

4th Annual Methods Summit

Rewriting the Playbook on Health Technology Assessment:
Equity and Economic Impacts on Patients and Families

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The Innovation and Value Initiative (IVI) is a 501(c)(3), non-profit research organization dedicated to advance the science, practice, and use of patient-centered health technology assessment to support decisions that make healthcare more meaningful and equitable.

A photograph of a woman in a white lab coat, likely a healthcare professional, assisting an elderly woman in a wheelchair. They are outdoors, with trees and greenery in the background. The scene is captured in a soft, natural light, suggesting a park or a similar outdoor setting. The woman in the wheelchair is wearing a light-colored outfit and is looking towards the healthcare professional. The healthcare professional is leaning slightly forward, appearing to be engaged in conversation or providing assistance. The overall mood is one of care and support.

ACKNOWLEDGMENTS

IVI thanks members of the Steering Committees for the [Health Equity Initiative](#) and the [Economic Impacts Project](#) for contributing to the content and format of the 4th Annual Methods Summit. We are grateful for the time and wisdom of our keynote and panel speakers (see Appendix), who made the event both informative and thought-provoking. Thank you to our facilitator, Ilisa Halpern Paul, and the support team at Venable LLP. Finally, we appreciate the vision and support provided by IVI team members, including Jennifer Bright, Tiffany Huth, Erica deFur Malik, Melanie Ridley, and Judy Thomas.

The 2023 4th Annual IVI Methods Summit is supported by contributions from PhRMA, Janssen Scientific Affairs, 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 our diverse membership, also support this work.

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EXECUTIVE SUMMARY

On March 13-14, 2023, the Innovation and Value Initiative (IVI) convened its 4th Annual Methods Summit, **Rewriting the Playbook on Health Technology Assessment: Equity and Economic Impacts on Patients and Families**.

PURPOSE

The Methods Summit demonstrated IVI's continued commitment to multi-stakeholder consensus-building to address the emerging and ongoing challenges to U.S. health technology assessment (HTA). The 4th Annual IVI Methods Summit included two days of presentation, panel dialogue, and audience exchange focused on centering equity in HTA, and on defining the full range of economic impacts on patients and caregivers. Discussion topics and invited speakers emerged from the projects informing the summit – IVI's Health Equity Initiative and Economics Impact Project. Throughout both projects, contributors emphasized the intersection of health equity and understanding wider economic impacts on patients and caregivers. These efforts yielded conceptual frameworks (see Figure 1 and Figure 2) intended to guide future research and action by stakeholders in the research, patient, and payer/purchaser communities.



And I certainly note that in your [\[No Value Without Equity report\]](#), you mentioned that it was important right from the start to be very intentional about the focus on equity. And that's very much aligned with our what our intent is at CMMI.

– Dora Hughes (CMMI)

Throughout the two-day event, several key themes arose, including:

