

2022
METHODS
SUMMIT

PROCEEDINGS
REPORT

IVI  INNOVATION AND
VALUE INITIATIVE

Valuing Innovation

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Innovation and Value Initiative

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The Innovation and Value Initiative (IVI) is a 501(c)(3) nonprofit, research organization committed to advancing the science, practice, and use of patient-centered health technology assessment to support decisions that make healthcare more meaningful and equitable. IVI's Annual Methods Summit brings together health policy and research leaders, patient and caregiver leaders, and researchers to address critical changes in patient-centered health technology assessment.



Background & Introduction

Innovation in health technologies (both pharmaceutical and non-pharmaceutical) has been a major contributor to improved life expectancy and quality of life over the past decades. However, as biomedical and digital innovations accelerate healthcare across disease states, the methods and practices to measure and reward innovation in the context of health technology assessment (HTA) are not keeping pace, and there is growing pressure to demonstrate the “value” of new healthcare technologies. These discrepancies and challenges were highlighted at the [2022 ISPOR Annual Conference](#), where participants from different

stakeholder perspectives engaged in extensive discussions about the methodological approaches to valuing innovation that need further research. Discussions also focused on the importance of designing the appropriate public policies and market mechanisms to incentivize future innovation. Key frameworks for HTA have also acknowledged the need to consider a more comprehensive set of attributes to define and measure the innovative properties of novel health technologies. For example, [Memorial Sloan Kettering's Drug Abacus](#) now includes a parameter for “scientific novelty.” Improved methods and processes to better define, measure, and reward innovations are essential to ensure the long-term sustainability and efficiency of the innovation system and ultimately improve the well-being of those who will receive care.

To advance the dialogue on defining value of innovation and identify consensus action steps across stakeholders, IVI convened the [2022 3rd Annual Methods Summit – Valuing Innovation](#). This convening was held as part of the Valuing Innovation Project, established to engage stakeholders across different sectors to discuss the challenges and opportunities of innovation in the context of HTA. A broad audience participated in the dialogue which included patient, family and caregiver organizations, employer-purchaser and payer entities, researchers, value assessors and their supporting research entities, investors, policymakers, and representatives from innovators across the healthcare industry.

“*The Methods Summit is a platform to bring together perspectives from across the healthcare sectors and identify areas where we can work together.*”



METHODS SUMMIT FOCUS

The specific objectives of the 2022 Methods Summit were to:

- Define areas of consensus about the importance of healthcare innovation to stakeholders
- Assess the strengths and limitations of existing HTA methods to support decision-making by patients, clinicians, payers, and purchasers
- Highlight areas of consensus among practitioners of HTA on appropriate approaches and actions needed to support investment in innovation
- Identify priorities for research to improve the valuation of “innovativeness” of health technologies

Events

The IVI 2022 3rd Annual Methods Summit convened nearly 200 participants and thought leaders from across the healthcare ecosystem in facilitated panel discussions (see Appendix A for full list of speakers). The forum showcased multi-stakeholder perspectives on the “status-quo” of how innovations in health technologies are being considered in decision-making, and opportunities and challenges that innovations in biopharmaceutical, digital, diagnostic, and delivery arenas for the science and practice of HTA.

Opening Sessions Feature IVI and Tufts NEWDIGS Leadership

IVI’s leadership team (Jason Spangler, Chief Executive Officer, and Rick Chapman, Chief Science Officer) kicked off the forum with a brief overview of the agenda and objectives of the Summit. This was followed by opening remarks by Mark Trusheim, Strategic Director of NEWDIGS at Tufts Medical Center, offering perspectives on the challenges in accounting for and rewarding innovation in HTA.

Multi-Stakeholder Panels Highlight Importance, Status Quo, and Challenges and Opportunities

The forum proceeded with three facilitated panel discussions. The first two panels, consisting of patient, manufacturer, investor, clinician, purchaser, and payer participants, featured cross-stakeholder perspectives on the importance of considering innovations in HTA, definitions and measurements of innovation, and the key challenges in decision-making in a rapidly evolving innovation landscape. The third panel convened stakeholders who conduct and use research in valuing innovations to discuss existing and emerging methods, key research needs, and opportunities for investment and collaboration to better incorporate innovation considerations in HTA. The forum concluded with a panel discussion that offered summary and reactions to the preceding dialogues, with a focus on identifying challenges for further exploration and opportunities for cross-stakeholder collaboration.

Key Themes

Six key themes have emerged from the Summit on valuing innovation.

