

## A Framework for Capturing Economic Impacts on People Living with Serious Health Conditions\*

### IVI 4th Annual Methods Summit March 14 Consensus Meeting

#### Pre-Read

#### Background

Current approaches to patient-centered outcomes research, clinical and comparative effectiveness research, and value assessment typically do not assess factors that matter most to patients, families and caregivers related to costs and broader financial impacts of their health and healthcare. Historically, outcomes measures have focused on a narrow view of clinical outcomes, often ones that are more focused on health care processes and utilization, and less about impacts or outcomes prioritized by patients<sup>i,ii,iii</sup>.

PCORI's *Principles for the Consideration of the Full Range of Outcomes Data in PCORI-Funded Research*<sup>iv</sup> prioritize the need to address the gaps in evidence on what matters to patients by expanding the types of outcomes and impacts that are captured through research. Included in these principles is the importance of defining potential burdens and particularly economic impacts to patients and caregivers related to utilization of healthcare services. Understanding the potential impacts and burdens of patients and their caregivers is essential to informing the decisions that patients make in partnership with their caregivers and care teams, but also those made by payers, employers, and health systems. The continued lack of data on heterogeneous patient preferences, treatment experiences in the real world, health equity implications of health care access, and potential burdens associated with accessing care prevents meaningful progress toward truly patient-centered, value-based healthcare.

#### Using the Term "Patient"

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.

There is over \$195 billion of collective medical debt in the U.S., and 1 in 10 Americans owe more than \$250 in medical bills. Impacts on people with lower incomes and people of color are even more dramatic. The [Everylife Foundation of Rare Disease](#) recently reported that the economic burden of rare disease was nearly \$1 trillion in 2019 alone. Researchers often will use a few proxies to capture the economic impacts on patients and caregivers (e.g., co-payments, co-insurance, transportation, etc.), but a deeper approach is often elusive. A wide range of researchers, policymakers, patient advocates, and decisionmakers are looking for a better way to understand the full range of economic impacts on people living with serious health conditions.

Collecting and incorporating data on patient-centered outcomes, burdens, and economic impacts in clinical and comparative effectiveness research is a vital first step to building the inputs required for data-driven decision-making capabilities<sup>v</sup> that aim to improve health outcomes and reduce the cost of healthcare.

The [Innovation and Value Initiative](#) (IVI) and [AcademyHealth](#) have partnered to develop a framework for researchers, value assessors, and other decisionmakers to offer guidance on how to address the full range of economic impacts on patients and caregivers in research studies and decision-making.

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## **Sample First-Hand Perspective**

### **Understanding Economic Impacts on Patients and Caregivers**

Danielle was a young woman in her final year in college who was rushed in an ambulance to the emergency room with severe abdominal pain. She had visited the health center multiple times in the past two months but had been told it was just menstrual cramps. During the evaluation, the physicians identified a mass in her abdomen, and she was diagnosed with a rare form of uterine (endometrial) cancer. As a result, Danielle and her family experienced a series of significant economic impacts over the course of her treatment.

Initially, Danielle remained on her parents' health plan, but she had to take a leave of absence from school and her mother took significant time off from work to care for her. Ultimately, Danielle's mother lost her job due to extended absences. The entire family was forced to switch to another health insurance with more limited benefits and higher co-insurance. The specialist was over an hour away, and the trip required multiple tolls, parking, and babysitting for Danielle's younger brother for every visit. Even when she recovered from her cancer treatment, Danielle had to go to work full time to maintain health insurance and could only take part-time evening classes through the local university. Treatment for the cancer included a hysterectomy, which meant that she would not be able to have children and she had an increased risk of other forms of cancer. In addition to the physical and psychological suffering from the illness, the uncertainty about her health condition and the shifts in insurance coverage result in a cascade of unexpected costs and economic impacts.

Questions to consider:

- Given the ripple effect of Danielle's health crisis, how can the "pebble" and the resulting waves of impacts on her educational and career trajectory be considered in evaluation of her health experience?
- Danielle's mother loses her job and health insurance because of her daughter's health journey; in what ways should these impacts be considered and how?
- Survival rates for black women are much lower for uterine cancer. How do you account for this in considering the long-term economic impacts?
- In thinking about these economic impacts that Danielle experiences, what are the priority areas to consider? What additional information would a researcher need?

## **Project Overview**

IVI and AcademyHealth have engaged with over 30 stakeholders to develop a framework for researchers and decision-makers that offers a touchstone on capturing the range of economic impacts on patients and caregivers to consider, the underlying factors that influence and drive the economic impacts, and guidance on how to approach the framework.

