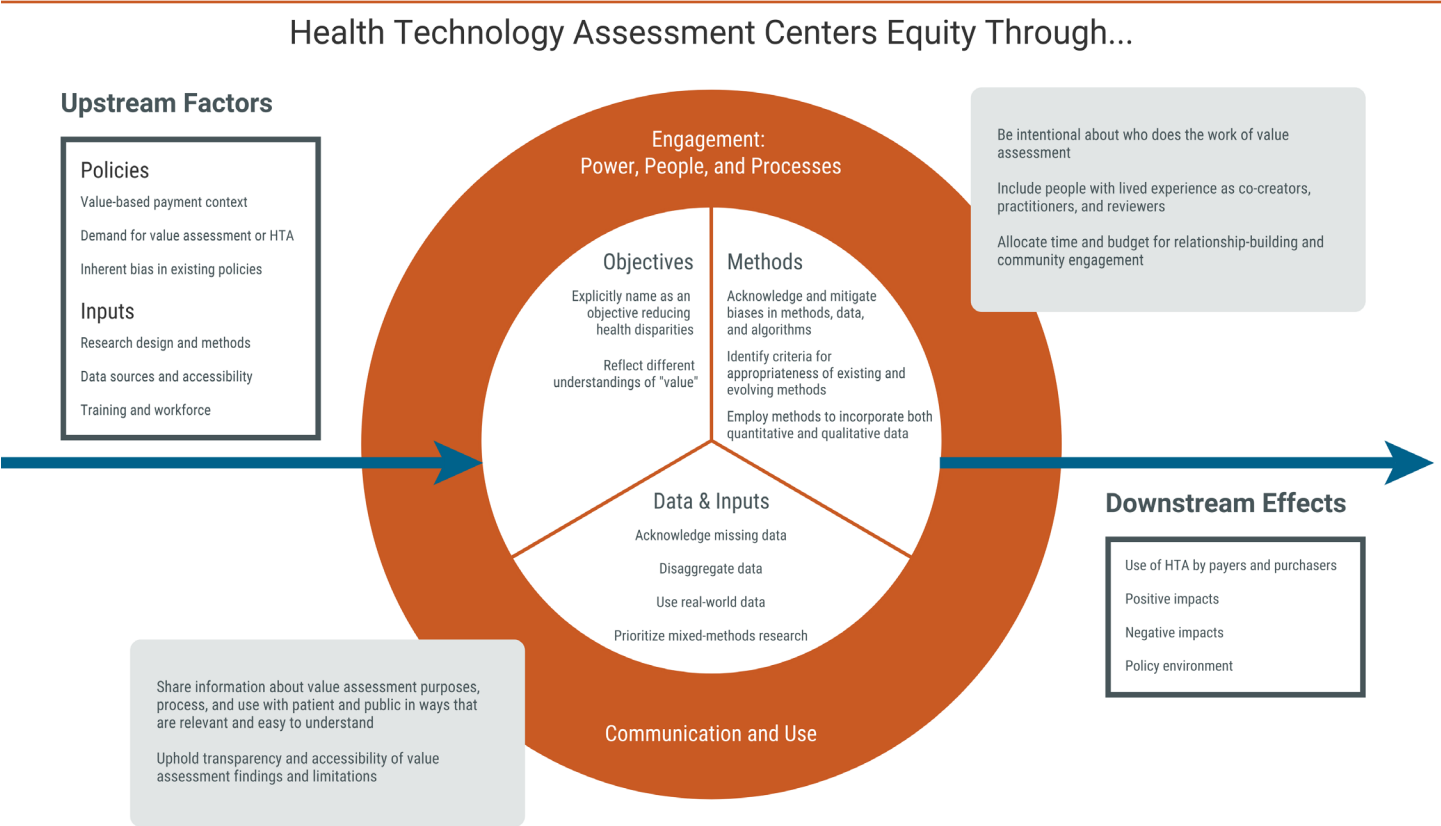


Figure 2. Revision of Framework, Accounting for Key Informant Insights



focused HTA can have, including use in medical, coverage and payment decision-making, impact on actual experience in care and both health and social outcomes, and influence on policy priorities. Fundamentally, this developing framework (see Figure 2) is intended to guide important redesign of health technology assessment methods and practice, so that it intentionally examines existing health disparities, and works to reduce their perpetuation in decision-making about value

Equity is Complex, and Critical to Value

Across all stakeholder representatives, broad agreement emerged about the intersection of equity and value. While interviewees emphasized different perspectives on solutions, all concurred that both the “Power, People, and Process,” and the “Data and Input” domains were high priority areas for action. Themes emphasized in the discussions include the following:

- **Equity must be considered in who does the work of health technology assessment** – In this context, lived experience is a priority, especially from communities that experience discrimination and health disparities. Language and cultural perspectives are also essential considerations, as is expertise in equitable processes and community engagement.
- **Transparency across all processes**, design, decision-making and communication of both limitations and findings is a non-negotiable characteristic of processes and actions that support equity
- **Equity is multi-dimensional** and includes fairness, justice, access, and equal opportunity to experience health and well-being. Therefore processes, data and methods must demonstrate the ability to represent these concepts within the analyses and application of HTA findings to decision-making.

“

How can VA/HTA be considered reliable and valid if it is not representative?

Interview Participant

”

- Inequities may arise from one or more factors, including race, health status, disability, health-related social conditions, language and culture, experience of care, and access issues. The intersectionality of these drivers must therefore influence all the domains of conducting health technology assessment. **Equity is both a driver and a result of action.**

Early Action Opportunities

We have consistently heard since the inception of this project that transparency and intentionality are characteristics of good practice to champion and integrate equity into all aspects of health technology assessment. This publication of our learning-in-progress is an effort to acknowledge that early and meaningful changes in each of the domains outlined above are both possible and essential to long-term, durable progress. Among the opportunities for early action are:

1. **Establish the benchmark that value cannot be measured without equity.** At all stages and across all domains of efforts to measure and pay for value, equity must be the lead driver. Clear commitment to this should be evident through decision-making, process design, transparency, data development and use, methods, and communication.
2. **Change who sets the health technology assessment agenda.** Including diverse patient and family communities in priority-setting processes, governance of health technology assessment, and design of research and methodologies to be used are achievable steps that advance processes and change power imbalances inherent in the current HTA efforts.
3. **Change health technology assessment processes.** Health technology assessors, researchers, and users of HTA must explore how to meaningfully change processes for learning from persons with lived experience, for co-design of research and methods, for shared prioritization and decision-making about investments needed in data collection, and for evaluating the use and impact of HTA on both access and health outcomes.
4. **Prioritize data sharing initiatives.** A growing trend toward data aggregation and data-sharing for more rapid-cycle learning is positive, but more work is



Equity demands that there be no more ad hoc workarounds and methods that adjust for equity at the end of a health technology assessment.

Interview Participant



needed to make such initiatives both transparent and more accessible to patient communities. Such initiatives remain siloed – for example within payer consortia or clinical research groups – and are often not connected to patient-designed resources of real-world data (e.g., registries or mixed-methods research). While HTA bodies are not usually builders of data sets, they must be champions for data-sharing and for improving data that reflect diverse experience of patients and caregivers.