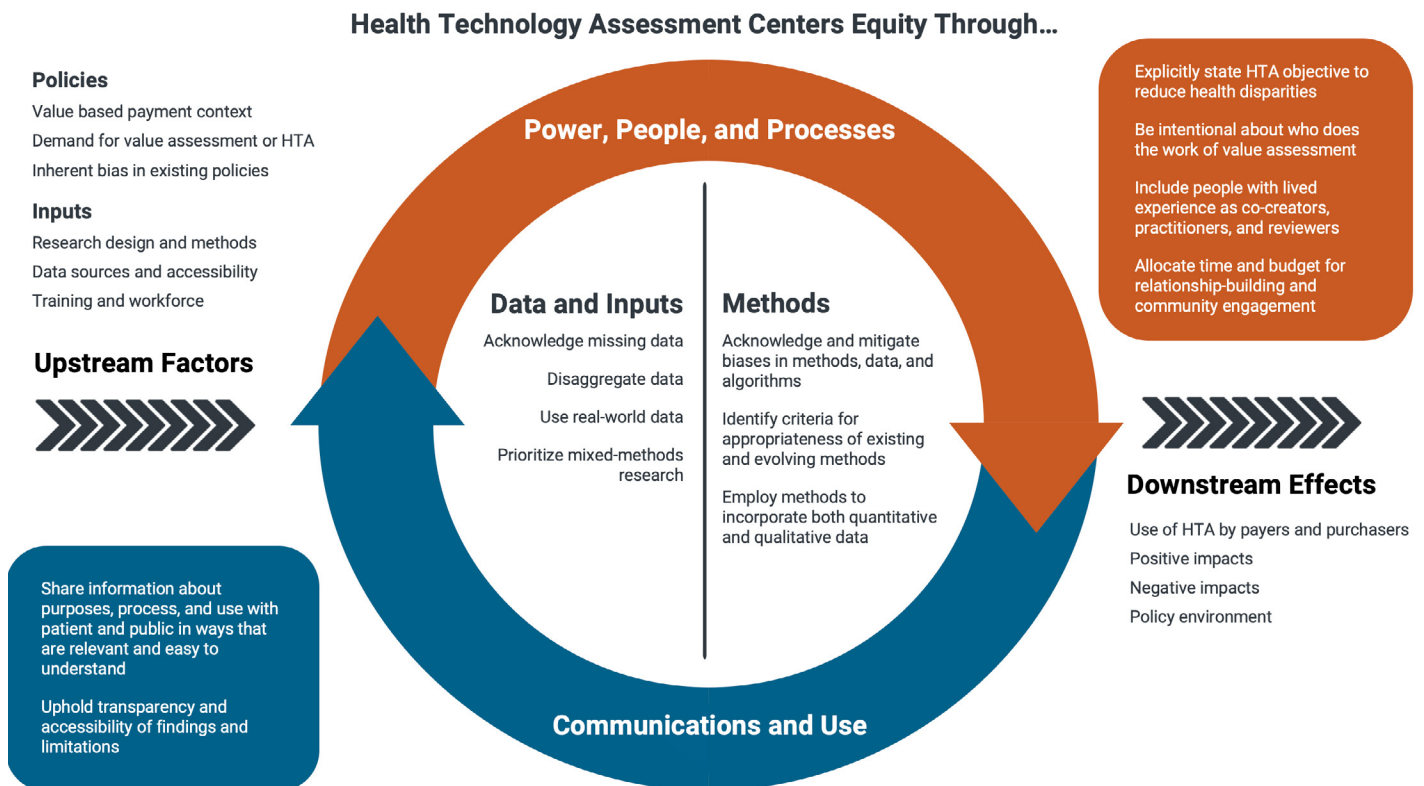
- Pursuing fundamental change
- Shifting to shared power with patients and caregivers
- Prioritizing redefining data
- Using a range of (mixed) methods
- Practicing transparent, accessible communication
- Emphasizing shared learning and continuous improvement
- Establishing clear accountability for change and measure progress

INTENTIONAL ACTION IS IMPERATIVE

Keynote speaker, Dr. Dora Hughes, emphasized the alignment of IVI reports and frameworks with the current efforts in Centers for Medicare and Medicaid Services/ CMS Innovation Center (CMS/CMMI) to improve equity and affordability for Medicare and Medicaid beneficiaries. She further highlighted the importance of improved data collection, the use of both quantitative and qualitative data, and improving equity in the design and delivery of health care. Likewise, Donna Cryer, JD, from the Global Liver Institute, shared the vital importance of ensuring patient and caregiver representativeness in the design and inputs (data, qualitative experience, preferences, priorities) of HTA. Ms. Cryer also reiterated the mantra emerging from both IVI projects, that there can be **no value without equity**. Dr. Nakela Cook, from the Patient-Centered Outcomes Research Institute (PCORI), emphasized the importance of IVI’s thought leadership and influence of the reports and frameworks emerging from the 4th Annual


IVI Methods Summit on the PCORI strategic vision and research prioritization. Gwen Darien, from the National Patient Advocate Foundation (NPAF), and Gretchen Wartman, from the National Minority Quality Forum (NMQF), expanded on these themes during the forum’s second day, emphasizing the importance of collaboration with patients and patient communities to drive changes in research methods, data, and their application to real-world decision-making (see Appendix 1 for the Methods Summit Agenda).

Figure 1. Health Equity Initiative Framework




Each IVI Methods Summit challenges all actors to consider wider viewpoints and advances in data and methods, to pursue change in their own work, and to lead others within their sector to do the same. The 2023 panel discussions focused on change by researchers, payers and purchasers, patients, and other actors in the HTA ecosystem. Primary change opportunities focused on transparency, shared learning, and commitment to the role and perspective of more representative patient and caregiver communities. Moreover, contributors and participants emphasized a growing call for accountability to ensure equity and broader economic impacts are integrated into HTA, tied to regulatory guidance, payment systems, research funding, and peer-reviewed scientific publication.

Recordings of the 4th Annual IVI Methods Summit are accessible on the IVI website.