Theme 1: Definitions Matter

- Throughout the discussions, all stakeholders emphasized the importance of defining innovation more broadly, and considering both pharmaceutical and non-pharmaceutical technologies (e.g., devices, diagnostics, and digital health).
- Different stakeholders have different definitions of innovation, vary in their time horizon to evaluate innovations, and use correspondingly different metrics and data for measurement to determine a given innovation's "value."

"...from that perspective (employers who are not having their needs met in the marketplace), when we think about innovation, it is really around transparency, patient choice, and prescriber choice." (Employer)

"...for payers, we have a very short-term view, typically a 12-month process. We set the prices for our products, and we will have to live with that price...We want to look for innovative approaches that can include improved outcomes, but ideally lower the cost of care..." (Payer)

"...most of the drugs are approved with wonderful clinical outputs, so what we look for is how do these drugs benefit our members. So, we look at the effectiveness of those medications, and we track such outcomes...to see whether we are paying for value for our members." (Integrated Health System)

"...when we talk about the value of innovations, we have to put value in the context of what it means to patients. It is meaningless unless the patient places value on it." (Industry)

"Simply, innovation means new and improved." (Value Assessor)

When it comes to innovation, patients want to see a robust pipeline. Patients want to be able to afford new therapies.
(Patient)

Theme 2: Expanding Perspectives is Important to Balanced Analyses of Innovation

- Traditionally, the value of innovations is conceptualized and measured from a limited health system perspective. We need to go beyond the health gains for patients and take a broader societal perspective in defining and rewarding innovations to sustain dynamic efficiency in our R&D system. Some examples of these considerations include impacts on caregivers and family members, health equity, and implications of future innovations (e.g., scientific spillover).

"I should add that about 88% of family members report the same high levels of anxiety and depression as their family members diagnosed with psoriasis. It really is a shared family challenge." (Patient)

When we are valuing innovations, we are looking at it from a very broad lens in terms of equity and societal value to the federal government and taxpayers.
(Policymakers)

Theme 3: Patients and Caregivers Should be Co-Creators in Valuing Innovation

- Currently, patient input is collected and applied inconsistently in the R&D and HTA processes. Stakeholders need to come together to define how patient input should be collected and incorporated into these processes.
- In collecting and analyzing patient input, we need to recognize that patient voice is not singular. Therefore, it is important to ensure that clinical trials and real-world data collection efforts include the [full range of patient voices and experiences](#), and that lived experiences from all appropriate subgroups (e.g., by income level) should be considered and incorporated. Otherwise, we are at risk of perpetuating or even exacerbating disparities. It is also important to acknowledge that patient voices are changing over time.
- Participants highlighted the need for additional research on how to incorporate both qualitative and quantitative patient input into methods used to inform HTA.
- Stakeholders should also work to simplify the process for patients to share their data. Digital health applications offer a promising approach to enable patient data collection in real-time.

"We need to be able to measure the value of what patients care about most. That's the key of value assessment." (Patient)

"Can we quantitatively measure things that matter to patients?" (Research)

"Historically, we have brought in the patient perspective in very limited settings and made those a one-time conversation and checked the box. We really need to be engaging patient communities regularly in an ongoing way about value and innovation...so that as patient perspectives change over time, we are able to adjust our perspectives about what is valuable to patients." (Patient)

How do you propose to change someone's life if you don't understand it? (Investor)

Theme 4: Data as Our Hurdle and Our Key

- While we seem to have an abundance of data across different stakeholders in the health system, we still lack processes or mechanisms to derive relevant insights from the data sources to enable rapid decision-making in real-time. This is partly due to the lack of data transparency and sharing. Currently, disparate data sources are collected by individual stakeholders in the system, and many of these are considered proprietary information.
- To ensure that data collection efforts can efficiently address the evidence gaps in healthcare, stakeholders should coordinate their efforts and work together to define standards for data collection, work on common data models to ensure interoperability, and incentivize real-world data collection for public use.
- We also need to look beyond clinical trial data and make better use of real-world data. Data from randomized control trials (RCT) are used to establish clinical efficacy in a pre-launch setting and might not be representative of the heterogeneous patient experiences in the post-launch world. Amid the constant tension between certainty and variance, stakeholders should come together to establish a mechanism to prepare for pre- and post-market evidence generation.



