



IVI Methods Summit: Defining Needs and Progress Toward Improving Methods in Value Assessment

Convening Proceedings Report
April 2020

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Introduction and Background

The national discussion on value in health care is an important dialogue for all participants and players in the health care system: patients and families, clinicians, payers, employers, and researchers. The limitations of current value assessment methods have been raised and explored in an emerging body of literature, both from the scientific research communityⁱ and from the patient advocacy community.ⁱⁱ These point to a need to not only identify and prioritize the development of new methods, but also to include a wider group of stakeholders to invest resources and expertise in improving value assessment and its application to decision-making.

To that end, IVI received a Patient-Centered Outcomes Research Institute® (PCORI) Eugene Washington Engagement Award (EAIN #00101-IVIF) to convene a multi-stakeholder forum in Washington, D.C. in February 2020 to explore unmet needs and gaps in value assessment methods development and identify the ways in which these deficiencies can be addressed so that value assessment is more meaningful and useful to all stakeholders, particularly patients.

Rationale for Improving Value Assessment Methods

New technologies and clinical innovations in health care offer real opportunities to transform how we treat and care for patients, but the ongoing rise in health care costs has led to many initiatives seeking to prioritize the highest “value” care. While there is no question that our health care system *ought* to provide health care that imparts value to the patient and health care system overall, the question of *how* remains the subject of vigorous debate. Determining value in health care is exceedingly complex.

There are different perspectives on the value of a given intervention dependent on who is making the judgment, the specific decision contexts where “value” is being applied, and the potential approaches to estimating value itself. Ultimately, value assessment must be flexible enough to accommodate these diverse demands while also being both scientifically credible and relevant to a broad array of users of such assessments, including patients, health care providers, and payers. To date, however, stakeholders have been unable to come to consensus on the priority factors that are most relevant to the value “equation” and identify the methods that will most improve the ability to evaluate and compare interventions. The lack of shared priorities has resulted in siloed action, fragmented research, and missed opportunities.

IVI convened a day-long summit on February 27, 2020 in Washington, D.C., “IVI Methods Summit: Defining Needs and Progress Toward Improving Methods in Value Assessment” to garner stakeholder input into a prioritized action agenda that can guide value assessment research and investment by IVI and other partners. The summit brought together leaders from patient health organizations, health systems, employer coalitions, and recognized experts in the field of health economics and outcomes research and health care value assessment.

IVI articulated to invitees the core assumptions that informed the Summit. First, current value assessment methods are insufficient to evaluate and inform other dimensions of decision-making (beyond cost), including appropriateness for patient sub-groups or impact on quality of life. Next, improving methods in value

assessment has the potential to ensure both scientific credibility of such analyses, and relevance to real-world decisions confronting both payers and patients and their clinicians and caregivers. Finally, developing consensus on what and how methods can be improved in value assessment will lead to greater investment in testing new approaches and collaboration among researchers, health systems, payers, industry partners and patients to improve value assessment methods in the U.S.

This report contains proceedings and recommendations from this summit, which are intended to inform a bold agenda for research and methods improvement that is supported by stakeholders and drives collaborative efforts to address gaps in current methods and evidence.

Building Consensus on Research Priorities: Planning for the Convening

IVI engaged in some key activities to prepare and plan for the Methods Summit, beginning in October 2019, including the convening of an Advisory Committee, literature review, development of advance materials

to prepare attendees, and a pre-meeting survey to assess initial perspectives on value assessment. These activities ensured a productive and informed dialogue for the convening.

Advisory Committee

In the planning phase of the project, IVI identified key stakeholders to take part in an Advisory Committee with 17 external members as well as IVI team members that informed the plans for the Summit (see list in Appendix A). The Advisory Committee met on three occasions and collaborated with IVI throughout the project. Engagement of the Advisory Committee helped to ensure that the Summit attendees were a diverse group of experts and stakeholders across the health care system providing their respective views on current gaps in measuring value in health care and the opportunities to develop new methods or build new collaborations to deliver insights for key decision contexts.

Pre-Meeting Materials and Survey

IVI team members prepared a report that was shared with convening attendees that offered a brief summary of literature on the state of value assessment in health care (see Appendix B). The report was intended

Convening Objectives



Identify methods-improvement needs by examining current barriers and gaps, and by reviewing established and emerging methods for improving value assessment.



Identify areas for research investment and collaborative solutions to address needs for methods improvement in value assessment.



Prioritize the research agenda for improving value assessment methods, especially to capture patient outcomes, patient preferences, and learning/evidence gained from comparative effectiveness research.



to support dialogue from a common starting point across a diverse group of attendees and to pose key discussion questions to help attendees prepare for the meeting. The report offered a brief bibliography with articles that offered relevant insight on the current state of value assessment and included a glossary of key terms.

In addition, IVI developed and distributed a brief online pre-meeting survey to attendees designed to assess current perspectives of value assessment held by attendees and begin to identify areas of convergence and divergence in priorities (see survey tool in Appendix C). The pre-meeting survey included five questions and asked attendees to identify top priorities to address from a curated list of gaps in value assessment methods and practice in the next 1-3 years, as well

as the feasibility of developing solutions to address them. The survey also asked participants to identify top barriers to value assessment methods improvement.

The survey responses highlighted priorities of summit attendees for methods improvement, including the need for methods that incorporate patient preferences that have an impact on treatment outcomes, better methods for engaging patients in value assessment research, and accounting for heterogeneity in treatment outcomes. Importantly, the first two were also identified as the more feasible actions to take. The survey response also underscored the importance of the summit as lack of consensus and lack of collaboration were cited as key barriers to progress in improving value assessment methods research. The findings from the survey are summarized in the next section.

A key purpose of these preparatory activities was to provide context and a common understanding for the purpose of the convening and to offer a launching point to focus dialogue on setting priorities for research on methods and removing barriers to action on a consensus research agenda.