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Participants at the 4th Annual IVI Methods Summit

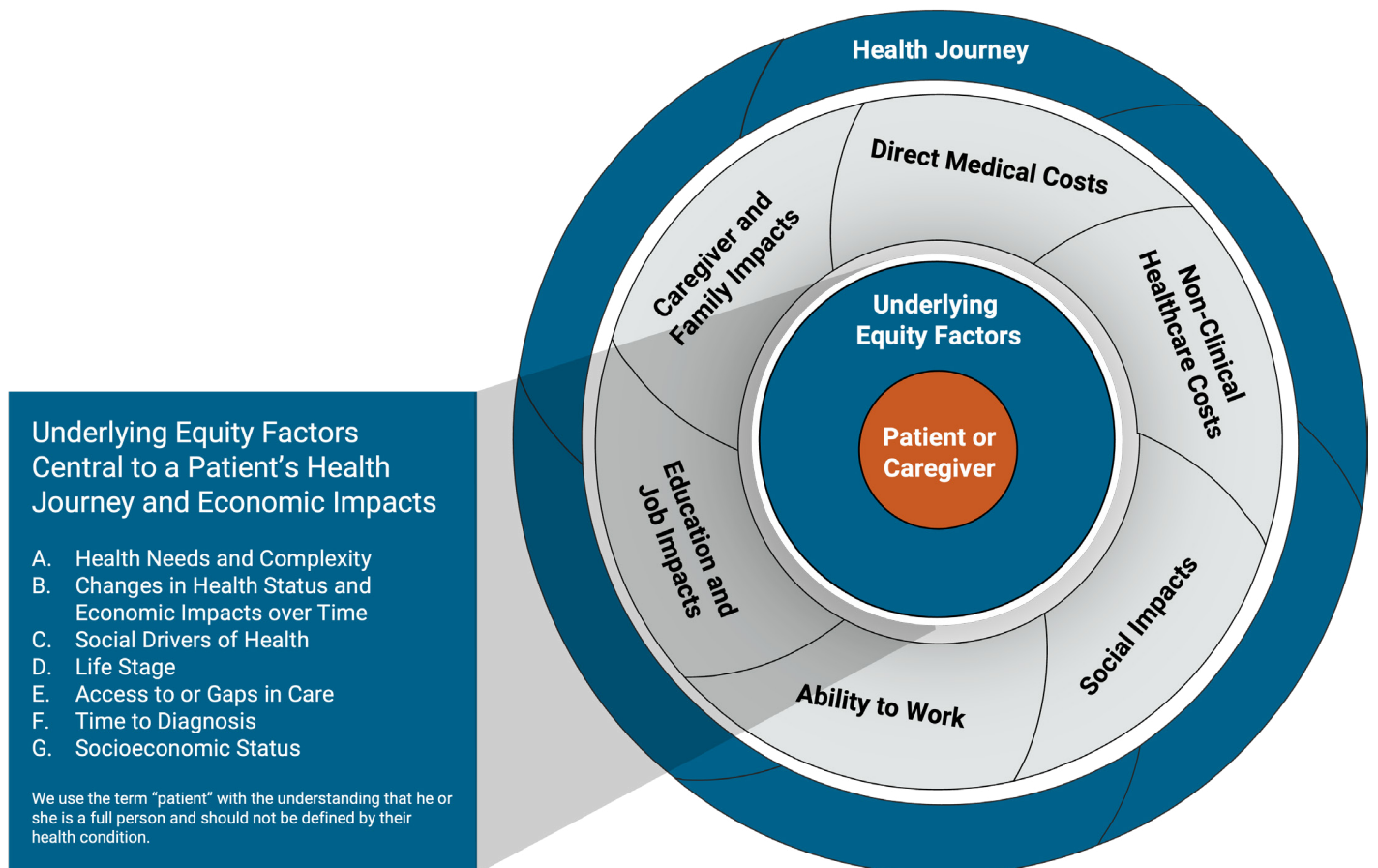


20+

Hours of Dialogue

- Patient Advocates / Non-Profits (33%)
- Government (2%)
- Payer / Purchaser / Employer (3%)
- Research / Academic (23%)
- Industry / For-Profit (39%)

Figure 2. Economic Impacts Project Framework





NO EQUITY, NO
VALUE.

NO ACCESS, NO
EQUITY OR VALUE.

Donna Cryer
Global Liver Institute

PROCEEDINGS AND THEMES FROM THE 4TH ANNUAL IVI METHODS SUMMIT

Over the course of the two-day 4th Annual IVI Methods Summit, the keynote speakers, panelists, and meeting participants raised important questions and made the case that are at a critical point where we can begin to fundamentally change HTA methods and bring patients¹ full economic impacts into healthcare research. Throughout the discussions, seven themes emerged (see Executive Summary, Page 4). This proceedings document summarizes the dialogue and offers specific call to action opportunities emerging from the 4th Annual IVI Methods Summit.