“We do placebo-controlled clinical trials because we want to have a nice tight experiment that is testing one hypothesis...that is completely at odds with this idea of embracing the variance in the real world.” (Investor)

“The challenge though, is that when everyone’s using their own data, and they don’t want to make their data public and they don’t want to make their analytics public, then it’s really hard to have a balanced conversation. Just because one’s voice is the loudest doesn’t necessarily mean that it’s the right one.” (Policymaker)

“In terms of data-driven decision-making, we have tons of data now. What we don’t have are the insights of what we need.” (Industry)

Theme 5: Methods Research Needs Attention

- To better capture the innovative properties of health technologies in decision-making, stakeholders highlighted priority areas for additional research and data collection efforts.
- First and foremost, stakeholders should come together to develop a consensus framework on the definition and measurement of innovations across different health technologies. Such a framework should specifically consider the value elements (e.g., [scientific spillover](#)) from a broader societal perspective.
- Based on such a framework, methods used to estimate the potential costs and benefits of innovative technologies (e.g., health economic models) should be updated to reflect a wider range of value elements and to reflect market realities (e.g., genericization following loss of exclusivity).

- In addition to estimates of the value of innovation, measurements of individual willingness to pay for such benefits are equally important in decision-making (e.g., for coverage and reimbursement). Additional research is needed to estimate within- and cross-country willingness to pay to better incorporate considerations of innovations in health technology assessment.

“We probably never will fully agree on what the best algorithm is, and that there is one, and only one, algorithm to solve all this.” (Value Assessor)

“We should keep in mind that through the life course, patient values change. Different communities and different socioeconomic groups may place value on different things. And we have to make sure that any value assessment tool that we are using is paying attention to those variations and reflecting the roots in the methodology.” (Industry)

“I think health technology assessment is flawed, but I am glad someone is doing it.” (Research)

“I worry about the fact that we do not fully account for the fact that drugs are expensive today, but in a few years, they are ‘almost’ free.” (Research)

“The tools that we have at our disposal to judge the value of innovation are only as good as the evidence we have.” (Industry)

Theme 6: Health System and Misaligned Incentives Led to Distortions in Valuing Innovation

- Our current pricing system to reward innovations is subject to the fragmented nature of the U.S. healthcare system and misalignment of incentives across different stakeholders.

- The misaligned incentives have led to issues, including lack of development in critical areas with huge unmet needs (e.g., antimicrobial resistance) and pricing distortions (e.g., manufacturers increasing market prices to counter higher rebates required by PBMs). In contrast, COVID-19 is an example where stakeholders are aligned on their objectives for innovation and achieved great social good through innovations.
- In areas where market incentives are sufficient, government regulations and policies may be used to address such inefficiencies. However, in practice, the regulatory framework lags behind technological innovation, meaning its adoption might be limited or delayed.
- To address this challenge, understanding how investment decisions might vary by different reward mechanisms is important to ensure that the optimal mix of market structure and public policies can be put in place to incentivize innovations across disease areas with unmet needs, improve patient well-being, and encourage innovators to push the boundaries.
- Finally, it is just as important to not reward low-value innovations as to reward high-value ones. This is highlighted by the recent debates on “low-value care” and “me -too” drugs.

*“Nowadays, we price a product to the opportunity (of being covered) and not necessarily always to their value.”
(Payer)*

“When we think about policies, we really need to know the responsiveness of innovation to these incentives... We tried to reach a consensus among economists last summer, which turned out to be impossible.” (Research)

“We can talk about how to reward things that are innovative, but just as importantly, more important to be thinking about not rewarding things that are not as innovative. (Value Assessor)

*We have a lot of room to narrow our focus to the get the investments centered towards the things where there is societal need, and we can create value that will help more people.
(Policymaker)*

Acknowledgments

The Innovation and Value Initiative acknowledges the contributions of the co-chairs in the Valuing Innovation Project Initiative, Mr. Michael Graglia (SynGAP Research Fund) and Professor Joshua Krieger (Harvard Business School), and our facilitator, Ms. Ilisa Halpern Paul (Venable LLP), in the success of the IVI 2022 Methods Summit. IVI appreciates the support provided for the project by Pharmaceutical Research and Manufacturers of America (PhRMA).