Summit Program: Defining Needs and Progress Toward Improving Methods in Value Assessment

The Summit was organized into a morning and an afternoon session, each centered on a framing question. The morning session focused on the question, “What can we most immediately affect by developing and applying new methods and new data in value assessment?” The afternoon session focused on the question, “How can we affect such change?” See Appendix D for the convening agenda. See Appendix E for the list of attendees.

Parameters for the Discussion

IVI designed the convening agenda to engage attendees in a robust dialogue to define immediate priorities for improving value assessment methods (within 1-3 years) and to explore how such actions can occur to achieve progress. In order to guide an inclusive and productive dialogue, IVI and the Summit facilitator identified several meeting parameters:

- Focus on pragmatic, positive, and solution-oriented comments;
- Emphasis on near-term opportunities for change and recommendations that are achievable in the 1- to 3-year time frame;
- Commitment to keeping comments and dialogue during the Summit unattributed (“Chatham House Rules”) to allow open dialogue and exploration of critical issues; and
- Remain germane to the Summit objectives, by avoiding debate about the wider definition of “value” or the merits or attributes of any one method or proposed solution.



Review of Pre-Meeting Survey

IVI's Executive Director, Jennifer Bright, offered a high-level overview of the pre-meeting survey responses. The survey received responses from 57% of attendees, representing all attendee stakeholder segments.

The survey asked respondents to rate the *priority* and then the *feasibility* of focal areas for improving value assessment methods and measures, based on a pre-determined, literature-informed list developed by IVI. The survey also asked respondents to rate the extent to which issues served as barriers to progress in improving value assessment

Responses signaled areas of consensus, including:

- **Methods to improve patient perspectives in value assessment are needed.** "Methods to incorporate patient preferences that inform treatment outcomes" received the highest rating for priority and second highest rating for feasibility with respondents indicating this was "Very Important" (69%)/"Important" (31%) and 96% of respondents reporting this as "Definitely or Possibly Feasible."
- **Common view of barriers indicated the need for consensus building.** The survey responses identified the top barriers to methods improvement research including, "Lack of agreement on the methods that should be tested and developed," inadequate "Collaboration among

researchers, health systems, industry partners and patients" and "Lack of consensus across stakeholders that methods improvement is a priority."

Subsequent discussion explored the scope of the term value assessment "methods" and ultimately clarified that the dialogue was intended to focus on solutions that address both process-oriented methods — such as approaches to engaging patients in value assessment research projects and improving access to relevant data — as well as technical, analytical methods, including how to quantify patient preferences, or using decision analysis tools to incorporate multiple factors in analysis.

Panel Discussions

The Summit featured two speaker panels: the first on perspectives from different vantage points across health care on our current understanding of value and how it is measured to achieve the aim of patient-centered care, and the second panel aimed at how we can work collaboratively to address barriers and change the methods and practice of value assessment in the U.S. Each panel discussion was followed by a full group facilitated discussion to further enumerate the issues and answer the questions posed during the panel conversations.

Panel: Methods Matter



Eleanor Perfetto

Moderator

Executive Vice President of
Strategic Initiatives
National Health Council



Lou Garrison

Panelist

Professor Emeritus
School of Pharmacy
University of Washington



Leah Howard

Panelist

Chief Operating Officer
National Psoriasis Foundation



Murray Ross

Panelist

Vice President
Kaiser Foundation Health Plan

PANEL DISCUSSION

Methods Matter: Can We Make Immediate Impact to Improve Credibility and Relevance of Value Assessment?

This opening panel framed the purpose of the meeting, offering perspectives from stakeholders on the question, “What needs to be changed to make immediate impact to improve credibility and relevance of value assessment?”

Panelists referenced the growing body of literature that explores methods for value assessment in health care, including recommendations published by the International Society of Professionals in Outcomes Research (ISPOR) in 2018 for advancement of value assessment methods, including a graphical representation of key domains, dubbed the “value flower.” This work offers a solid framework for guiding value assessment methodology and research, especially regarding factors of value not yet well-represented or incorporated into value assessment as well as novel elements that may help us identify future benefit.

Panelists cautioned while there may be a need for research on advancing some aspects of value assessment methodology, we should not have an aim of creating new valuation science for everything we want to measure. The methods exist now, but what is lacking is practical application in a range of decision contexts. Moreover, better understanding of which methods yield important insights and for which decision context is needed.

Value assessment should focus on the end result that matters most, namely “what is the desired patient outcome?” Panelists shared perspectives that we need to understand from a patient’s perspective what the desired patient outcomes are and then explore how to apply that information to better inform care. Panelists also shared that even when value assessment findings are aligned, problems with access to care may persist. This may be in part due to how value assessment is currently conducted and applied in a de-centralized process.

Finally, an important aspect of the panel’s discussion was illustrating a cascade of decision contexts within which value assessment takes place to guide the method selection and inputs required. Each circumstance may require different value assessment methods and inputs. The types of decision contexts and the methods/inputs referenced included:

- Regulatory decision: benefit/risk, clinical efficacy;
- Insurance benefit design and coverage: health technology assessments;
- Utilization management: clinical pathways, clinical guidelines, patient preference and outcomes; and
- Clinician-patient shared decision-making: subgroup and treatment heterogeneity insight.

Key takeaways from the first panel discussion are detailed in Figure 1. Following the panel presentation, vigorous dialogue with the full group revealed several common themes, such as the need to include relevant patient preferences and quality of life factors in value assessment, the need to expand the discussion of comparative value beyond medications, and the need to better incorporate real-world data sources and to evaluate diverse patient populations.

Figure 1. Panel 1: Discussion Key Points

- » Dialogue about improving value assessment is an important tactic to manage the complexity of defining value and prioritizing which factors are most important to understanding value from multiple perspectives.
- » Value assessment is a very siloed activity that is labor intensive to provide input, particularly for patient participants.
- » The importance of augmenting methods in value assessment is influenced by decision context (e.g., regulatory, coverage, clinical). Practical application of value assessment methods in different contexts is lacking.
- » Active research is needed to understand which novel elements of value and which scientific methods are additive to the evaluation of value, in each contextual situation.
- » Value assessment ideally should inform decision making (in whatever context) that improves patient outcomes.