IVI and AcademyHealth held nine key informant interviews and one roundtable discussion with individuals and organizations representing patient, caregiver, policy, employer, researcher, and payer perspectives. Over the course of the project, the multi-stakeholder Steering Committee has recommended resources and partners, refined the draft framework, and augmented feedback from the interviews and roundtable discussion. After each phase of the project, we revised the visual aid to reflect the discussions and recommendations from the experts.

The final project convening will bring together project participants to:

1. Review and confirm principles to guide the use of the framework;
2. Make recommendations on needed guidance to use the framework;
3. Identify potential uses of the framework by different stakeholder groups; and
4. Explore initial resources and other tools needed to apply the framework.

This preparatory document shows the current version of the visual aid which will inform the development of the final framework and supporting materials and outlines the proposed principles to guide framework use.

## Framework for Economic Impacts

This evolving framework offers an organizing guide for researchers and decision-makers to consider the economic impacts on patients and caregivers. Some considerations when reviewing the draft visual aid include:

- We have put the person (and/or caregiver) experiencing a health condition at the center and behind the visual representation to demonstrate how important these individuals and their families are to the framework.
- Where possible, we use person-centered language, but with the understanding that the framework is intended to inform researchers and decisionmakers focusing on patient-centered outcomes research (PCOR) and other healthcare research. When we use the term “patient or caregiver,” we are not intending to imply that a person is their disease and want to emphasize that he or she is a full person within the context of larger society.
- The framework attempts to provide organizing principles for the full range of economic impacts, but some of these concepts do not fit into neat categories, as they intersect and overlap across domains.
- With each identified input, we acknowledge the intersection of lived experience, social and environmental factors, and health needs of the person will drive the experience of that economic impact.

Figure 1 represents the overall factors for consideration for the framework. The first feature is that the person or caregiver with the health condition is both at the center and foundation of the framework. Second, the person’s health journey and the underlying lived experience (e.g., social determinants of health, health complexity, etc.) need to be considered to understand the economic impacts in a meaningful way. Finally, the economic impacts may change over time.

The framework is organized in six domains representing types of economic impacts: Direct medical costs, non-clinical healthcare costs, caregiver and family impacts, ability to work, job and education impacts, and social impacts.

Figure 1. Accounting for Economic Impacts on Patients and Caregivers

### Framing the Economic Impacts on People Experiencing Serious and/or Chronic Health Conditions

#### Underlying Factors Central to a Person’s Health Journey and Economic Impacts

- A. Lived Experience and Health Needs
- B. Changes in Health Status over Time
- C. Social Determinants of Health
- D. Health Complexity
- E. Life Stage
- F. Access to or Gaps in Care
- G. Changes in Economic Impacts Over Time
- H. Lived Experience and Health Needs