Appendices

- A. List of Speakers
- B. Agenda

Appendix A
List of Speakers

2022 Methods Summit Speakers



Greg Baker

EmsanaRx



Jennifer Bright

Innovation and Value Initiative



Randy Burkholder

PhRMA



Jon Campbell

Institute for Clinical and Economic Review



Harold Carter

Express Scripts



Rick Chapman

Innovation and Value Initiative



Linette Demers

Digital Medicine Society



Lou Garrison

University of Washington



Jennifer Graff

Academy of Managed Care Pharmacy



Michael Graglia

SynGAP Research Fund



Joe Honcz

C4i



Leah McCormick Howard

National Psoriasis Foundation



Walter Kowtoniuk

Third Rock Ventures



Josh Krieger

Harvard Business School



Jen Madsen

MITRE



Michelle McMurry-Heath

Biotechnology Innovation Organization



Samuel Peasah
UPMC Health Plan



David Ridley
Duke University



Jason Spangler
Innovation and Value Initiative



Mark Trusheim
NEWDIGS, Tufts Medical Center



Tiffany Westrich-Roberstson
AiArthritis

Appendix B

Agenda

Agenda

Innovation in health technologies (both pharmaceutical and non-pharmaceutical) has been a major contributor to improved health and well-being. As biomedical and digital innovation accelerates however, the methods and practice to measure and reward innovation in the context of value assessment are not keeping pace. Recent scientific meetings and published papers reveal exploration and debate about methodological approaches that need further research, as well as the importance of ensuring that future innovation is incentivized. Value frameworks have also acknowledged the need to more appropriately identify and reward biomedical innovation.

IVI's 2022 3rd Annual Methods Summit, a one-day, virtual public forum, will emphasize the following learning objectives:

- Define areas of consensus about the importance of innovation to stakeholders.
- Assess the strengths and limitations of existing value assessment methods to support decision-making by patients, clinicians, payers, and purchasers.
- Highlight areas of consensus among practitioners of value assessment on appropriate approaches and needed actions to support investment in innovation.
- Identify priorities for research to improve the valuation of “innovativeness” of health technologies.

Time	Agenda Description	Presenters/Panelists
10:00 AM	Introduction and Objectives of the IVI Methods Summit and Valuing Innovation Project	Jason Spangler, IVI CEO Rick Chapman, IVI CSO
10:10 AM	Vision for Valuing Innovation The opening remarks will offer perspectives on the challenges in account for and rewarding innovation in value assessment/health technology assessment.	Moderator: Jason Spangler, IVI CEO Mark Trusheim, NEWDIGS, Tufts Medical Center
10:30 AM	Perspectives on the Value of Innovation, Part 1 Panelists from patient, innovator, and investor sectors will discuss their viewpoints on innovation and the purpose and guard-rails needed in value assessment to sustain balance.	Moderator: Mike Graglia, SynGAP Research Fund, IVI Innovation Co-Chair Panelists: Leah Howard, National Psoriasis Foundation (NPF) Michelle McMurry-Heath, BIO Linette Demers, DiME Society Walter Kowtoniuk, Third Rock Ventures
11:10 AM	Question and Answer Session	
11:20 AM	Break	

Time	Agenda Description	Presenters/Panelists
11:30 AM	<p>Perspectives on the Value of Innovation, Part 2</p> <p>Panelists from clinical, innovator, purchaser, and payer sectors will discuss their viewpoints on innovation and their questions and challenges in decision-making in a rapidly evolving market-place.</p>	<p>Moderator: Josh Krieger, Harvard Business School, IVI Innovation Co-Chair</p> <p>Panelists: Greg Baker, EmsanaRx Sam Peasah, UPMC Jen Madsen, MITRE Corporation Joe Honcz, C4i (formerly of Aetna)</p>
12:10 PM	Question and Answer Session	
12:20 PM	Meal Break	
12:50 PM	<p>How Can HTA Methods Align Our Perspectives on Innovation?</p> <p>This panel will feature a facilitated discussion with stakeholders who conduct and use research to emphasize areas of work in methods, including issues of rigor, novel methods, and fit-for-purpose in decision-making. Dialogue will consider existing and emerging approaches, research needs, and opportunities for investment and collaboration.</p>	<p>Moderator: Rick Chapman, IVI</p> <p>Panelists: Lou Garrison, University of Washington, CHOICE David Ridley, Duke University Jon Campbell, ICER Randy Burkholder, PhRMA</p>
1:30 PM	Question and Answer Session	
1:40 PM	<p>Finding Balance in Valuing Innovation</p> <p>A panel offers summary and reaction to the day's dialogues, identifies challenges for further exploration, and observes opportunities for action.</p>	<p>Moderator: Jennifer Bright, IVI</p> <p>Panelists: Tiffany Westrich-Robertson, AiArthritis Jennifer Graff, AMCP Harold Carter, Express Scripts</p>
2:00 PM	Next Steps and Adjourn	Jason Spangler , IVI

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 health technology 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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