Rapid-Cycle Consensus Building

Working in small groups, attendees were asked to reflect on the discussion from the first panel and answer a series of questions as a group. The purpose of the activity was to offer all attendees an opportunity to provide input on priorities for addressing gaps or challenges in value assessment, exploring how value assessment methods impact stakeholders, and discuss how to focus near-term investments in methods research. Through discussion, the groups were tasked with identifying key opportunities for methods development, and consider solutions that accelerate

change and overcome barriers. Scribes were assigned to each group to record notes. After the discussions were closed, each group was asked to share the top priorities for improving value assessment that were identified. The six small groups together identified a master list of 24 key opportunities for improving value assessment.

In order to clarify areas of consensus and refine the overall priorities, attendees voted by ballot for five (out of the 24) key opportunities in rank order (Figure 2). A “top five” list of items emerged and provided focus for the afternoon discussion on how to take action.

Figure 2. Key Opportunities for Improving Value Assessment

- | | |
|--|--|
| 01 New nomenclature or re-defined terms, especially for describing patient “preferences” | 13 Recognize there is flexibility in data collection in and around clinical trials |
| 02 Data and assessment methods that have face validity | 14 Improve disease specific frames now |
| 03 Better sources of data and better system for collecting data on patient reported outcomes (e.g., patient preference for independence over survival time)¹ | 15 Long-term develop trans-diagnostic approaches (or general principles for this) |
| 04 Real world data that includes patient heterogeneity and incentives to drive use² | 16 Holistic view of clinical pathways or course of care |
| 05 Better integration of value assessment in value-based insurance design³ | 17 Consensus on a single measure across disease states |
| 06 Uniform measures for patient-reported outcomes | 18 Focusing value assessment components first on the intervention and the value it brings |
| 07 More inclusive/holistic assessment of cost and outcomes | 19 Ensure the full range of things that are valuable are captured |
| 08 Value assessment is static – need more longitudinal and dynamic | 20 Understand how resources are being spent on care that is of low value |
| 09 Starting approach from patient perspective not the payer perspective | 21 Identifying what is valuable and what is not valuable and realigning policy to incentivize high value care⁵ |
| 10 Post-approval, longitudinal data collection of real-world data⁴ | 22 Contextualize value assessment results |
| 11 Assess bias in real-world evidence and risks in using it in decision contexts | 23 Improve methods to better define interventions and related contextual factors |
| 12 Capture failure in or to treatment in value assessment | 24 Capturing value assessment of offerings outside of health plan benefit |

Note: Items in bold indicate top five priority methods domains for action with number indicating rank order.

In reflecting on these priorities defined by the overall group, some key reflections shared by IVI included that the critical gaps lie perhaps more prominently in the data (or access to the data) versus solely in the methods for conducting value assessment. This theme emerged in pre-convening survey comments; however, it was interesting to observe how much this was underscored in the small group dialogue. The other main reflection was that the priority for improving value assessment methods must also be guided by the intended use and decision context, with the understanding that value assessment must be meaningful for and representative of patients.

PANEL DISCUSSION

Moving from Discussion to Deliverables: How do we get from here to there?

The second panel (see Page 11) was asked to consider the dialogue of the first part of the day that focused on *what* needs to change and consider what resources and commitments will be needed to accelerate efforts to modernize value assessment methods. This offered a focus on *how* to make this change happen.

Panelists were asked to share their perspectives on what barriers may impede progress on the priorities identified through the consensus process. Panelists agreed that a culture shift in the value conversation is needed. All stakeholders must embrace a willingness to test new methods and to widely share information about impact on value assessment results. Building a learning ecosystem is a must to support health plans and health systems as they move towards value-based care arrangements.

A shift in focus is also required to make patient insight, preferences, and priorities essential inputs from the beginning through to the end of the value assessment process. This requires investment in infrastructure, expertise and capability for payers, employers and industry to be able to assess real-world value elements, make a firm commitment to ongoing research and find the best practices through a continuous learning process.

Panelists also acknowledged that while there are many elements and factors of value that have been

identified through research, testing them in practice is a necessary next step to understand whether they deliver insights in different decision contexts and help inform decisions that are subject to the various incentives and interests of all actors within the health care ecosystem.

The discussion also highlighted the importance of considering how to build into value assessments the factors of social determinants of health impacting patients and non-pharmacological interventions as treatment options. As health plans seek to extend the reach of health care to address transportation, housing, and access to other support services to improve patient outcomes, for example, methods that can measure and determine the value of these interventions against other treatments will be a necessity. Figure 3 provides a summary of the key discussion points.

During group discussion, the need for a wider commitment to knowledge-sharing and the openness of data emerged as strong factors in achieving value assessment that is both scientifically credible and meaningfully relevant. Success factors that emerged from the discussion included greater investment in “adventurous” research, wider inclusion, and collaborative efforts among clinicians and patients, working with payers, employers (purchasers), and researchers to define and test which factors and measures are important.

Figure 3. Panel 2: Discussion Key Points

- » All stakeholders need to support a learning ecosystem in health care to translate theory into action.
- » Significant investment and changes are needed to make patient insights, preferences and priorities necessary inputs from the beginning to the end of the value assessment process.
- » Defining priority disease areas where focused research and testing regarding data elements, collection methods, analytical methods and viability of use by clinicians, employers and payers could accelerate learning by all.
- » All theories and research findings are irrelevant if stakeholders do not understand what or how to put value assessment into practice. This emphasizes a need to evaluate and communicate what insights derived from value assessment matter and in which decision contexts (e.g., payment, coverage, care delivery).

What Actions Will Make a Difference?

Participants subsequently discussed questions that focused on defining catalyst actions to accelerate change in value assessment methods in the near term.