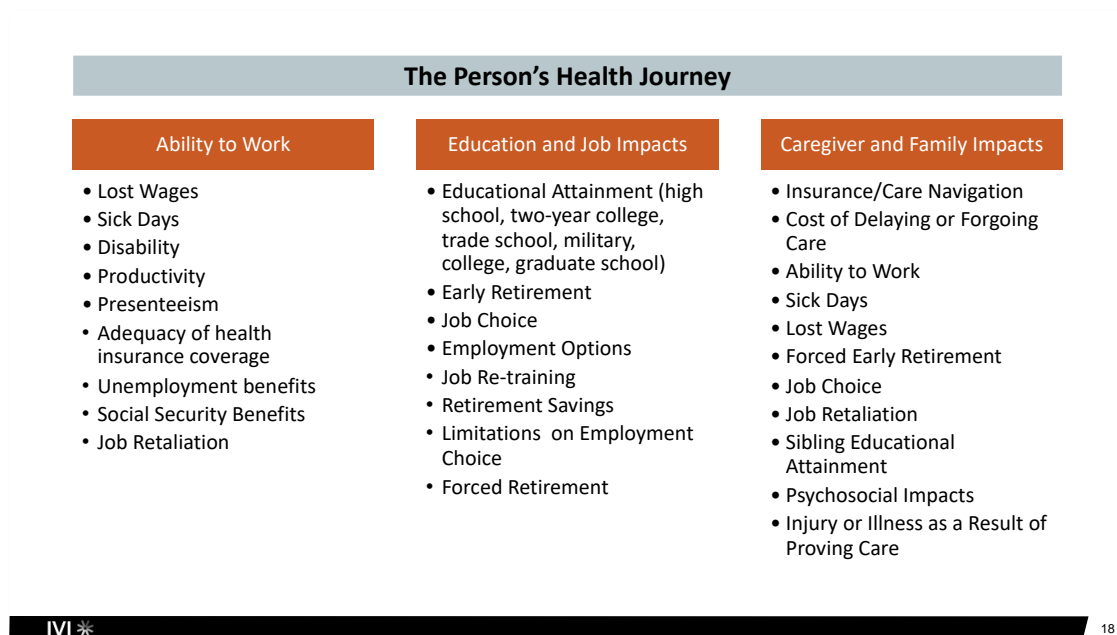
## Specific Impacts by Domain

As the domains represent complex and varied types of economic factors to be measured, stakeholders recommended clarifying examples within each domain. Figures 2 and 3 offer initial examples of what impacts fit into each domain. Stakeholder dialogue emphasized that these examples often overlap. This is consistent with real-world economic experiences by patients and families. As one roundtable participant noted: these might appear in different categories, but for the person and their family, “it all comes from one wallet.”

Figure 2 Specific Inputs by Domain (Direct Medical Costs, Non-Clinical Healthcare Costs, Social Impacts)



Figure 3 Specific Inputs by Domain (Ability to Work, Education and Job Impacts, Caregiver and Family Impacts)



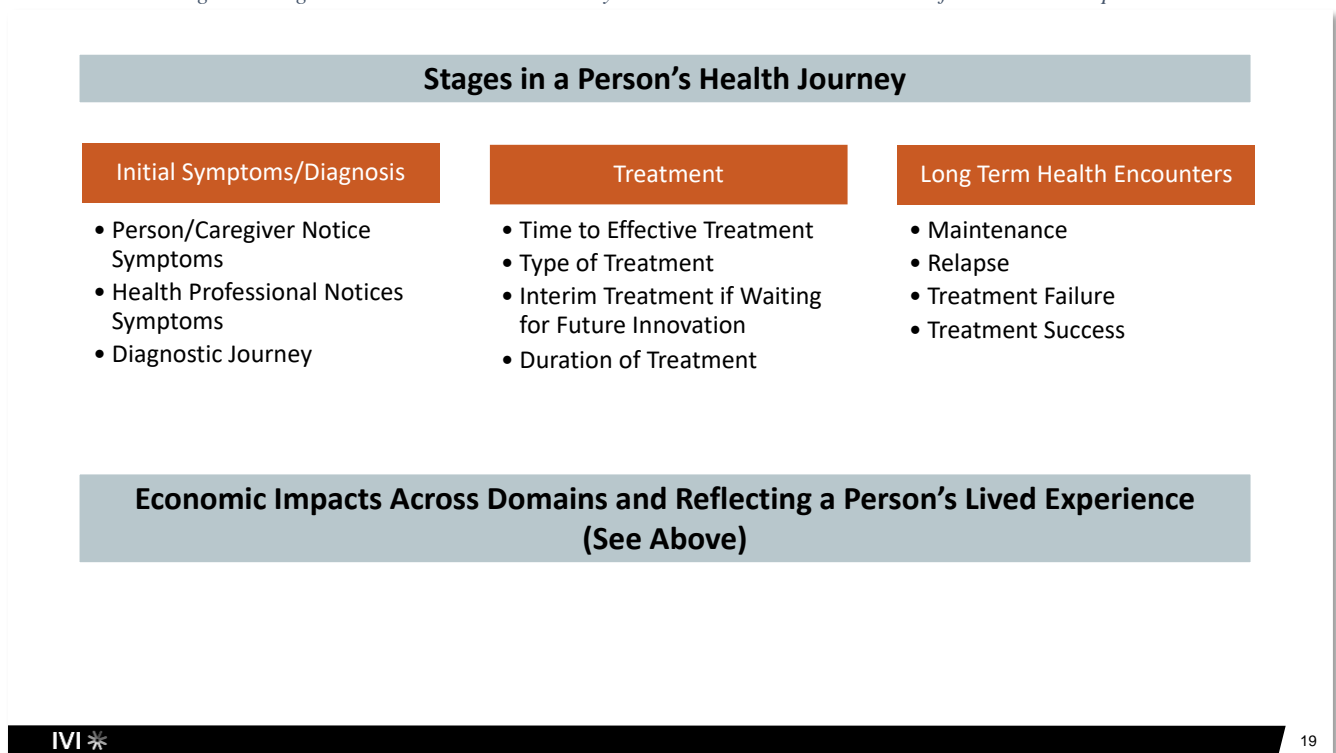
## Health Journey Map

Throughout the project, participants emphasized the importance of evaluating the full range of economic impacts in the context of health journey of a patient or caregiver in healthcare research. By starting with a person's story, researchers and decisionmakers can select the most relevant economic impacts and data sources at different timepoints of the journey.

As one key informant interview participant stated, "The impact is personal first. The impact on your non-medical and medical expenses is immediate because you have to figure out how to care for your family, how to keep the lights on, keep the gas on, and keep your job. You still have to dress and feed your children. When we're talking about the financial impact of cancer, people don't take this into account."