THEME 1: PURSUE FUNDAMENTAL CHANGE

Throughout the 4th Annual IVI Methods Summit, presenters made the case that all stakeholders have an obligation to take action, and pursue fundamental, multi-modal change. This requires changes in research design and methods, data collection, community engagement, and dissemination to ensure that health research centers health equity and accounts for a full range of economic impacts on patients and caregivers. Specific recommendations include:

- **Take responsibility** to lead change in research and engagement approaches and encourage peers to do so. Use the IVI Equity Insights recommendations and the IVI Economic Impacts Framework as a guide.
- **Start with the perspectives of patients and caregivers** regarding factors that define value – including the range of costs affecting their experience. Several speakers noted that “all costs and all economic burden comes from one wallet for the patient.”
- **Adopt a shared learning mindset.** Expect and acknowledge challenges, gaps, and setbacks to share learning with the community affected. Transparency and continuous improvement of data collection and methods are essential elements.
- **Encourage policy changes** that incentivize health equity and prioritize leadership from people with lived experience. Policy includes research funding requirements, publication standards, coverage and reimbursement, and contract requirements, for example.

¹ Throughout this document, we use the term “patient” or “patient advocate” to refer to a person who has had a significant encounter with the healthcare system and has lived expertise in the healthcare system. We do not suggest that a person is their disease or that is a person’s only area of experience or expertise. We use this term in recognition of their lived experience and the importance of this experience to improving the healthcare system.



**Because if we can solve for people that are most vulnerable, we can solve for everybody.
And a rising tide lifts all boats.**

– Kistein Monkhouse (Patient Orator)



...we have a responsibility as researchers to document how the patient voice is integrated with the methods, beginning with the research question, development of the intervention, all of those things, so we can document which places the patient voice impacted the way the study was designed. It is also a best practice that when we say partners, that means that the patients or community members, they are co-investigators, or possibly even co-PI, where that's appropriate.

— Leticia Moczgamba (University of Texas)

THEME 2: SHIFT TO SHARED POWER WITH PATIENTS AND FAMILIES

Building on themes from IVI's prior Methods Summits, speakers and participants universally emphasized the imperative to accelerate collaboration with patients and caregivers as full partners in the design and execution of health research and HTA. While steady progress has occurred, implementation of such practices are not yet standard, particularly in the HTA arena. Actions can include:

- **Start with the people.** Patient and caregivers should be involved as co-leaders early in research formation and through the research process and dissemination.
- **Acknowledge the complexity of people's lived experience,** including their health journey and the full set of impacts resulting from their health condition(s).
- **Invest in diverse voices, time, and resources** to build trust and fairly compensate patient and caregiver contributions.
- **Document the impact** of patient and caregiver input to process and outcomes of the research and HTA.



THEME 3: PRIORITIZE REDEFINING DATA

Collecting and using information and data in a meaningful way was a recurring theme during the 4th Annual IVI Methods Summit. Across stakeholder perspectives, panelists and participants acknowledged that improving the data is a difficult, but an essential action step in moving from *talking* about health equity and measuring economic impacts to implementing real change. Actions identified include:

- **Be intentional** and transparent when identifying relevant data for research and HTA, incorporating impacts defined by patient and caregiver lived experience.
- **Diversify data development** and use, including clinical trials, economic impact studies, burden of disease, patient preference studies, outcomes (e.g., PROs/PROMs), and medical record and claims.
- **Accelerate data improvement** by publicizing gaps and limitations as priorities for research investment. Ally with affected communities to advocate for data generation and accessibility.

- **Establish expectations in research contracts, vendor agreements, and practice models for the use of qualitative and quantitative patient defined and derived data.** Build on federally-established metrics for race and ethnicity, and social determinants/drivers of health, for example.
- **Quantify economic impacts** to society, average individuals and unique populations, considering the total cost of care across multiple dimensions, and over time.



I'm confident that equity as a priority is not going to go away. But I do think the data is really difficult – it is our key vulnerability and our weakness. That is where all of our efforts will fail if we are not able to increase the collection of socio-demographic data from our providers.

– Dora Hughes (CMMI)

THEME 4: ADOPT A RANGE OF (MIXED) METHODS

Discussions during the 4th Annual IVI Methods Summit reflected a growing recognition of the limitations of randomized controlled studies and the need for expanded focus on real-world data development that reflects the experience and wider economic impacts on patients and caregivers. Further, participants emphasized the need to develop novel mixed-methods approaches to derive qualitative and quantitative patient input for use in healthcare research and HTA, and investing in skill development for wider applications of such methods.. Action ideas include:

- **Showcase existing work that seeks to test and operationalize mixed-methods approaches**, such as an approach proposed by researchers from the RAND Corporation and IVI that leverages the principle of goal attainment scaling to derive patient goals for use in multi-criteria decision analysis (MCDA).²
- **Increase incentives for using mixed-methods research approaches** (e.g., research funding requirements, HTA scoping parameters, journal publication guidelines).
- **Utilize rapid cycle methods testing, dissemination, and iteration** to cultivate learning and methods improvement focus within HTA.
- **Invest in workforce training** on patient engagement, qualitative research methods, methods for incorporating such data into HTA, and methods for managing missing data (e.g., imputation).