Important highlights emerging from the dialogue included:

- Value is complex. Defining the inputs that will inform the value equation, that capture the multidimensional aspects of value, particularly from the patient perspective, will lead to higher levels of confidence in the results.
- It is vital to define and prioritize what to measure. Work is needed to understand the most important factors that represent value for patients and for regulators, payers, employers and clinicians in varying decision contexts.
- The methods exist; the critical problem is the data. Greater capability for data sharing and data mining will lead to better insights and inputs. Involving patients in defining data points that are relevant to the outcomes they seek will improve evidence generation.
- Rapid-cycle research through pilot testing and collaborative projects will help translate theory into practice.
- Implementation science will be needed to support deployment of value assessment into practice.

One step towards progress in moving from theory to practical application may be to collectively identify common metrics. Value is a multi-dimensional concept and may require multiple measures. It may be possible to test whether a set of outcome measures has some common application in practice and how they impact value, and whether they truly resonate for patients. But, it is important to note that measurement has to be pragmatic. Outcome measures can't require clinician to administer a 20-minute assessment; that won't work in practice. There may be opportunities to create a priority cluster of diseases for such translational research on data collection, testing methods and viability of measuring value within different decision contexts.

This dialogue, as well as previous discussions with the Advisory Committee, underscored the fact that the definition we are seeking for "value" has multiple dimensions. IVI acknowledges the complexity and did not seek to debate or define value through the convening, nor determine whose definition is right or best. Rather the Summit provided an opportunity to explore the many dimensions of value from the unique context of various decision makers – payer, clinician, patient, and researchers' perspectives – recognizing that while they may differ, each are equally relevant and there are opportunities to adapt value assessment practice so that it meets a variety of needs and informs decision making in various contexts.

Panel: Moving from Discussion to Deliverables



Ilisa Paul

Moderator

President

District Policy Group
Faegre-Drinker



Eric Stanek

Panelist

Principal Scientist
HealthCore, Inc.



Donna Cryer

Panelist

President and CEO
Global Liver Institute



Richard Wilke

Panelist

Chief Science Officer
ISPOR



Eboni Price-Haywood

Panelist

Director
Center for Outcomes & Health
Services Research
Ochsner Health

Recommendations

The priorities identified during the Summit serve as a call to action for both the health economics community and decision stakeholders to acknowledge the current gaps in value assessment and identify scientifically valid, emerging avenues to measure value. To ensure a patient-centered and value-focused system – from research to bedside – all stakeholders in the value conversation must contribute input to and make commitments towards a prioritized research agenda. For IVI, the next actions are to take the priorities identified during the convening and integrate them into a robust research and action agenda. Moreover, IVI views the identified priorities as a benchmark for measuring progress that can foster mutual commitment and collaboration to improving value assessment methods. Building from the top five priorities identified by attendees and discussion from the day, IVI has identified the following five domains of action (Figure 4).

Improving Data Inputs for Value Assessment

Participants universally acknowledge a lack of credible and widely accessible data inputs to answer important questions related to the value of treatment interventions. Improving methods to define patient factors and inputs, and better connect patient-reported outcomes and real-world data sources, represents an important, shared priority.

Engaging and Including Patients is a Universal Starting Place

Methods for consistent patient engagement throughout the life-cycle of value assessment – from evidence generation to comparative clinical and cost-effectiveness assessment – are being refined in real time by patient organizations, researchers, and health systems. Greater effort to disseminate shared learning and to define best practices will improve both the inputs and the factors used to answer the question “value for whom?”

Figure 4. Five Domains of Action



Improving Methods for Applying Value Assessment to Decision-Making

Value assessment has potential impact beyond considerations of price, including potential insights for value-based insurance design, as well as clinical pathway development and dissemination. Efforts to create a learning system regarding application to decision-making could improve engagement across stakeholder sectors and improve the consistency and relevance of such approaches.

Improving Understanding of Total Cost of Care Factors

Methods that help all stakeholders consider factors like comparative value across treatments (drug and non-drug), the cost and impact of an intervention on caregivers, the cost and impact on workplace productivity, and emerging concepts like social determinants of health were identified as important to ensure the relevance of value assessment, particularly to employer-purchasers and health systems.

Evaluating Novel Methods: What Works Best, In What Decision Contexts

Building on ISPOR Task Force 2018 recommendations, greater investment and collaborative research is needed to evaluate methodological approaches that improve the relevance of metrics. More emphasis on shared learning in methods will aid in validation and application into value assessment processes.

Conclusion

In reflecting on the priorities identified during the convening, IVI offered several concluding reflections that inform future actions. First, a key takeaway from the dialogue was that the gaps perhaps lie less with technical methods than in the data (or access to data). While this was well understood among the stakeholders prior to the convening, the level to which this was underscored in the large and small group discussions reinforced thinking that this is a primary area for collaborative effort and acceleration.

Another clear theme underpinning the dialogue was the need to ensure that improving methods in value assessment correlates to the specific purpose. For example, value assessment must be meaningful for patients. This will differ based on the unique decision contexts and populations involved; value assessment processes, methods and tools must be flexible to accommodate these differences.

Including patients and clinicians alongside payers (including employers) in this discussion was critical to show the complexity of the environment within which value assessment is being applied. Payers and clinicians are actively working to build and implement value-based care arrangements that deliver on improved population health outcomes, enhanced patient experience of care, while operating at a reduced total cost of care. Value assessment methods exist that can deliver insights necessary to inform insurance design, but they must be tested in the near term in practice using real-world inputs. Collaboration across health system partners will be required to build this infrastructure for this continuous learning health system.