5. Acknowledge gaps in methods. HTA bodies need to collaborate more on the exploration and pilot testing of novel and mixed-method approaches to address equity – to specifically address subgroup analyses and uncertainty, for example. They also must consistently identify and acknowledge where current methods and tools traditional to the field are inadequate and even have discriminatory impacts. Limitations in methods must be clearly acknowledged as preventing decision-making about people who are not represented, for whatever reason. Moreover, methodological efforts to use “proxy” measures or estimates that have not been developed collaboratively with communities with lived experience must be identified as such, with resulting analyses de-emphasized as relevant to decision-making.

6. Explicitly communicate equity implications of HTA. In keeping with the overall theme of transparency and acknowledgment, HTA bodies must clearly communicate in all publications an analysis of the potential implications of an assessment on health equity. Better still, they should publish a joint analysis with affected communities that reflects on the

above issues of decision-making and data, methods limitations, and clear evaluation of what decisions, if any, can be informed by the HTA.

Future Research and Implications

IVI's Health Equity Initiative reinforces the organization's commitment to ally with all stakeholders seeking to improve how we define, measure, and represent equity in the discussion of value in the U.S. healthcare system. The early findings in this brief will guide our own research practice and inform the next phase of our work, in which we will convene roundtable dialogues with individuals across sectors to refine and prioritize areas for action. Through such intentional collaboration, IVI aims to accelerate learning and create practical processes and tools that ensure equity in value.

Resources/Further Reading:

- STAT News Commentary: [“Exploring Equity in Health Care Value”](#)
- IVI and Sick Cells White Paper: [“Finding Equity in Value: Racial and Health Equity Implications of U.S. HTA Processes”](#)
- American Journal of Managed Care Commentary: [“A Vision for Patient-Centered Core Impact Sets—A Unifying Approach to Patient Centricity”](#)
- PIPC White Paper: [“Aligning Health Technology Assessment with Efforts to Advance Health Equity”](#)
- Frameworks: [Racial Equity and Policy](#), [FasterCures Patient-Perspective Value Framework \(PPVF\)](#), [Asthma and Allergy Foundation of America](#)



Equity is about removing barriers and obstacles to having just opportunity for health. If you have not worked to understand the social, cultural and community drivers that affect people, then you are not assessing value.

Interview Participant



Essential Questions to Improve Equity in HTA (A Starter List)

- Who must be involved in prioritizing and designing HTA processes and structure?
- What expertise is needed on the team to ensure equity is a consistent driver of HTA work?
- How can processes and partnerships ensure data and methods are representative?
- What additional value elements, data and perspectives are needed to ensure HTA addresses equity?
- What data needs must be understood and invested in to ensure equity can be supported in HTA?
- What methods for engagement of lived experience will ensure relevance of HTA results?
- What are appropriate time horizons for HTA – both design of analysis, adjusting for care journeys, and reassessment based on evolving data?
- What criteria regarding power and processes, data, perspective, and methods must be met to demonstrate equity in HTA?

Author

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About the Innovation and Value Initiative

IVI is a 501(c)(3) nonprofit research organization committed to advancing the science, practice, and use of value assessment in healthcare to make it more meaningful to those who receive, provide, and pay for care through collaboration among thought leaders in academia, patient organizations, payers, life science firms, providers, delivery systems, and other organizations.

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Appendix 1. List of Key Informants Interviewed

Key Informant Organization	Date of Interview	Stakeholder Perspective
Eberechukwu Onukwugha, PhD, MS (University of Maryland)	August 23, 2022	Research
Bayley A. Raiz, DBH, MBA, LCSW (CVS Health)	September 12, 2022	Payer, Clinician
Madhuri Jha, MPH, LCSW (Kennedy-Satcher Center for Mental Health Equity, Morehouse School of Medicine)	September 12, 2022	Research, Clinician
Brian Meissner, PharmD, PhD (AbbVie) Robyn Carson, MPH (AbbVie)	September 19, 2022	Life Science Industry, Research
Kenneth Mendez, MBA (Asthma and Allergy Foundation of America)	September 21, 2022	Patient Advocacy
Eboni Price-Haywood, MD, MPH, FACP (Ochsner Xavier Institute for Health Equity and Research)	September 26, 2022	Health System, Research, Clinician
Jessica Brooks Woods, MPM, PHR (Pittsburgh Business Group on Health)	October 7, 2022	Employer, Purchaser, Patient Advocacy
Megan Morris, PhD, MPH (University of Colorado Denver and Disability Equity Collaborative)	October 12, 2022	Patient Advocacy, Research, Clinician
Lisa Prosser, PhD, MS (University of Michigan)	October 12, 2022	Research
Alma McCormick (Messengers for Health)	November 30, 2022	Patient, Research

Appendix 2. Key Informant Interview Guide

Interviewer's Introduction

Today, we appreciate you taking the time to speak with IVI about the issue of how value assessment should address and support health equity.

The purpose of these conversations is to elicit participants' perspectives on innovations in equity-centered value assessment methods and processes, domains on which IVI's Health Equity Initiative should focus, and practical considerations for equitable value assessment. Learning from these conversations will inform roundtable dialogues in late 2022 and a multi-stakeholder consensus meeting in 2023.

We'd like to record today's conversation for note taking purposes. We won't share that recording with anyone outside of the team and won't identify you in anything we share publicly from these interviews. Would it be ok with you if we record today's interview?

[Start recording if permission is granted.]

As a starting reference, we hope you've had time to review the project overview and framework explanation. The framework is a working draft reflecting our learning to date and will continue to evolve.

During the next 60 minutes, we would like to explore several questions with you relevant to health equity and the intersection with value, and specifically value assessment. We are interested in your work and views on these topics broadly, and welcome candor and your critical thinking to help shape our future phases of work. Above all, our intent is an interactive discussion with you. Before we get started, do you have any questions?

****Next Section is Background and Introduction Questions****

Background and Introduction Questions

In this section, listen for:

- Different views or understandings of health equity
- Different views or understandings of value or the practice of value assessment
- Tensions between individual and organizational/institutional views of equity or value
- What's not clear about IVI's initiative. Not important to clarify all details during interview, but is a sign of areas needing more clarity in future communications.

1. *Please tell us a bit about yourself and your role in your organization.*
2. *We shared with you some materials describing the purpose of this interview and how IVI views the intersection of health equity and value assessment. Before we get started, we wanted to make time for any questions or reactions to that.*

If pre-read material is not fresh in their minds, provide brief level-setting:

- Value assessment is one approach to health technology assessment, which is the evaluation of costs and benefits for health technologies to better inform decision-making about access, reimbursement and health care delivery, as well as other policy decisions that affect both health outcomes and resource utilization.
- Through discussion with the initiative's steering committee, we are starting this work by defining equity in value assessment as: *Value assessment advances health equity when it reduces health disparities by aligning access and affordability of healthcare technologies and services with the different needs and values of diverse patient populations, especially those who are most marginalized.*

****Next Section is Vision and Problem Statement Questions****

Vision and Problem Statement Questions

In this section, listen for:

- What aspects of equity do key informants raise as most important?
- How much do key informants focus on the process or methods of value assessment?
- How much do they focus on the outcomes or impact of value assessment?
- Where do key informants struggle to answer these questions – what are the aspects of value or equity they seem to need to wrestle with in fleshing out these statements?