² Zachary Predmore, Emily K Chen, Thomas W Concannon, Suzanne Schrandt, Susan J Bartlett, Clifton O Bingham, Richard Z Xie, Richard H Chapman & Lori Frank Treatment goals for rheumatoid arthritis: patient engagement and goal collection. (2023) Journal of Comparative Effectiveness Research. DOI: 10.57264/ceer-2022-0097



There's an important need to look beyond a peer-reviewed literature or a meta-analysis to talk to patients and be able to take this anecdotal evidence and start to work with it, even if there's some uncertainty around it.

— Stacey Kowal (Genentech)

THEME 5: PRACTICE TRANSPARENT, ACCESSIBLE COMMUNICATION

Speakers at the 4th Annual IVI Methods Summit reiterated the importance of communicating findings, regardless of the results, both within the research community and especially with patients, caregivers, employers, and other decision-makers. Researchers – and those using the research to make decisions – need to use accessible, plain language in open-access communications to clarify questions asked, methods used, research findings and limitations, and their impact. While not a new aspect of dialogue within the research and HTA arenas, the 4th Annual IVI Summit emphasized the need for consistency and establishing accountability for such actions.



Action ideas include:

- **Be transparent and clear about objectives, methods, processes, representativeness, and findings.** Open access during all phases of the process, and as part of research dissemination efforts, are vital.
- **Use plain language in all communication.** Collaboration with patient and caregiver communities can identify both methods and language relevant to the communit(ies) the research will affect.
- **Acknowledge gaps in the data, the limitations of findings, and their potential impact on people affected by the research.** Given the evolving data landscape, participants emphasized that such transparency is vital to driving research priorities and establishing parameters for ethical use of HTA.



I think it's a best practice, where you have to share results back to the communities that you're working with.

– Leticia Moczygemba (University of Texas)



I think that many researchers, including myself, try to do some of this work and we do it sort of piecemeal. We do what we can get funded, and what we can reasonably capture. And I think we know that we're not really capturing the whole picture, and that's a frustrating thing for us and for patients. And I think the [Economic Impacts Framework] enables us a chance to do our best to see the whole picture.

– Mary Reed (Kaiser Permanente)

THEME 6: EMPHASIZE SHARED LEARNING AND CONTINUOUS IMPROVEMENT

The 4th Annual IVI Methods Summit speakers called out the importance of the Health Equity Initiative and the Economics Impact Project, and the potential applications that the emerging frameworks have beyond comparative and cost-effectiveness research and HTA. Participants saw these frameworks as important guides for all researchers to consider in their design and implementation. As well as for patients, caregivers, and patient advocacy organizations to use in setting expectations and accountability for researchers, HTA bodies, and decision-makers. Further, the Frameworks offer employer-purchasers, payers, regulators, and policy makers focal areas for establishing expected shared knowledge and cycles of improvement that benefit both clinical and economic outcomes for patients and caregivers. Action ideas include:

- **Develop, refine, and use checklists, patient engagement tools, and “best in class” resources** to put the framework elements into practice.
- **Drive continuous assessment of gaps** in patient leadership, data, research objectives, and coverage and outcomes, with focus on patient impact and equity. Research funders, payers-purchasers, and regulators can establish important guidance and expectations.
- **Prioritize research initiatives and funding** that align with the principles and actions emerging from the health equity and economic impacts frameworks.
- **Publish research findings and processes as public domain resources**, using open access publishing, shared research repositories and other mechanisms to promote wider dissemination and uptake.
- **Publish progress – and setbacks** – regarding how the incorporation of equity, patient leadership and wider measurement of economic impacts affects decisions ranging from research design and analysis plans, to use of findings.

THEME 7: ESTABLISH ACCOUNTABILITY FOR CHANGE AND MEASURE PROGRESS

IVI's initiatives focused on health equity and economic impacts highlight the dual need for comprehensive action and accountability of all actors to the needs and outcomes important to patients and caregivers.