ⁱ Garrison, L., Pauly, M., Willke, R., and Neumann, P. An Overview of Value, Perspective, and Decision Context--A Health Economics Approach: An ISPOR Special Task Force Report [2]. *Value in Health*. 2018; 21(2):124-131. Available: [https://www.valueinhealthjournal.com/article/S1098-3015\(17\)33891-3/fulltext](https://www.valueinhealthjournal.com/article/S1098-3015(17)33891-3/fulltext)

ⁱⁱ Perfetto EM, Harris J, Mullins CD, dosReis S. Emerging Good Practices for Transforming Value Assessment: Patients' Voices, Patients' Values. *Value in Health*. 2018; 21(4):386-393. Available: <https://www.sciencedirect.com/science/article/pii/S1098301518301931>

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Appendices

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Appendix A: Advisory Committee Roster

Sector	Representatives	Organization
Patient	Eleanor Perfetto	National Health Council
Patient	Sara van Geertruyden	Partnership to Improve Patient Care
Patient	Leslie Ritter	National MS Society
Patient; Research	Sue Peschin	Alliance for Aging Research
Patient; Research	Amy Miller	Society for Women's Health Research
Clinician/Health Plan	Murray Ross	Kaiser Permanente
Clinician/ Value Framework	Robert Carlson	National Comprehensive Cancer Network
Research/HEOR/Methods	Charles Phelps	University of Rochester
Research/HEOR/Methods	Richard Wilke	ISPOR
Research/HEOR/Methods	Sean Tunis	Rubix Health LLC (former CMTP)
Research/HEOR/Methods	Peter Neumann	Tufts, CEVR
Research/HEOR/Methods	Lou Garrison	University of Washington, CHOICE
Research/HEOR/Methods	Jeroen Jansen	Precision HEOR; IVI
Industry	Greg Daniel	Edwards Lifesciences
Industry	Newell McElwee	Boehringer Ingelheim
Patient; Research	Daryl Pritchard	Personalized Medicine Coalition
At Large		
Sponsor	Andrew Hu	Patient-Centered Outcomes Research Institute®
Facilitator	Ilisa Halpern Paul	District Policy Group at Faegre Drinker
IVI	Jennifer Bright	Innovation and Value Initiative
IVI	Erica deFur Malik	Innovation and Value Initiative
IVI	Melanie Ridley	Innovation and Value Initiative
IVI	Mark Linthicum	Innovation and Value Initiative

Appendix B: Convening Pre-Read Briefing

Overview

The national discussion on value in health care is an important dialogue for all participants and players in the health care system: patients and families, clinicians, payers, employers, and researchers. The limitations of current value assessment methods have been raised and explored in an emerging body of literature both from the scientific research community (illustrated in Garrison et al, 2018) and from the patient advocacy community (as described in Perfetto et al, 2018).¹ These point to a need to not only identify and prioritize the development of new methods, but also to bring in different stakeholders to help invest time and resources to improve the process.

To that end, IVI received a Patient-Centered Outcomes Research Institute® (PCORI) Eugene Washington Engagement Award (EAIN #00101-IVIF) to convene a multi-stakeholder forum in Washington, D.C. in February 2020 to explore the current limitations in value assessment, the unmet needs and gaps in value assessment methods development, and identify the ways in which these deficiencies can be addressed so that value assessment in the future is more meaningful and useful to all stakeholders, particularly patients.

Proceedings and recommendations from this engagement are intended to inform a bold agenda for research and methods improvement that is supported by stakeholders and drives collaborative efforts to address gaps in current methods and evidence.

Rationale for Improving Value Assessment

New technologies and clinical innovations in health care offer real opportunities to transform how we treat and care for patients, but the ongoing rise in health care costs has led to many initiatives seeking to prioritize the highest “value” care. While there is no question that our health care system ought to provide health care that imparts value to the patient and health care system overall, the question of how remains the subject of vigorous debate. Determining value in health care is exceedingly complex.

There are different perspectives on the value of a given intervention dependent on who is making the judgment (e.g. patient vs. insurer vs. society), the specific decision contexts where “value” is being applied, and the potential approaches to estimating value itself. Ultimately, value assessment must be flexible enough to accommodate these diverse demands while also being both scientifically credible and relevant to both patients and payers. To date, however, stakeholders have been unable to come to consensus on the priority factors that are most relevant to the value “equation” and identify the methods that will most improve the ability to evaluate and compare interventions. The lack of shared priorities has resulted in siloed action, fragmented research, and missed opportunities.

If the usefulness of value assessment is to improve significantly, the data and the methods of analysis must improve. Some of the primary opportunities to advance and enhance the current value construct include:

- Developing new methods or practices for systematic engagement with patient communities to define value in specific contexts.
- Refining strategies for accommodating individual patient-level data and analyses that utilize the wealth of patient-level data that exists within “big data.”
- Accounting for patient heterogeneity more generally—including impacts of patient characteristics, previous therapies, and comorbidities on treatment effects (see Basu 2019).

¹ Links to all referenced articles are available in the Reference section of this document.

- Including non-clinical outcomes such as caregiver burden or loss of income at the patient level in assessments of value.
- Accounting for patient preferences—both for attributes of a given therapy such as mode of administration, as well as attitudes toward risk (encompassed in the “value of hope” (Lakdawalla et al, 2012) or insurance value (Lakdawalla et al, 2017), for example).
- Account for broader societal costs/benefits such as risk of contagion, disease prevalence, and scientific spillovers (Lakdawalla et al, 2018).
- Developing complementary approaches to decision analysis, such as MCDA (Phelps and Madhavan, 2017).
- Augmenting the cost-per-quality adjusted-life-year (QALY) analysis, which may be discriminatory towards those with lower quality of life, to incorporate patient factors and additional novel elements of value.
- Developing new partnerships for data-sharing that deliver insights into heterogeneous treatment effects and challenges in quantifying non-clinical end points for factors of value for patients and caregivers.

Questions to Consider and Prepare You for the Summit

IVI’s principal goal for the Summit is to identify areas of consensus about methods improvement in value assessment and to enumerate and advance a research and practice agenda to address those needs. The contribution of all stakeholders during this convening is critical to build consensus and define both immediate and long-term priorities that propel research, value assessment model design, and initiatives to interpret and use value assessment to ensure high-quality, optimized treatment for patients and affordable health care for patients and payers. Participant contributions will also help identify targets that all stakeholders can use to evaluate progress in methods development.