For key informants with HTA/HEOR expertise, spend less time in this section and more on research action.

3. *Could you tell us a bit about how you or your organization focuses on value and/or equity? We're especially interested in any ways that your work brings those two threads together.*
4. *What are the problems related to equity that you and or your organization are trying to resolve? Please share what good looks like to you or your organization.*
 - *For example, we're interested to hear how you would flesh out this statement: Making equity a consistent focus on value assessment would require...*
 - *Why are these aspects of equity a priority for you and your organization?*

****Next Section is Framework Questions****

Input on Working Framework from IVI Health Equity Initiative Steering Committee

In this section, listen for:

- What elements of the framework seem to resonate most with key informants?
- Is there anything missing from the framework they would add? Anything they would remove?
- Where do they have questions or seem confused?
- What kinds of impacts or decisions do participants highlight as important upstream or downstream factors? Which of these are observable (e.g., data collection, statistical analyses, interpretation) and which are less transparent (e.g., study team composition, selection of research questions, choice of intervention and comparison groups, etc.)?

IVI staff partner pulls up framework image, if needed.

Now we would like to hear your feedback on the working framework we shared describing domains of equitable value assessment (also in the pre-read materials). This framework reflects work to date and guidance from the initiative's steering committee. It will continue to evolve and we would like to hear your thoughts on how to refine it.

5. *Which of the framework domains are highest priority or most essential in health equity considerations in value assessment? If you had to pick a single most important domain, what would it be? Why?*
 - *Are there any domains missing that you feel are important to include in our working framework?*
 - *For the domain you feel is highest priority, are there any attributes (sub-bullets under the domain) missing, in need of further explanation or examples, or unnecessary? Why?*
6. *Are upstream issues as defined in the framework clear? Are we missing any other aspects that are essential factors in health equity, but which may be precursors or contributors to value assessment that advances health equity?*
7. *Are the downstream impacts of equitable value assessment clear? Are there additional aspects of the potential applications and impacts of value assessment that may affect equity or disparities?*

****Next Section is Research Action Questions****

Research Action Questions

In this section, listen for:

- What additional types or sources of data do key informants point to (e.g., SDOH data, patient-reported data, real-world data sources)? How or when might those data become available for value assessment (e.g., where in the pipeline)?
- What additional methods or practices do key informants point to? Do these come from within value assessment or other fields? What makes them promising?
- How optimistic are key informants about adopting equity-centered data, methods or practices into standard value assessment practice?

Next we would like to clarify some of the opportunities and challenges around equitable practice of value assessment.

Broad Questions (for all key informants):

8. *What methods or best practices do you look for as evidence that a project, research study, or analysis is equity-centered? Why?*
 - *What is required to ensure those methods or best practices are used widely and consistently?*
9. *What new data sources, methods or processes must be developed to ensure equitable practice of value assessment?*
10. *What can IVI learn from people doing this work in other fields? Where should we look, for examples to learn from?*
 - *Back Pocket: For example, we have looked at A Toolkit for Centering Racial Equity Throughout Data Integration for racial equity best practices when using algorithms and statistical tools, analyzing data, and reporting data or sharing findings.*
11. *What are the “bright spots” for making change happen (i.e., promising actions and/or attention to bring equity into the discussion of value? What makes your example(s) a solution or promising direction?*

Value Assessment-Specific Questions (for key informants with value assessment or health technology assessment expertise; prioritize about 15 minutes for this section):

12. *What new data sources, methods or processes must be developed to ensure equitable practice of value assessment? How will these help?*
 - *What can/should we do about the ongoing inadequacies of data to support decision-making?*
 - *What would you communicate to researchers in the value assessment field about the inadequacies of data? Are there immediate priorities that should get more attention and resources?*
13. *What aspects of value assessment require investment to support incorporating health equity considerations into value assessment practice? Which of these investments would you prioritize?*
14. *What feasibility issues arise for measuring and incorporating health equity in value assessment?*

****Next Section is Wrap-Up Questions****

Wrap-Up Questions

8. *What attributes do you look for in value assessment to evaluate how well it incorporates health equity?*

- *Why are these important?*
- *Adapt this question as needed to focus on value assessment, measurement, data, research, etc., depending on informant's expertise and conversation up to now.*

Before we wrap up, [Ellen/Melanie/Rick], any key question we missed?

Then ask informant:

- *Is there anything else we should have asked but did not?*
- *Who else would you recommend we connect with to help inform this initiative?*

Thank you for your participation in IVI's Health Equity Initiative and for your candor and insights today. We will share a brief summary of key takeaways from this phase of our work with you and look forward to your further input and questions.

About IVI

The Innovation and Value Initiative is a 501(c)(3) nonprofit research organization committed to advancing the science, practice, and use of value assessment in healthcare through collaboration among thought leaders in academia, patient organizations, payers, life science firms, providers, delivery systems and other organizations.

www.thevalueinitiative.org



Health Equity Initiative

IVI  **INNOVATION AND
VALUE INITIATIVE**

KEY INFORMANT INTERVIEWS

Summary

November 2022



TABLE OF CONTENTS

INTRODUCTION	3
WHAT IS VALUE?	3
WHAT IS HEALTH EQUITY?	5
FRAMEWORK FOR INCORPORATING EQUITY IN VALUE ASSESSMENT	6
CONCLUSION	11
APPENDIX	12

Introduction

During September and October 2022, Innovation and Value Initiative staff conducted a series of nine one-hour virtual interviews with “key informants” — individuals with lived experience, professional expertise, and skills in research, clinical delivery, policy, or data analysis. Individuals invited to participate were identified by the multi-stakeholder Steering Committee during both virtual meetings and via post-meeting referrals. In addition, IVI staff reviewed key papers, external equity initiatives, and presentations, and sought additional nominees from the IVI Board and Patient Advisory Council. This document summarizes key themes arising from the discussions. IVI has shared these findings with the Steering Committee and with interview participants. We intend to publish key learnings from this phase of work in November and will explore areas for process and methods action during one or more roundtable discussions. All quotes and comments are unattributed.

What is VALUE?

Although we did not ask key informants to define value specifically, throughout the conversations they highlighted specific aspects of value as important or missing from value assessment discussions.