Speakers at the 4th Annual IVI Methods Summit acknowledged that sustained, incremental change is imperative, and that the Frameworks offer ideas for action. Further, they begin to define the “signals” that can help all stakeholders measure progress. Action ideas include:

- **Funders, publishers, employer-purchasers, and payers can establish expectations and incentives that center equity and wider economic impacts** in research processes, data, methods, communications, and use.
- **Patients and patient- and caregiver-focused organizations can monitor** research and HTA processes and outputs to evaluate alignment with the Frameworks’ principles and practices and the impact on outcomes and access.
- **Employers and payers can establish expectations of researchers, data organizations, and health technology assessors** for centering equity and broader capture of economic impacts in the processes, data development and use, analysis, and reporting.
- **Researchers from all stakeholder sectors** can measure and communicate limitations, learning regarding processes and improvements in data, patient partnership and application to future research and decision-making.



[Health equity] is incorporated in the way in which we’re now designing our funding announcements, the way in which we’re thinking about review. We’re incentivizing our applicant community to really address these issues by explicitly asking for how projects are going to meet goals like equity or economic outcomes.

— Nakela Cook (PCORI)



EQUITY DOES NOT
AFFECT ONLY
CERTAIN POPULATION
COHORTS.

IT AFFECTS ALL OF
US, EITHER IN THE
MOMENT, OR IN THE
FUTURE.

Gretchen Wartman
National Minority Quality Forum

DO MORE THAN TALK; ACT

A resounding theme at the 4th Annual IVI Methods Summit was the imperative to act. All individuals and entities with interest in health equity and improved decision-making for identifying value in the design, delivery, and economic impact of health care can benefit from the Summit's learning dialogues and emerging ideas for action.

Regardless of perspective or role, early actions by any stakeholder can include:

- **Reading and sharing** within one's professional circles the Health Equity Insights Paper and Framework and the Economic Impacts Framework.
- **Building partnerships with community-based leaders and non-traditional partners** focused on health equity and improving data collection on patient experience, preferences and economic impacts.
- **Formalizing organizational patient and family engagement processes and structures**, to emphasize shared leadership and co-development of research and implementation, with emphasis on underrepresented and marginalized communities.
- **Seeking skill development in patient engagement, data collection, and mixed-methods research** that emphasizes and upholds equity principles, and supports focus on wider economic impacts.
- **Requiring transparent, accessible communication** of research results and implications for affected communities.
- **Establishing criteria for research funding and scientific publication** that create accountability for centering equity in HTA and research.
- **Publishing "positive" and "negative" findings to improve transparency** and contribute to a shared learning ecosystem that promotes equity and assessment of full economic impact on patients and families.
- **Defining metrics to measure progress**, including both process measures and impact on research design, decision-making, data improvement, representativeness, and methods.



Don't let perfection stand in the way of progress. It's going to take all of us years of hard work to get there. But, we can all start making really small steps today to make a better decision.

— Stacey Kowal (Genentech)





I think where we would be looking to IVI and diving deep is on the operational side. That's where I think at a high level, we're completely aligned. But as you talk to your members and stakeholders, it'll be really helpful to find out more about how people are actually doing it. And particularly with technology assessments. I mean, that's an area that has a lot of different opinions and ripe with controversy, it would be really helpful to get guidance in that area.

— Dora Hughes (CMMI)

IVI FUTURE ACTIONS

The IVI Annual Methods Summits have historically influenced our research priorities and organizational practice. Examples include our defined approach to [patient](#) and stakeholder engagement in our Open-Source Value Project (OSVP) models, and our investment in research addressing methods for assessing patient-important attributes and valuing innovation in HTA. In addition to publishing the frameworks from its respective Health Equity Initiative and Economic Impacts Project, IVI will incorporate these key takeaways in our work, including:

- Using representative patient preference data in our [Major Depressive Disorder model](#), and publishing the impact patient and stakeholder input had on the design and creation of the model,
- Working with [rare disease](#) community organizations and individuals to explore opportunities for defining common outcomes and data on economic impacts important to the consideration of value, and
- Defining metrics by which progress on centering equity in HTA might be measured and evaluated in the public domain to benefit all stakeholders.

Throughout 2023, IVI will release further recommendations and resources emerging from both initiatives highlighted at the 4th Annual IVI Methods Summit, and continue to lead change in collaboration with all entities that embrace patient-centered, equitable measurement of value.



EQUITY EQUALS
EXCELLENCE FOR
EVERYONE.

Gwen Darien
National Patient Advocate Foundation

APPENDIX

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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	Presenters / Panelists
	Purpose:	
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

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	<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 <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 <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.