In preparation for this important dialogue and priority-setting session, please consider the following key questions:

1. What methods need to be explored, refined, or validated in the next 1-3 years to ensure improvement in **patient-representativeness** in value assessment, and the relevance of value assessment to patient decisions?
2. What other methodological approaches need to be refined to improve the **scientific validity** of value assessment?
3. What investments and commitments are needed to accelerate methods development in value assessment? From whom? What are your/your organization’s commitments to improving methods?

Key Things to Know (or Remember) for the Summit Discussion

Many of the Summit participants are experienced in value assessment methods, while others may be less familiar. We offer the following summary information as background for those who are newer to the topic and as important framing concepts for all participants.

- There is not yet consensus on what fully constitutes value in health care, including (a) the factors that inform value, (b) effective methods to measure those factors, and (c) valid and usable sources of data (the inputs) that help all stakeholders discern comparative value in terms of outcomes, quality of life, and affordability.
- Value is a concept that encompasses multiple dimensions, including (but not limited to) cost, quality, outcomes and impact on patient and family experience of one or co-occurring health conditions.
- While value assessment should be flexible and designed for the specific decision-contexts and purpose of the end-user, status quo methods more traditionally hew to the following definition: *The assessment of a target population’s health outcomes (inclusive of harms) generated by a given health care intervention relative to the costs associated with the intervention.*
- Formal value assessment systematically synthesizes relevant information on benefits, costs, and risks in order to support efficient decision-making, delivering the most value for the resources spent. Yet, it is

challenging to offer a more specific definition without encountering disagreement at every step—how to conduct the assessment, what is meant by effectiveness, what inputs should go into any analysis, what tools should be used, and even how results should be interpreted and applied to decision-making.

- Current methods used in value assessment in the U.S. generally evaluate clinical outcomes and cost considerations of interest to payer stakeholders, but are often deemed inadequate to evaluate and inform other dimensions of value assessment, such as patient heterogeneity and impact on quality of life.
- At this time, patient value is commonly included in value assessments as qualitative information alongside quantitative estimates, and there is little agreement on what factors are most important to include, or on how to capture and measure patient perspectives. Patient data sources are increasingly available, but have not been utilized effectively for value assessment to date.
- In 2016, The International Society for Pharmacoeconomics and Outcomes Research (ISPOR)–The Professional Society for Health Economics and Outcomes Research–formed a special task force of recognized experts in the field of health economics to review approaches and methods to support the definition and use of high-quality U.S. value frameworks. The group developed a series of reports published in 2018, detailing conclusions and recommendations.² This work set in motion vigorous discussion of methods and areas for improvement in value assessment and sets the stage for this Summit.
- The ISPOR Special Task Force emphasized the importance of perspective (e.g., patient, insurer, policymaker, etc.) and decision context (e.g., formulary decisions, pathway design, etc.) in determining the best approach to value assessment.
- The Special Task Force also recommended that cost-effectiveness analysis based on the analysis of cost-per-QALY be the starting point for quantitative value assessment, but also recognized the limitations of this approach and called for the development and testing of a broader form of analysis via either “augmented cost-effectiveness analysis” or “multi-criteria decision analysis (MCDA)” that can better reflect societal considerations (such as fear of contagion) and patient attitudes toward risk.
- While value assessment in the U.S. is not where it needs to be, promising new methodological approaches are emerging. A recent paper (Lakdawalla and Phelps, 2019), for example, proposed a relatively straightforward approach to incorporate attitudes toward risk (e.g., of negative health outcomes or financial impact) directly into estimates of cost-effectiveness (something currently absent).
- The potential impacts of improved methods for value assessment are ensuring both scientific credibility of such analyses, as well as increasing their relevance to real-world decisions confronting both payers and patients and their clinicians and caregivers.

Conclusion

This information is intended to facilitate a common “starting point” for the Summit discussions. We welcome your questions in advance of the Summit; please direct your questions to Mark Linthicum at mark.linthicum@thevalueinitiative.org. We look forward to collaborating with you to explore priority opportunities to improve value assessment methods that are meaningful for patients, families, clinicians, employers, and payers.

² Several chapters of the ISPOR Special Task Force Report are referenced in this document. The full report is open access and available at [https://www.valueinhealthjournal.com/issue/S1098-3015\(17\)X0012-0](https://www.valueinhealthjournal.com/issue/S1098-3015(17)X0012-0).

Glossary

Acronym	Term	Definition
CEA	Cost-Effectiveness Analysis	Form of economic analysis that compares the relative costs and outcomes (effects) of different courses of action. In healthcare, this often takes the form of comparison of programs or interventions to a single comparator (generally the standard of care) in terms of incremental change in health benefits versus incremental changes in cost. CEA contains the basic elements needed to calculate a net monetary benefit of a new intervention versus the standard of care for the target population of interest.
CER	Comparative Effectiveness Research	Studies that compare the benefits and harms of two or more treatments, clinical strategies, or other approaches to health care.
HEOR	Health Economics and Outcomes Research	A term that includes both outcomes research studies encompassing real-world evidence of treatment patterns among patients, health outcomes, resource utilization, and economic evaluation of the costs associated with treatment. Multiple disciplines contribute to this type of research, including clinical research, clinical outcomes assessment, epidemiology, health economics, policy research, and health services research.
HTA	Health Technology Assessment	A method of evidence synthesis that considers clinical effectiveness, safety, cost-effectiveness, and other factors of the use of health technologies in comparison with a current standard. One use of health technology assessments is in informing reimbursement and coverage decisions by insurers.
QALY	Quality Adjusted Life-Year	The fraction of a perfectly healthy life-year that remains after accounting for the damaging effects of an illness or condition.
MCDA	Multi-Criteria Decision Analysis	A framework for supporting complex decision-making with multiple and often conflicting criteria that stakeholder groups and/or decision-makers value differently. Through the use of MCDA, priorities and preferences of patients, insured individuals, and experts can be integrated systematically and transparently into the decision-making process.
NMA	Network Meta-Analysis	Allows for comparisons of more than two interventions in a single, coherent analysis of all the relevant randomized controlled trial data available. This type of analysis can produce estimates of the relative effects of all interventions compared with every other in a single analysis using both direct and indirect evidence. This results in the ability to rank all the interventions in a coherent way.
NMB	Net Monetary Benefit	A calculation of the benefit of an intervention (expressed in monetary terms) net of all costs. It represents the value of an intervention in monetary terms when a threshold for the willingness to pay for a unit of benefit (such as a measure of health outcome) from the intervention is known.
PCOR	Patient Centered Outcomes Research	One type of comparative effectiveness research that is focused on outcomes that are important to patients.
PROs	Patient Reported Outcomes	A health outcome directly reported by the patient who experienced it. This is in contrast from clinical or other outcomes reported by physicians, nurses, or other individuals.