Important Elements of Value

- Many key informants referred to **financial considerations** as implied in the meaning of value. But they varied in how they framed these considerations. Some spoke about costs to payers or employers, other focused on cost-benefit tradeoffs, and others on prices. Incentives for investors and manufacturers were implied in many of the comments around financial components of value. One informant called out needing to rethink the “winners and losers” in economic theory currently undergirding conversations about value in healthcare. Another informant reinforced the idea that we must be intentional to avoid the unintended consequence that is portrayed as zero-sum game of resource allocation.
- Several key informants also called out the importance of considering **quality** alongside or on a level playing field with costs. This begged the question of what constitutes quality. While we did not specifically explore definitions of quality, one informant emphasized equity as an essential element of quality (as underscored by the Institute of Medicine in its 2001 *Crossing the Quality Chasm* report) while another called out the inconsistency in definitions of quality as assessed by many different healthcare performance measures.
- One key informant highlighted **consumer choice** as an important element of value.
- Many informants highlighted the role and importance of **language and culture** to equity and value. A researcher noted that attitudes about inequity in health vary regionally in the U.S. and that researchers needed to add diversity of perspectives in framing and prioritizing research questions. Another informant noted that social and cultural values in the U.S. stratify people into classes with different educational, job and income opportunities based on race, sex, ethnicity and disability. Such stratification ignores multidimensional identities and factors of value. Another dimension raised by informants

addressed diversity of research workforce to ensure people with disabilities, cultural needs and communication preferences were included in equity-designed research.

Missing Elements of Value

- Key informants repeatedly raised questions about differing perspectives on value, asking questions such as: **Whose view of value are we prioritizing and value to whom?** They called for the value assessment process to include broader perspectives on value beyond the payers, researchers, and economists who currently shape discussions and decisions around value and value assessment.
 - Key informants prioritized the **perspectives of people with lived experience** (also referred to as patients, consumers, or employees). One informant specifically called centering perspectives of underserved communities; another insisted that people must define value for themselves. Other informants emphasized needing diversity across a range of perspectives, with special focus on bringing together stakeholders who don't (currently) discuss value.
 - One key informant raised questions about **societal perspectives on value**, noting that regional and political differences often track with dramatically different notions of value. Another informant called out harm, such as denied treatment or technology, that specific communities experience when their lives are de-valued by healthcare. This makes any value-based discussion a risky undertaking for those within that community.
- Key informants repeatedly raised **time frame considerations** as missing from current definitions of value. They called out the need to consider longer time horizons, update value assessments over time, and examine not only *what* is important to patients, but also *when* specific factors are important to them. For example, one informant shared that what's valuable to newly diagnosed patients may be very different for those who have been living with a chronic disease for many years and have already tried several different therapies.
- Several key informants called out blind spots or gaps in current understandings of value. These included **focusing too narrowly on quantitative data** or measures; ignoring the **intersecting influences of race, income, and gender** on value; and prioritizing patient adherence and treatment efficacy over **other dimensions of value**.
- One key informant called out qualitative data and the **patient experience** as missing from definitions of value, noting that looking at cost-benefit only is inadequate. Current practice focuses outcomes but neglects upstream factors (societal perspective). Another called out the "aha!" moment for those paying for healthcare services when they recognize that many patients, particularly patients of color, **experience harm** from their interactions with the healthcare system. This diminishes the value of services or technology that the employers are offering. Several other informants called out the importance of acknowledging and preventing harm without tying it to definitions of value.
- Several informants highlighted missing elements of **value in the context of purpose**. For example,

disability communities that may reject medical model framing of seeking to “cure” or “fix” disabilities are not well represented in the structural design of health technology assessment, which emphasizes cost-effectiveness of a treatment as opposed to accommodations for supporting quality of life and ability to “live the life they want.”

What is Health Equity?

A State of Health Equity

- Key informants described **health equity in terms of justice, fairness, access, and equal opportunities for health**. They spoke about equity in two dimensions: in health-related social conditions and in access to healthcare.
 - In describing **health-related social conditions**, informants focused on environmental, social, and political factors that drive differential rates of disease, disability and need for healthcare. They emphasized the importance of tying disparities in health outcomes to these upstream factors, and ultimately acknowledging and addressing root causes of health disparities.
 - In describing **access to healthcare**, informants focused on health literacy, availability of health services in patients’ preferred language, location of health services, and absence of barriers to health. One key informant described health inequity as denied access to quality of life.
- Across these definitions, key informants primarily focused on describing equity. In contrast, only two focused on **defining health**, emphasizing quality of life and a complete state of physical, mental, and social wellness. One informant called out needing to examine community-level impacts rather than focusing only on individual-level health. Another informant discussed notions of quality of life at length, recognizing controversy around how quality-of-life measures harm people with disabilities, particularly when used to deny treatment or assistive technology. This informant called for **broader understanding of what quality of life means** to people with very different life experiences.
- One key informant emphasized the **distinction between equity and equality**. Equality is focusing on providing the same thing for everyone. Equity is understanding differential experiences and outcomes for different groups of people, providing what they need in a tailored way.
- Two key informants emphasized **distinguishing** observed differences in treatment or outcomes based on **patient preferences** from **health disparities**. They highlighted this distinction as particularly important when shifting from a population-level focus (such as making recommendations for coverage, treatment, or reimbursement for a whole population) to individual decision-making at the point of care.

Equitable Process

- Across nearly all the interviews, key informants consistently emphasized **equity in who does the work**

of value assessment. They called out the need for intentionally including diversity of thought in framing questions about value, diversity among value assessment practitioners, and transparency in who conducts value assessments, and the research that underpins such evaluations. As discussed below (see Key Questions to Guide Equity-Centered Practice), they raised many of these “who” questions throughout the interviews.

- One key informant noted the importance of **embedding equity throughout the value assessment process**. And across the interviews, key informants focused most consistently on what they look for as evidence that a process (be it value assessment, research, engagement, etc.) is equitable. They also raised questions about how to make value assessment equitable through simplification of the process and through intentional efforts to build trust. This may also point to the need for more public/private collaborations and funding streams.
- In describing equitable processes, informants focused on **equity in engagement, methods and data, and communication**, highlighting specific practices to integrate throughout the value assessment process (Table 1).

Framework for Incorporating Equity in Value Assessment

During the Key Informant Interviews, we displayed on screen the working Framework or logic model (see Figure 1) that IVI developed in consultation with the Steering Committee. A series of questions (see Appendix 1) guided interviewees through the key dimensions outlined in the Framework and gathered input on how it could be further refined to reflect a pathway towards more equity-centered value assessment.

Overall, there was agreement that the framework captured the key domains that must be addressed to incorporate equity into value assessment. These discussions overall validated the working Framework.

At the same time, several of the discussions underscored the need for fundamental redesign of health technology and value assessment in order to actually incorporate health equity. The conclusion that there is no value without equity emphasized critical shifts in thinking and action, including:

- A wider “lens” is required to focus on equity, beginning with upstream factors all the way through the outputs and use of value assessment.
- Patients’ lived experience must be visible for there to be trust.
- There must be an examination of the “Why?” – Why is value assessment being conducted? Why is value assessment being applied for this purpose? Why are the people conducting the value assessment involved? These questions will help us understand: Who stands to benefit from conducting the value assessment?
- Power structures and power dynamics between the value assessment entity and patient communities must be intentionally addressed and biases explicitly acknowledged and mitigated.

In the sections that follow, we discuss key informants' views on each of the domains within the working Framework (as presented to them during the interviews). We also include an initial summary (see Table 1) of equity-centered practices that will guide further phases of IVI's Equity Initiative foster open dialogue with all stakeholders in health technology assessment.