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March 13-14, 2023

SPEAKERS

Keynote Speaker



Nakela Cook, MD, MPH
Patient-Centered Outcomes
Research Institute

Keynote Speaker



Donna Cryer, JD
Global Liver Institute

Keynote Speaker



Gwen Darien
National Patient Advocate
Foundation

Keynote Speaker



Dora Hughes, MD, MPH
Centers for Medicare & Medicaid
Services

Keynote Speaker



Gretchen Wartman
National Minority Quality Forum



Greg Baker, RPh
EmsanaRx



Nicole Boschi, PhD
National Multiple Sclerosis
Society



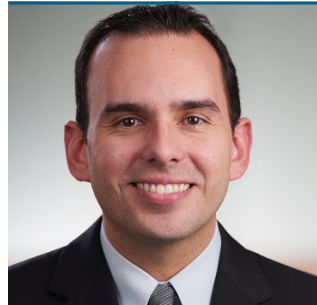
Jennifer Bright, MPA
Innovation and Value Initiative



Vakaramoko Diaby, PhD, MSc,
CRA
Otsuka Pharmaceutical
Companies



Nelly Ganesan, MPH
JPMorgan Chase & Co. – Morgan
Health



Juan Marcos González
Sepúlveda, PhD
Duke University



Annie Kennedy
EveryLife Foundation for Rare
Diseases



Stacey Kowal, MSc
Genentech



Yasmeen Long, MS
FasterCures



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Eberchukwu Onukwugha, PhD,
MS
University of Maryland



Kistein Monkhouse, MPA
Patient Orator



Ilisa Halpern Paul, MPP
Venable LLP



Mary Reed, DrPH
Kaiser Permanente Northern
California Division of Research



Jason Spangler, MD, MPH,
FACPM
Innovation and Value Initiative



Daniel Touchette, PharmD
University of Illinois Chicago



Ashley Valentine, MRes
Sick Cells

GLOSSARY

This glossary emerged from the IVI projects on which the 4th Annual IVI Methods Summit was based.

Term	Definition
Affordability	An assessment of a person's ability and willingness to pay. It is an interaction of spending, income, and judgments about the value of something relative to its price. ¹
Comparative Effectiveness Research (CER)	The generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy-makers to make informed decisions that will improve health care at both the individual and population levels. ²
Cost-Effectiveness Analysis (CEA)	A method to examine both the costs and health outcomes of one or more interventions. It compares an intervention to another intervention (or the status quo) by estimating how much it costs to gain an additional unit of some health outcome, such as a life-year gained or a case prevented.
Co-Insurance	The percentage of costs of a covered health care service you pay (20%, for example) after you've paid your deductible. ³
Co-Payment or Co-Pay	A fixed amount (\$20, for example) you pay for a covered health care service after you've paid your deductible. ⁴
Cost-Sharing	The share of costs covered by your insurance that you pay out of your own pocket. This term generally includes deductibles, co-insurance, and co-payments, or similar charges, but it doesn't include premiums, balance billing amounts for non-network providers, or the cost of non-covered services. Cost-sharing in Medicaid and CHIP also includes premiums. ⁵
Deductible	The amount you pay for covered health care services before your insurance plan starts to pay. With a \$2,000 deductible, for example, you pay the first \$2,000 of covered services yourself. ⁶
Economic Burden	In medicine, a term used to describe problems a patient has related to the cost of medical care. Not having health insurance or having a lot of costs for medical care not covered by health insurance can cause financial problems and may lead to debt and bankruptcy. Economic burden can also affect a patient's quality of life and access to medical care. For example, a patient may not take a prescription medication or may avoid going to the doctor to save money. Cancer patients are more likely to have economic burden than people without cancer. Also called economic hardship, financial burden, financial distress, financial hardship, financial stress, and financial toxicity. ⁷
Financial Burden	Healthcare financial burden is defined as the proportion of total out-of-pocket medical expenditures divided by total income for each family. ⁸
Health Economic Modeling	A set of analytic approaches in health economic analysis that synthesize clinical, epidemiological, and economic evidence from different data sources into an evaluation framework that will enable researchers or decision-makers to generate estimates for specific outcomes of interest. Models are usually a simplified representation of the real world to inform decision-making by characterizing uncertainty in projecting outcomes. ⁹
Health Technology Assessment (HTA)	A multi-disciplinary process that uses explicit methods to determine the value of a health technology at different points in its life cycle. A health technology is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of lives for individuals affected. ¹⁰

1 University States of Care (2018). University of Pennsylvania LDI of Economics. https://ldi.upenn.edu/wp-content/uploads/archive/pdf/Penn%20LDI%20and%20USofC%20Affordability%20Issue%20Brief_Final.pdf

2 Sox HC. Defining comparative effectiveness research: the importance of getting it right. *Med Care*. 2010 Jun;48(6 Suppl):S7-8. doi: 10.1097.MLR.0b013e3181da3709. PMID: 2073202.