Acronym	Term	Definition
RCT	Randomized Controlled Clinical Trials	A randomized controlled trial is considered the “gold standard” for determining the efficacy of a given treatment. NIH definition includes: one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
RWD	Real World Data	Data relating to patient health states and/or delivery of health care routinely collected from a variety of sources. Sources of data may include: electronic health records, claims and billing data, product and disease registries, and data gathered through personal devices and health applications.
RWE	Real World Evidence	The analysis of real-world data in an observational study and/or pragmatic clinical trial.

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Appendix C: Pre-Meeting Survey Tool

Survey Questions for Summit Participants

Dear Colleague:

We are excited to see you soon at the upcoming Methods Summit, at which we will explore progress in value assessment methods development and identify priorities where testing and application of advanced methods can have greatest impact on the usefulness of value assessment for patients, clinicians, payers/purchasers, and health systems. Following the Summit, IVI intends to develop a white paper summarizing key meeting discussion points and conclusions, and incorporate such considerations into its research agenda and its support for novel research by collaborating partners.

To help ensure we make the most of our time together, we ask that you take 3-5 minutes to respond to this brief four-question survey, which will be used to inform our discussion.

In responding to the survey, and for our discussion at the Summit, please keep in mind the following core assumptions:

- Value is a concept that encompasses multiple dimensions, including (but not limited to) cost, quality, outcomes and impact on patient and family experience of one or co-occurring health conditions.
- Current methods used in value assessment in the U.S. generally evaluate cost considerations of interest to payer stakeholders, but are often deemed inadequate to evaluate and inform other dimensions, such as appropriateness for patient subgroups and impact on quality of life.
- Greater investment is needed in new methods to measure quality of life to inform value assessment in the U.S.
- Great collaboration among researchers, health systems, payers, industry partners and patients is needed to improve value assessment methods in the U.S.
- The potential impact of improved methods for value assessment is ensuring both scientific credibility of such analyses, as well as increasing its relevance to real-world decisions confronting both payers and patients and their clinicians and caregivers.

Thank you in advance for responding to these brief questions. We appreciate your time and input.

1. While we recognize that individuals may identify with different stakeholder categories (e.g., researcher and practicing clinician), please choose the primary stakeholder group that you will be representing at the Methods Summit.

☐ Patient or Family Member

☐ Regulator/Government

☐ Research

☐ Clinician

☐ Value Assessor/Value Framework Developer

☐ Industry

☐ Payer Purchaser

☐ Other (please specify)

2. To advance value assessment over the next 1-3 years, please indicate how important it is to address each of the following methods gaps.

	Very Important	Important	Slightly Important	Unimportant
Methods for patient partnership in value assessment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methods that augment measurement of quality of life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methods that address how to incorporate patient preferences that inform outcomes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methods to understand how to incorporate real-world data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Novel elements of value such as insurance value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Novel elements of value such as impact on productivity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Novel elements of value such as impact on caregivers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Accounting for heterogeneity in treatment outcomes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Accounting for patient heterogeneity (sub groups characteristics)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Facilitating the use of value assessments for different decision contexts (e.g., contracting, benefit design, clinical pathways)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methods for data aggregation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methods for decision analysis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. Please indicate how feasible it will be to develop at least one tractable solution to each of the following methods issues over the next 1-3 years.

	Definitely Feasible	Possibly Feasible	Possibly Unfeasible	Definitely Unfeasible
Methods for patient partnership in value assessment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methods that augment measurement of quality of life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methods that address how to incorporate patient preferences that inform outcomes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methods to understand how to incorporate real-world data	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Novel elements of value such as insurance value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Novel elements of value such as impact on productivity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Novel elements of value such as impact on caregivers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Accounting for heterogeneity in treatment outcomes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Accounting for patient heterogeneity (sub groups characteristics)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Facilitating the use of value assessments for different decision contexts (e.g., contracting, benefit design, clinical pathways)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methods for data aggregation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methods for decision analysis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please specify)	<input type="text"/>			

4. From your perspective, choose the top three barriers to methods improvement research.

- ☐ Lack of consensus across stakeholders that methods improvement is a priority
- ☐ Data transparency
- ☐ Data accessibility
- ☐ Lack of transparency in model design
- ☐ Lack of agreement on the methods that should be tested and developed

- ☐ Financial resources
- ☐ Human resources/expertise
- ☐ Protection of intellectual property
- ☐ Collaboration among researchers, health systems, industry partners and patients
- ☐ Other (please specify)

5. What else do you think is a priority for discussion during the Summit?

Appendix D: IVI Methods Summit Agenda

Defining Needs and Progress Toward Improving Methods in Value Assessment

February 27, 2020

Kaiser Permanente Center for Total Health
700 2nd Street, NE
Washington, D.C. 20002

Objections:

- Identify methods-improvement needs by examining current barriers and gaps, and by reviewing established and emerging methods for improving value assessment
- Identify areas for research investment and collaborative solutions to address needs for methods improvement in value assessment
- Prioritize research agenda for improving value assessment methods, especially to capture patient outcomes, patient preferences, and learning/evidence gained from comparative effectiveness research

Central Questions:

What can we most immediately affect by developing and applying new methods and new data in value assessment? How can we advance such change?