Objectives: Importance of Addressing Bias in Value Assessment

A bullet point included under the Objectives domain of "explicitly naming as an objective reducing health disparities" resonated with a number of informants. Intentionality and being deliberate were shared as important from the outset. Discussion from many of the key informants centered on the lack of trust among many patients and stakeholders in the healthcare system and in the enterprise of health technology assessment itself.

There Is No Value Without Equity: Equity must be a fundamental driver of value assessment. A first step is reframing notions of scientific rigor to require equity, as one key informant asked, "Is work reliable and valid if it is not representative?"

Patient Lived Experience: Healthcare, at its core, is a complex delivery of preventive services, treatments for acute conditions, and ongoing care for complex, chronic conditions in people throughout their lifespan. Feedback from a range of stakeholders focused on the clear lack of patient and family lived experience in existing value assessment approaches. Movement toward more equitable value assessment will require the inclusion of patients, families, and caregivers in defining research questions addressed through value assessment and throughout the assessment process.

Intentionality Is Required to Account for Social Determinants of Health, Unmet Health-Related Social Needs, and Health Disparities in Value Assessment: Key informants emphasized linking disparities in health outcomes and upstream factors that drive these disparities (i.e., social drivers of health), especially the environmental, social, and political conditions that create differential unmet needs among marginalized populations. They called for value assessment to acknowledge root causes by incorporating qualitative information and communities' unique social, political, and historical contexts.

One key informant noted: "If you don't see how race, income, gender, and other patient characteristics inherently drive value, then you are not assessing true value in healthcare."

Mitigating Bias: A number of key informants raised the need to mitigate biases built into value assessment methods, data, and algorithms, particularly in the context of the increasing use of Artificial Intelligence (AI) in healthcare.

Processes: It All Begins with Patient, Caregiver, and Family Engagement

Most key informants highlighted the Processes domain as essential, emphasizing that equitable processes must be present for value assessment to advance health equity. For some, the Processes domain was more important than the Objectives or Methods domains.

Equity is Essential from Beginning to End: Informants emphasized integrating equity throughout the value assessment process, from defining objectives and key questions through choice of data, application of methods, and interpretation and communication of findings. They also highlighted the need for equity-centered approaches upstream of value assessment (for example, in generating evidence through research) and downstream in how value assessment is used to guide decision-making and policy.

Engagement is Central to Rebalancing Power and Process: Most key informants focused in on patient engagement, caregiver engagement, and other stakeholder engagement as the most important aspect of value assessment processes. Interviewees expressed that good engagement practices that intentionally embed equity throughout the value assessment process are necessary. One informant also touched on the importance of making value assessment more accessible to patients, payers, providers, and other stakeholders.

Who is Engaged is Important: While key informants indicated that engagement is essential, more important is WHO is engaged in the process. Some of the informants discussed the responsibility of those leading the value assessment process to convene and build consensus among stakeholders, most importantly people who bring lived experience and represent marginalized communities. Informants acknowledged that engagement is resource-intensive, long-term work. One informant noted, “the most important thing is that you don’t start something and it goes away when funding ends. People see too much of that.”

Engagement Must Begin Upstream: Designing for engagement and diversity from the start of any study or value assessment process is paramount. Key informants emphasized that this cannot be an activity that comes at the end of the process. Patient engagement provides necessary context to center value assessment on the outcomes that matter to patients and the real-world tradeoffs they face in their care. Key informants also emphasized defining with patients what value means to them.

Fair Compensation and Support are Essential: One informant noted that “not paying patients to share their lived experience is extortionist,” emphasizing the importance of investment in fair compensation to patient contributors to research and health technology assessment. This theme also arose in the context of research funding, where those making funding decisions should emphasize inclusion and compensation of patient, family and caregiver partners in research design and execution. Finally, informants emphasized the importance of investing in accessibility, knowledge building and other support to ensure “equal footing” for the voice and contributions of lived experience.

Methods

Mixed Methods are Required: Equity cannot be incorporated into value assessment without integrating both quantitative and qualitative data and methods (for example, sole dependence on randomized controlled trials [RCTs] must be addressed/undone).

Real-World Data Allows for Insight: Pairing real-world evidence (RWE) with evidence from RCTs will inform *how* to ensure clinical trials, comparative effectiveness research, and other evidence better represents the population of patients affected by a health condition or health technology in the real-world.

Explore and Adapt Methods: Equity in health technology assessment will force the field to adapt and test new methods that quantify patient preferences, that explore how to balance population-level preferences with individual preferences, and that account for wide variation at both levels accounting for multiple dimensions of diversity and the intersections thereof.

Data

Lack of Standardization of SDOH Data is a Problem: Incentives are currently lacking in research, healthcare delivery, and in value assessment for consistently collecting standardized data on social needs. On the other hand, some marginalized communities raise concerns about ways such data could be used to deny them services, treatments, or technology on the basis of cost or perceived lack of benefit. Researchers and value assessment practitioners must weigh benefits, harms, and feasibility considerations in collecting and using data.

Collection and Use of Qualitative Data on Patient Lived Experience is Essential: Collection of qualitative data on patients' lived experience must be systematically incorporated into the research and healthcare value ecosystem. Several informants cautioned about "over privileging" randomized-controlled data over other evidence sources. Rather, many called for commitment to broader definition of data for value – including wider representation in clinical data, and incorporation of real-world data sources and patient perspectives. Another informant also called out the need to use the substantial quantitative and qualitative data already collected, emphasizing calls for wider data sharing over status quo proprietary silos. One informant shared that new methods of analysis in a holistic way will be required. They shared that the view from their patient community was that "we don't pick stories apart." Respecting patients meant retaining the rich complexity of the story in the data.

Communication

Need for Knowledge Exchange: The importance of communicating information in ways that users can easily understand came up in discussion both in the context of making value assessment more accessible to patients and other stakeholders through use of plain language, as well as the need for research translation when communicating with policymakers.

Equity-Centered Communication as a Skill: One informant raised the issue that training in equity-centered communication is important for the field of value assessment practitioners.

Need for Greater Transparency: Many key informants highlighted the importance of transparently communicating the objectives, processes, methods, and data used as part of value assessment. Informants also highlighted the need to communicate about the impact of data (quality, type and even gaps) on decisions and recommendations. The latter point emphasized that transparency about decisions to include or omit data, and its effect on the resulting analysis is vital to ensuring equity in the use of health technology assessment for decision-making.