Figure 4 summarizes the key stages in health journey that researchers should consider in study design. Researchers and decisionmakers can select the most relevant economic impacts described in Figures 1-3 specific to each stage to fully capture the economic impacts along the health journey.

*Figure 4 Stages in a Person's Health Journey - Potential Moments to Consider for Economic Impacts*



## Principles to Guide Framework Use

Below are proposed principles to help guide researchers and decisionmakers in using the framework. Based on ongoing discussions and insights from the project participants, these principles reflect an effort to shift the approach and incentive structure to improve how researchers include and consider economic impacts.

- **Include patient and caregiver experts as partners throughout the research study.** Plan to invite one or more individuals with lived expertise to serve as advisors, partners, and/or co-authors on the project. These ongoing collaborations can help strengthen fidelity to patient preferences and impact of the project.
- **Begin with the whole person.** Before starting any research initiative, consider building a health journey map or survey that understands the whole person and his/her/their family and social circumstances. This approach can help improve the relevance of the research questions, increase the specificity of the project, and build ongoing partnerships with the patient community.
- **Acknowledge the complexity of the health journey.** Any research or project will not fully capture all relevant inputs, but it can incorporate those that patients identify as most important. A recognition of the complexity and limitations or gaps can build credibility.
- **Be intentional in considering issues of health equity and incorporate into all research plans.** As IVI wrote in its recent report, there is [no value without equity](#). Any study addressing economic impacts on patients and caregivers needs to consider methods and approaches to incorporate a health equity lens.
- **Account for patient factors such as social determinants of health, age, and racial/ethnic background.** When looking at economic impacts on people with lived experience, the research approach should account for patient demographic factors where possible.
- **Use the framework to guide which inputs to consider.** In partnership with patients, the framework can be used to identify the economic impacts most relevant to the research question.

## Next Steps – Questions to Consider

The final project convening will bring together project participants and other interested individuals to help ensure that the framework is both useful and relevant to PCOR/CER researchers and others in the healthcare research space. In preparing for this discussion, please consider the following questions:

### Review and Confirm Principles

- What principles are missing?
- Are there principles that can be combined?
- Which principles are most relevant to guide the use of the framework?

### Putting the Framework into Practice

- What additional guidance do researchers need to use the framework?
- What are potential uses of the framework, especially by different stakeholder groups?
- What additional resources and tools are needed to finalize and apply the framework?

In the coming months, IVI and AcademyHealth, along with contributors to the project, will release a final version of the framework and recommendations for implementation.

If you have questions about the framework or this project, please contact Erica deFur Malik at the Innovation and Value Initiative ([erica.malik@thevalueinitiative.org](mailto:erica.malik@thevalueinitiative.org)).

## Additional Resources:

Brown, D., Srinivasan, M., Zott, C., Wilson, K., Dullabh, P., and Smith, S. Medicare Data Linkages for Conducting Patient-Centered Outcomes Research on Economic Outcomes. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. September, 2022. Available: <https://aspe.hhs.gov/sites/default/files/documents/66b598da75b717c6b2181ffe63d5830d/medicare-linkages-white-paper.pdf>

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<sup>i</sup> "Directing Human Capabilities Toward Flourishing: A Measurement Framework For Health Services Research, " Health Affairs Blog, December 8, 2021. DOI: 10.1377/hblog20211203.194104

<sup>ii</sup> Tseng, E.K., Hicks, L.K. Value Based Care and Patient-Centered Care: Divergent or Complementary?. *Curr Hematol Malig Rep* **11**, 303–310 (2016). <https://doi.org/10.1007/s11899-016-0333-2>

<sup>iii</sup> Gandhi GY, Murad MH, Fujiyoshi A, Mullan RJ, Flynn DN, Elamin MB, Swiglo BA, Isley WL, Guyatt GH, Montori VM. Patient-important outcomes in registered diabetes trials. *JAMA*. 2008 Jun 4;299(21):2543-9. doi: 10.1001/jama.299.21.2543. PMID: 18523223.

<sup>iv</sup> Patient-Centered Outcomes Research Institute. *Principles for the Consideration of the Full Range of Outcomes Data*. Available: <https://www.pcori.org/sites/default/files/PCORI-Principles-for-Consideration-of-Full-Range-of-Outcomes-Data-in-PCORI-Funded-Research.pdf>.

<sup>v</sup> A Review of Current Approaches to Defining and Valuing Innovation in Health Technology Assessment. Hofmann, Sarah et al. *Value in Health*, Volume 24, Issue 12, 1773 – 1783. DOI:10.1016/j.jval.2021.06.006