3 <https://www.healthcare.gov/glossary/co-insurance/>

4 <https://www.healthcare.gov/glossary/co-payment/>

5 <https://www.healthcare.gov/glossary/cost-sharing/>

6 <https://www.healthcare.gov/glossary/deductible/>

7 National Institute for Health, National Cancer Institute.

8 Kielb ES, Rhyan CN, Lee JA. Comparing Healthcare Financial Burden With an Alternative Measure of Unaffordability. *Inquiry*. 2017 Jan 1;54:46958017732960. doi: 10.1177/0046958017732960. PMID: 28975850; PMCID: PMC5798734.

9 Glossary – Health Economics [online]. (2016). York; York Health Economics Consortium; 2016. <https://yhec.co.uk/glossary/>

10 O'Rourke, Brian, Wija Oortwijn, and Tara Schuller. "Announcing the New Definition of Health Technology Assessment." *Value in Health* 23.6 (2020): 824-825.

Term	Definition
Patient-Centered Value Assessment	Value assessment that reflects the diversity of patient preferences and circumstances, includes patients as equal partners throughout the development process, incorporates methods to address health equity, and reflects real-world patient and caregiver experiences.
Patient-Centered Outcomes	Any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else. ¹¹
Patient-Centered Core Impact Set	A "patient-derived and patient-prioritized list of impacts a disease and/or its treatments have on a patient (and/or their family and caregivers). Intentionally broad and inclusive, the term 'impacts' includes short-term and long-term health outcomes and any other related implications (e.g., career/family stresses, economic burden, career loss)." ¹²
Patient Engagement	"The active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process, where research decision-making is guided by patients' contributions as partners, recognizing their specific experiences, values, an expertise." ¹³
Patient Inputs	A wide range of information and perspectives from patients including, but not limited to, informal comments; patient opinions expressed publicly, including social media; patient responses to qualitative surveys; and quantitative measurements of patient-reported outcomes.
Patient Perspective	A specific type of patient input describing patients' experiences with a disease or condition and its management.
Patient Preference	Qualitative or quantitative assessment of the relative desirability or acceptability to patients of specified alternatives or choices among outcomes or other attributes that differ among alternative health interventions. ¹⁴
Premium	The amount you pay for your health insurance every month. In addition to your premium, you usually must pay other costs for your healthcare, including a deductible, co-payments, and co-insurance. If you have an ACA Marketplace health plan, you may be able to lower your costs with a premium tax credit. ¹⁵
Real-World Data (RWD)	Real-world data are the data relating to patient health status and/or the delivery of healthcare routinely collected from a variety of sources. RWD can include: <ul style="list-style-type: none"> • Electronic health records (EHRs) • Claims and billing activities • Product and disease registries • Patient-generated data including in-home-use settings • Data gathered from other sources that can inform on health status, such as mobile devices.¹⁶
Real-World Evidence (RWE)	Real-world evidence is the clinical evidence regarding the usage and potential benefits of risks of a medical product derived from analysis of RWD. RWE can be generated by different study designs or analyses, including but not limited to randomized trials, including large simple trials, and observational studies (prospective and/or retrospective). ¹⁷
Social Determinants (or Drivers) of Health	Social determinants (or drivers) of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. ¹⁸
Value Element	Refers to specific aspects or components that stakeholders may consider to be part of an overall assessment of value (e.g., different mode of administration, reduced risk, lower cost).
Value Assessment (VA)	Comparison of the relative benefits of the costs of a given technology or service for a specific person or population.

11 National Quality Forum

12 Perfetto, E.M., Oehrlein, E.M., Love, T.R. et al. Patient-Centered Core Impact Sets: What They Are and Why We Need Them. *Patient* (2022). <https://doi.org/10.1007/s40271-022-00583-x>

13 <https://www.sciencedirect.com/science/article/pii/S1098301520301418>

14 ISPOR-FDA Summit 2020: Using Patient-Preference Information in Medical Device Regulatory Decisions: Benefit-Risk and Beyond [internet]. Available from: <https://www.ispor.org/conferences-education/conferences/past-conferences/ispor-fda-summit-2020>

15 <https://healthcare.gov/glossary/premium/>

16 <https://fda.gov/science-research/science-and-research-special-topics/real-world-evidence>

17 <https://fda.gov/science-research/science-and-research-special-topics/real-world-evidence>

18 Healthy People 2030, U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. <https://health.gov/healthypeople/objectives-and-data/social-determinants-health>



WHAT IS IT THAT THIS
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NEEDS?

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