Table 1: Emerging Ideas To Improve Equity in Value Assessment

Value Assessment Processes	Equity-Centered Practices	Questions Driving Action
Engagement and Leadership	<ul style="list-style-type: none"> Design for engagement and diversity from beginning to end Co-create value assessment with people who bring lived experience <i>and</i> are representative of marginalized populations Allocate budget for relationship-building and compensation of patient partners Work with communities on their priorities first before asking for their time Form long-term relationships with communities whose voices have been missing from value assessment Invest to build partners' capacity to engage in the value assessment process, especially discussing tradeoffs Invest upstream in community-based research to generate community-centered evidence Consider representativeness across dimensions in research team, data collection personnel and stakeholder engagement 	<ul style="list-style-type: none"> <i>Whose view of value is the focus? Value to whom?</i> <i>Who frames the questions? Who are the researchers and authors – do they have experience in equity work?</i> <i>What lived experience perspectives are included? From whom?</i> <i>Who does the work? Who gets hired? Who is on the team? Who leads?</i> <i>Who is at the table? Who is heard?</i> <i>Who decides?</i> <i>Are skills and compensation fair and balanced?</i>
Methods and Data	<ul style="list-style-type: none"> Design for equity in how data are collected, analyzed, and used – don't forget culture and language, health literacy and accessibility Clarify up-front what is being valued and what disparities are of interest (e.g., which outcomes examined) Report demographic data (race, ethnicity, age, and gender) for all samples Specify what data are missing and why (e.g., how it relates to research, design, data collection methods, historical practices) Examine, acknowledge, and mitigate biases in algorithms Contextualize quantitative data with qualitative stories Prioritize mixed methods approaches to data Include social, political, and historical context within all discussions and analyses of value Make value assessment an iterative process with updates over time to reflect additional data and evidence shifting context, and broader inclusion 	<ul style="list-style-type: none"> <i>How can we measure upstream factors?</i> <i>Why is a particular practice infeasible? What will make it feasible?</i> <i>Which questions get asked and which get funded?</i> <i>How can work be considered reliable and valid if it is not representative?</i> <i>How does society value equity? How do we handle variation in value in equity?</i>
Communication	<ul style="list-style-type: none"> Be clear that equity is part of the culture of health technology assessment – rather than a method or procedure, it is an embedded way of thinking and acting Be transparent about how value assessment practitioners integrate equity through their processes (e.g., report equity-specific practices, demographics of practitioners) and practitioners' own biases In reports, distinguish disparities from root causes by tying language on disparities in outcomes to upstream factors that drive those disparities Use plain language to communicate value assessment findings to policymakers to ensure equity-centered value assessments are acted upon 	<ul style="list-style-type: none"> <i>Does value assessment do more harm than good? For whom?</i> <i>Do value assessments center data gaps and limitations that may obscure analysis of equity impact?</i> <i>Do value assessments explicitly discuss the equity implications of analyses and directions?</i>

Conclusion

Across these interviews, we heard broad consensus that **there is no value without equity**, so an intentional focus on equity is essential from the beginning and throughout the process of health technology assessment. Figure 2 reflects the adaptation of our original Framework to reflect the cyclic process and the importance of people, processes, and communications to building an environment of trust and equity that supports measurement of value.

Key informants called out that equity in processes is essential to achieve equity in outcomes. In practical terms, informants noted that there must be equity in who does the work of value assessment, and equity should be integrated throughout all value assessment processes. Examples of practical and intentional change for value/health technology assessors that were suggested by interviewees include:

- Make time and invest to build authentic and meaningful partnerships with patients and communities;
- Clearly prioritize lived-experience expertise in leadership, design, and execution;
- Increase representation from marginalized communities, both among value assessment practitioners and in quantitative and qualitative data used within assessments;
- Define and invest in equity expertise as an essential skillset for researchers and others involved in health technology assessment; and
- Be consistently transparent about biases and gaps in decision-making, data, methods and algorithms used in health technology assessments.

Additional areas key informants called out as needing further exploration and development included:

- Combining quantitative and qualitative data through mixed methods and conceptualizing value assessments by identifying differences across populations, understanding health disparities, and acknowledging social, environmental, and historical factors driving health inequities.
- Rethinking time frames within value assessments, including considering longer term outcomes, acknowledging differing views on value along the care journey, and updating assessments iteratively over time.
- Increasing transparency in who does the work of value assessment, who frames research and value questions, and whose perspectives are reflected within value assessments. Informants also emphasized transparency in reporting biases and missing data.

In the coming months, IVI will continue to develop and refine its Framework, identifying promising practices, and developing actionable guidance for equity-centered value assessment. We are grateful for the time and thoughtful insight from key informants and our steering committee, who are deeply committed to equity in their own professional and personal journeys.

APPENDIX

01 LIST OF KEY INFORMANTS INTERVIEWED	13
02 KEY INFORMANT INTERVIEW GUIDE	14
03 FIGURES	21

Appendix 1. List of Key Informants Interviewed

Key Informant Organization	Date of Interview	Stakeholder Perspective
Eberechukwu Onukwugha, PhD, MS (University of Maryland)	August 23, 2022	Research
Bayley A. Raiz, DBH, MBA, LCSW (CVS Health)	September 12, 2022	Payer, Clinician
Madhuri Jha, MPH, LCSW (Kennedy-Satcher Center for Mental Health Equity, Morehouse School of Medicine)	September 12, 2022	Research, Clinician
Brian Meissner, PharmD, PhD (AbbVie)	September 19, 2022	Life Science Industry, Research
Robyn Carson, MPH (AbbVie)		
Kenneth Mendez, MBA (Asthma and Allergy Foundation of America)	September 21, 2022	Patient Advocacy
Eboni Price-Haywood, MD, MPH, FACP (Ochsner Xavier Institute for Health Equity and Research)	September 26, 2022	Health System, Research, Clinician
Jessica Brooks Woods, MPM, PHR (Pittsburgh Business Group on Health)	October 7, 2022	Employer, Purchaser, Patient Advocacy
Megan Morris, PhD, MPH (University of Colorado Denver and Disability Equity Collaborative)	October 12, 2022	Patient Advocacy, Research, Clinician
Lisa Prosser, PhD, MS (University of Michigan)	October 12, 2022	Research
Alma McCormick (Messengers for Health)	November 30, 2022	Patient, Research

Appendix 2. Key Informant Interview Guide

Interviewer's Introduction

Today, we appreciate you taking the time to speak with IVI about the issue of how value assessment should address and support health equity.

The purpose of these conversations is to elicit participants' perspectives on innovations in equity-centered value assessment methods and processes, domains on which IVI's Health Equity Initiative should focus, and practical considerations for equitable value assessment. Learning from these conversations will inform roundtable dialogues in late 2022 and a multi-stakeholder consensus meeting in 2023.

We'd like record today's conversation for note-taking purposes. We won't share that recording with anyone outside of the team and won't identify you in anything we share publicly from these interviews. Would it be ok with you if I record today's interview?

[Start recording if permission is granted.]

As a starting reference, we hope you've had time to review the project overview and framework explanation. The framework is a working draft reflecting our learning to date and will continue to evolve.

During the next 60 minutes, we would like to explore several questions with you relevant to health equity and the intersection with value, and specifically value assessment. We are interested in your work and views on these topics broadly, and welcome candor and your critical thinking to help shape our future phases of work. Above all, our intent is an interactive discussion with you. Before we get started, do you have any questions?

****Next Section is Background and Introduction Questions****

Background and Introduction Questions

In this section, listen for:

- Different views or understandings of health equity
- Different views or understandings of value or the practice of value assessment
- Tensions between individual and organizational/institutional views of equity or value
- What's not clear about IVI's initiative. Not important to clarify all details during interview, but is a sign of areas needing more clarity in future communications.