8:30 a.m.	Registration and Breakfast
9:00 a.m.	Welcome and Introductions <ul style="list-style-type: none"> • Jennifer Bright, Executive Director, Innovation and Value Initiative • Kristin Carman, Director of Public and Patient Engagement, PCORI® • Facilitator: Ilisa Paul, President, District Policy Group / Faegre Drinker Biddle & Reath
9:15 a.m.	Mission Impossible? Finding a Common Starting Place <ul style="list-style-type: none"> • Jennifer Bright, Executive Director, Innovation and Value Initiative • Ilisa Paul, President, District Policy Group/FDBR
9:30 a.m.	Panel Discussion Methods Matter: Where Can We Make Immediate Impact to Improve Credibility and Relevance of Value Assessment? <ul style="list-style-type: none"> • Moderator: Eleanor Perfetto, Executive Vice President of Strategic Initiatives, National Health Council • Murray Ross, Vice President, Kaiser Foundation Health Plan and Director, Institute for Health Policy • Lou Garrison, Professor Emeritus, Comparative Health Outcomes, Policy, and Economics (CHOICE) Institute, School of Pharmacy, University of Washington • Leah Howard, Chief Operating Officer, National Psoriasis Foundation
10:00 a.m.	Question and Answer
10:30 a.m.	Break

10:45 a.m.	Rapid-Cycle Consensus Building <i>Working in small groups, participants will identify most immediate priorities in methods, data access, and usability of value assessment.</i>
11:00 a.m.	Light-Bulb Moments <i>Participants will discuss their unique takeaways from group discussion about priorities and opportunities to improve methods in value assessment.</i>
11:45 a.m.	Value Assessment Caucus
12:00 p.m.	Networking Lunch
1:00 p.m.	Panel Discussion Practical Considerations: How Do We Change Our Methods? <ul style="list-style-type: none"> • Facilitator: Ilisa Paul, President, District Policy Group/FDBR • Eric Stanek, Principal Scientist, HealthCore, Inc. • Donna Cryer, President and CEO, Global Liver Institute; Interim Executive Director, PCORNet®, People Centered Research Foundation • Dick Willke, Chief Science Officer, ISPOR • Eboni Price-Haywood, Director, Center for Outcomes and Health Service Research, Ochsner Health System
1:30 p.m.	Question and Answer
1:45 p.m.	Group Dialogue: What Actions Will Make a Difference? <ul style="list-style-type: none"> • <i>What changes need to occur to facilitate progress?</i> • <i>What partnerships can get us started?</i> • <i>How do we build collaborations to make progress?</i> • <i>What actions are needed to catalyze these collaborations?</i>
2:30 p.m.	Break
2:45 p.m.	Group Dialogue: Envisioning Progress <ul style="list-style-type: none"> • <i>What priorities have emerged from this dialogue?</i> • <i>What are short-term opportunities to move forward?</i> • <i>Where is investment in long-term solutions needed?</i> • <i>What will tell us we're making progress?</i>
3:30 p.m.	Summary and Call to Action; Future Steps
4:00 p.m.	Acknowledgements, Evaluation and Adjourn

Appendix E: IVI Methods Summit Attendee List

First Name	Last Name	Company
Elise	Berliner	AHRQ
Jennifer	Bright	Innovation and Value Initiative
Bob	Carlson	National Comprehensive Cancer Network
Kristin	Carman	Patient Centered Outcomes Research Institute
Donna	Cryer	Global Liver Institute
Erica	deFur Malik	Innovation and Value Initiative
Bansri	Desai	National Health Council
Patricia	Deverka	Innovation and Value Initiative
Sarah	Emond	Institute for Clinical and Economic Review
Lou	Garrison	University of Washington, School of Pharmacy
Bernie	Good	UPMC Health Plan
Marianne	Hamilton-Lopez	Duke Margolis Center for Health Policy
Eric	Hoffman	Schmidt Public Affairs
Leah	Howard	National Psoriasis Foundation
Andrew	Hu	Patient-Centered Outcomes Research Institute®
Kyle	Hvidsten	Sanofi
Jeroen	Jansen	Innovation and Value Initiative, Precision HEOR
Barry	Liden	Edwards Lifesciences
Mark	Linthicum	Innovation and Value Initiative
Greg	Martin	Patient Centered Outcomes Research Institute
Newell	McElwee	Boehringer Ingelheim
Amy	Miller	Society for Women's Health Research
Peter	Neumann	Tufts Medical Center
Elizabeth	Oehrlein	National Health Council
Ilisa	Paul	District Policy Group at Faegre Drinker
Eleanor	Perfetto	National Health Council
Sue	Peschin	Alliance for Aging Research
Charles	Phelps	University of Rochester
Eboni	Price-Haywood	Ochsner Health System
Daryl	Pritchard	Personalized Medicine Coalition
Bruce	Pyenson	Milliman, Inc.
Margaret	Rehayem	National Alliance for Healthcare Purchaser Coalitions
Alejandro	Reti	OptumCare
Melanie	Ridley	Innovation and Value Initiative

First Name	Last Name	Company
Murray	Ross	Kaiser Foundation Health Plan
Lewis	Sandy	UnitedHealthcare
Alyssa	Schatz	National Comprehensive Cancer Network
Julia	Slejko	University of Maryland, School of Pharmacy
Jason	Spangler	Amgen
Eric	Stanek	HealthCore, Inc.
Sara	van Geertruyden	Partnership to Improve Patient Care
Gretchen	Wartman	National Minority Quality Forum
Neil	Weissman	MedStar Health
Kimberly	Westrich	National Pharmaceutical Council
Richard	Wilke	ISPOR
Wei-Shi (Danny)	Yeh	Genentech

About the Innovation and Value Initiative

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



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