1. *Please tell us a bit about yourself and your role in your organization.*
2. *We shared with you some materials describing the purpose of this initiative and how IVI views the intersection of health equity and value assessment. Before we get started, we wanted to make time for any questions or reactions to that.*

If pre-read material is not fresh in their minds, provide brief level-setting:

- Value assessment is one approach to health technology assessment, which is the evaluation of costs and benefits for health technologies to better inform decision-making about access, reimbursement and health care delivery, as well as other policy decisions that affect both health outcomes and resource utilization.
- Through discussion with the initiative's steering committee, we are starting this work by defining equity in value assessment as: *Value assessment advances health equity when it reduces health disparities by aligning access and affordability of healthcare technologies and services with the differing needs and values of diverse patient populations, especially those who are most marginalized.*

****Next Section is Vision and Problem Statement Questions****

Vision and Problem Statement Questions

In this section, listen for:

- What aspects of equity do key informants raise as most important?
- How much do key informants focus on the process or methods of value assessment?
- How much do they focus on the outcomes or impact of value assessment?
- Where do key informants struggle to answer this question – what are the aspects of value or equity they seem to need to wrestle with in fleshing out these statements?

For key informants with HTA/HEOR expertise, spend less time in this section and more on research action.

3. *Could you tell us a bit about how you or your organization focuses on value and/or on equity? We're especially interested in any ways that your work brings those two threads together.*
4. *What are the problems related to equity that you and or your organization are trying to resolve? Please share what good looks like to you or your organization?*
 - *For example, we're interested to hear how you would flesh out this statement: Making equity a consistent focus of value assessment will require...*
 - *Why are these aspects of equity a priority for you and your organization?*

****Next Section is Framework Questions****

Input on Working Framework from IVI Health Equity Initiative Steering Committee

In this section, listen for:

- What elements of the framework seem to resonate most with key informants?
- Is there anything missing from the framework they would add? Anything they would remove?
- Where do they have questions or seem confused?
- What kinds of impacts or decisions do participants highlight as important upstream or downstream factors? Which of these are observable (e.g., data collection, statistical analyses, interpretation) and which are less transparent (e.g., study team composition, selection of research questions, choice of intervention and comparison groups, etc.)?

IVI staff partner pulls up framework image (end of this document), if needed.

Now we would like to hear your feedback on the working framework we shared describing domains of equitable value assessment (also in the pre-read materials). This framework reflects work to date and guidance from the initiative's steering committee. It will continue to evolve and we would like to hear your thoughts on how to refine it.

5. *Which of the framework domains are highest priority or most essential in health equity considerations in value assessment? If you had to pick a single most important domain, what would it be? Why?*
 - *Are there any domains missing that you feel are important to include in our working framework?*
 - *For the domain you feel is highest priority, are there any attributes (sub-bullets under the domain) missing, in need of further explanation or examples, or unnecessary? Why?*
6. *Are upstream issues as defined in the framework clear? Are we missing any other aspects that are essential factors in health equity, but which may be precursors or contributors to value assessment that advances health equity?*
7. *Are the downstream impacts of equitable value assessment clear? Are there additional aspects of the potential applications and impacts of value assessment that may affect equity or disparities?*

****Next Section is Research Action Questions****

Research Action Questions

In this section, listen for:

- What additional types or sources of data do key informants point to (e.g., SDOH data, patient-reported data, real-world data sources)? How or when might those data become available for value assessment (e.g., where in pipeline)?
- What additional methods or practices do key informants point to? Do these come from within value assessment or other fields? What makes them promising?
- How optimistic are key informants about adopting equity-centered data, methods or practices into standard value assessment practice?

Next we would like to clarify some of the opportunities and challenges around equitable practice of value assessment.

Broad Questions (for all key informants):

8. *What methods or best practices do you look for as evidence that a project, research study, or analysis is equity-centered? Why?*
 - *What is required to ensure those methods or best practices are used widely and consistently?*
9. *What new data sources, methods or processes must be developed to ensure equitable practice of value assessment?*
10. *What can IVI learn from people doing this work in other fields? Where should we look for examples to learn from?*
 - Back Pocket: For example, we have looked at [A Toolkit for Centering Racial Equity Throughout Data Integration](#) for racial equity best practices when using algorithms and statistical tools, analyzing data, and reporting data or sharing findings.
11. *What are the “bright spots” for making change happen (i.e., promising actions and/or attention to bring equity into the discussion of value? What makes your example(s) a solution or promising direction?*

Value Assessment-Specific Questions (for key informants with value assessment or health technology assessment expertise; prioritize about 15 minutes for this section):

12. *What new data sources, methods or processes must be developed to ensure equitable practice of value assessment? How will these help?*
 - *What can/should we do about the ongoing inadequacies of data to support decision-making?*
 - *What would you communicate to researchers in the value assessment field about the inadequacies of data? Are there immediate priorities that should get more attention and resources?*
13. *What aspects of value assessment require investment to support incorporating health equity considerations into value assessment practice? Which of these investments would you prioritize?*
14. *What feasibility issues arise for measuring and incorporating health equity in value assessment?*

****Next Section is Wrap-Up Questions****

Wrap-Up Questions

15. *What attributes do you look for in value assessment to evaluate how well it incorporates health equity?*

- *Why are these important?*
- *Adapt this question as needed to focus on value assessment, measurement, data, research, etc., depending on informant's expertise and conversation up to now.*

Before we wrap up, [Ellen/Melanie/Rick], any key question we missed?

Then also ask informant:

- *Is there anything we should have asked but did not?*
- *Who else would you recommend we connect with to help inform this initiative?*

Thank you for your participation in IVI's Health Equity Initiative and for your candor and insights today. We will share a brief summary of key takeaways from this phase of our work with you and look forward to your further input and questions.

Appendix 3. Figures

Figure 1. Visual Representation: Original Framework for Equitable Health Technology Assessment

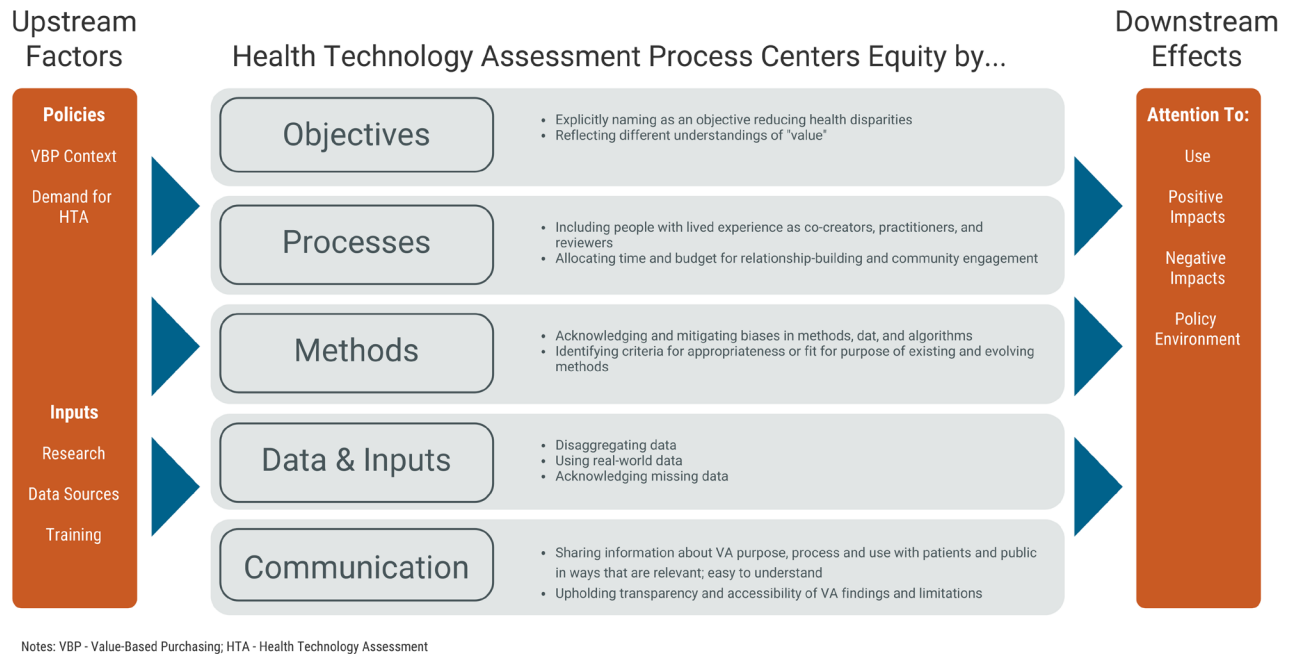
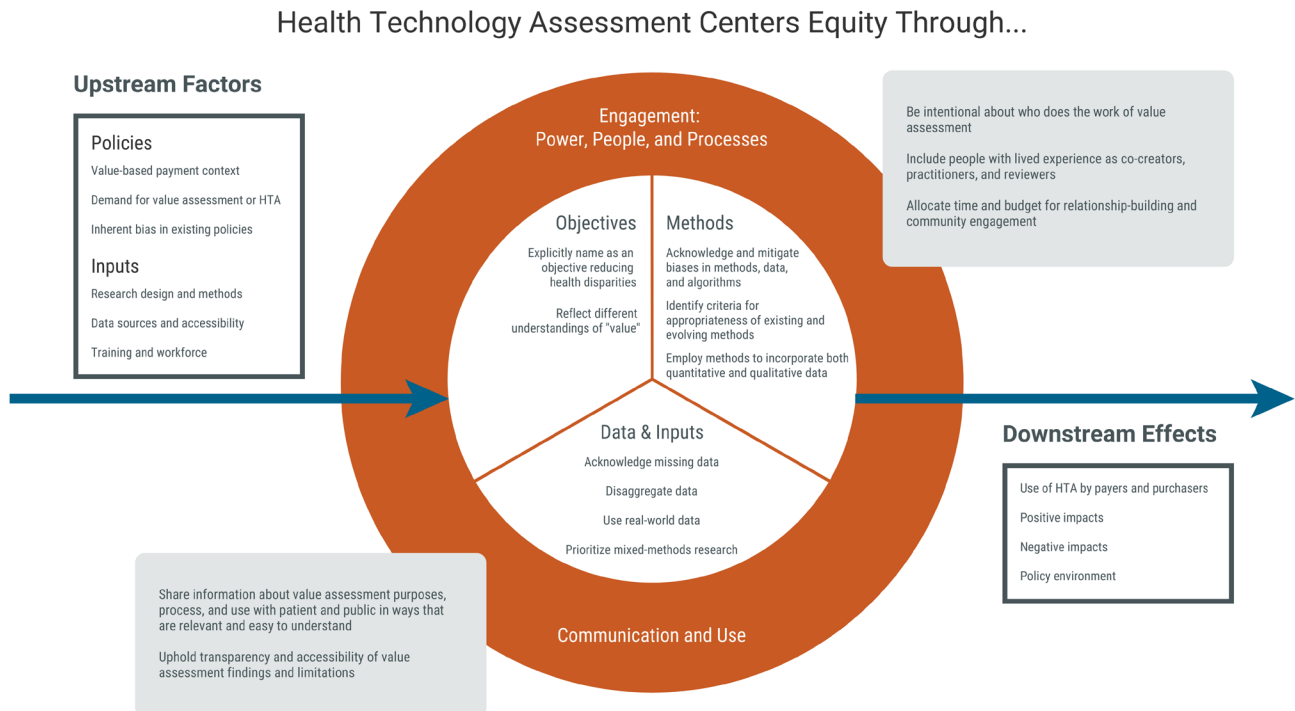


Figure 2. Revision of Framework, Accounting for Key Informant Insights





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Principles for Value Assessment in the U.S.

Value assessment is an important process to inform national and local deliberations about allocating resources and achieving the best clinical health and quality-of-life outcomes. As exploration of a systematic, centralized process for review of drugs and other health interventions in the U.S. accelerates, the Innovation and Value Initiative (IVI) believes there is a need to define the principles that must guide future policy and practice.

An overarching theme of these principles is defining best practice in the applied use of value assessment; there must be consensus among stakeholder communities on the most effective methods and use cases that are relevant to the U.S. marketplace.

Sustains Authentic Patient-Centricity

Value assessment must consistently establish diverse patient partnerships in governance, priority setting, and the creation of models.

Assessors should lead robust research in patient preference and data improvement to ensure value assessment is authentic and relevant to the diverse patient experience.

Cultivates Modernized Methods

Value assessment initiatives must support the evolution of traditional cost-effectiveness analyses and complementary approaches that address societal perspectives and broader cost parameters, as well as reduce discrimination and disparities based on patient heterogeneity or disability.

Improves Clinical and Real-World Data

Value assessment must define priorities for data resource investments, including patient-provided information. The standardization of real-world data generation and the practical implication of data sources in value assessment must also be prioritized.

Adapts To and With Evolving Evidence

Value assessment must contribute to a continuous learning environment. Model developers can do this by accounting for scientific uncertainty, patient heterogeneity, and evolving evidence related to disease states and clinical outcomes, quality-of-life impacts, and disparities in care.

Fosters Long-Run Innovation

Value assessment must be able to recognize and distinguish transformative therapies and inform national dialogue about incentivizing and rewarding technological innovation.



Advances Transparency

Value assessment in the U.S. should accelerate the development of open-source modeling and application to improve stakeholder trust and establish open dialogue. Assumptions and coding should be transparent to allow public validation and stimulate replication across disease and interventional analyses.

Focuses Value Discussion Across Treatment Interventions

Value assessment must evolve beyond siloed comparisons within a class or intervention type to consider benefit, risk, and trade-offs for optimal treatment approaches.

Facilitates Customizable Decision-Making

Decision-maker needs should inform the development of value assessment methods and tools. In turn, such resources should include customizable analyses and tools to support localized decisions.

Supports Health Equity

Value assessment should facilitate subgroup and distributional impact analyses; drive improved methods in clinical, outcomes, and preferences research to reflect diverse communities and experiences; and inform policy dialogue about improving access and equity.