

A Research Framework to Understand the Full Range of Economic Impacts on Patients and Caregivers

May 2023

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About IVI

The Innovation and Value Initiative (IVI) is a 501(c)(3) tax-exempt, non-profit research organization dedicated to advancing the science and improving the practice of health technology assessment through development of novel methods and creation and application of enhanced health technology assessment models to support local decision-making needs in healthcare.

About AcademyHealth

AcademyHealth, a 501(c)(3) non-profit organization, is a national professional organization serving the fields of health services and policy research and the professionals who produce and use this important work. Together with their members, they offer programs and services that support the development and use of rigorous, relevant, and timely evidence to increase the quality, accessibility, and value of healthcare, to promote equity, and to improve health.

Contents

Executive Summary	04
Background and Rationale	07
Framework Development	09
The Framework Principles	11
The Framework	12
Framework Applications	18
Next Steps	20
Appendix	22
Acknowledgments	23
Key Terms	25
Endnotes	27

Innovation and Value Initiative
917 Prince Street
Alexandria, VA 22314

www.thevalueinitiative.org

Executive Summary

When people encounter the healthcare system – either through a medical emergency, management of a chronic health condition, or through acute care, for a serious disease – they often experience significant economic impacts in addition to the physical and emotional impact of the disease(s). These economic impacts can range from medical costs not covered by insurance to other costs that result from medical debt, transportation, and accessing care – child or family respite care. These are rarely evaluated in research, even when using a patient-centered or societal perspective.

The **Innovation and Value Initiative (IVI)** and **AcademyHealth** partnered to develop consensus around a common Economic Impacts Framework (the Framework) that identifies the scope of economic impacts affecting patients and caregivers (see Figure 1). The Framework offers structure and an initial map to guide researchers, research funders, and other decision-makers to consider what economic impacts are important to include in research design. It also offers a reference point to evaluate the adequacy of research and evidence generation and can guide further consensus development about how to incorporate such data in comparative effectiveness, outcomes research, and health technology assessment.

We developed the Framework through an iterative process informed by the guidance and insights from over 20 hours of multi-stakeholder engagement activities. We are deeply grateful for the ongoing support and partnership from the participants in this initiative (see Appendix A). Three overarching themes emerged:

1. Put patients, caregivers, and families at the center of understanding economic impacts.

2. Include a wider set of impacts that reflect lived experience, access to care, and affordability to improve understanding of issues around health equity and economic impacts.
3. While complex and challenging, adapt approaches and methods to build a better understanding of how the full range of economic impacts shape health behaviors, care delivery, and outcomes.

Participants identified six main areas of economic impacts: direct medical costs, non-clinical healthcare costs, caregiver and family impacts, social impacts, ability to work, and education and job impacts.

The patient or caregiver is at the center of the Framework, and the patient's health journey is the foundation for understanding, prioritizing, and interpreting the economic impacts. The full report outlines the detailed inputs for each of the six areas, and provides guidance on how researchers, patients, payers, and others can use the framework.

This project is the first phase exploring needed change in defining, measuring, and applying a full range of patient-centered economic impacts in research and decision-making. Project participants recommend that researchers and decision-makers establish ongoing partnerships with patients and caregivers to provide context for the complexities of people’s lived experience and inform research priorities. Future priorities and collaboration opportunities that derive from this work include:

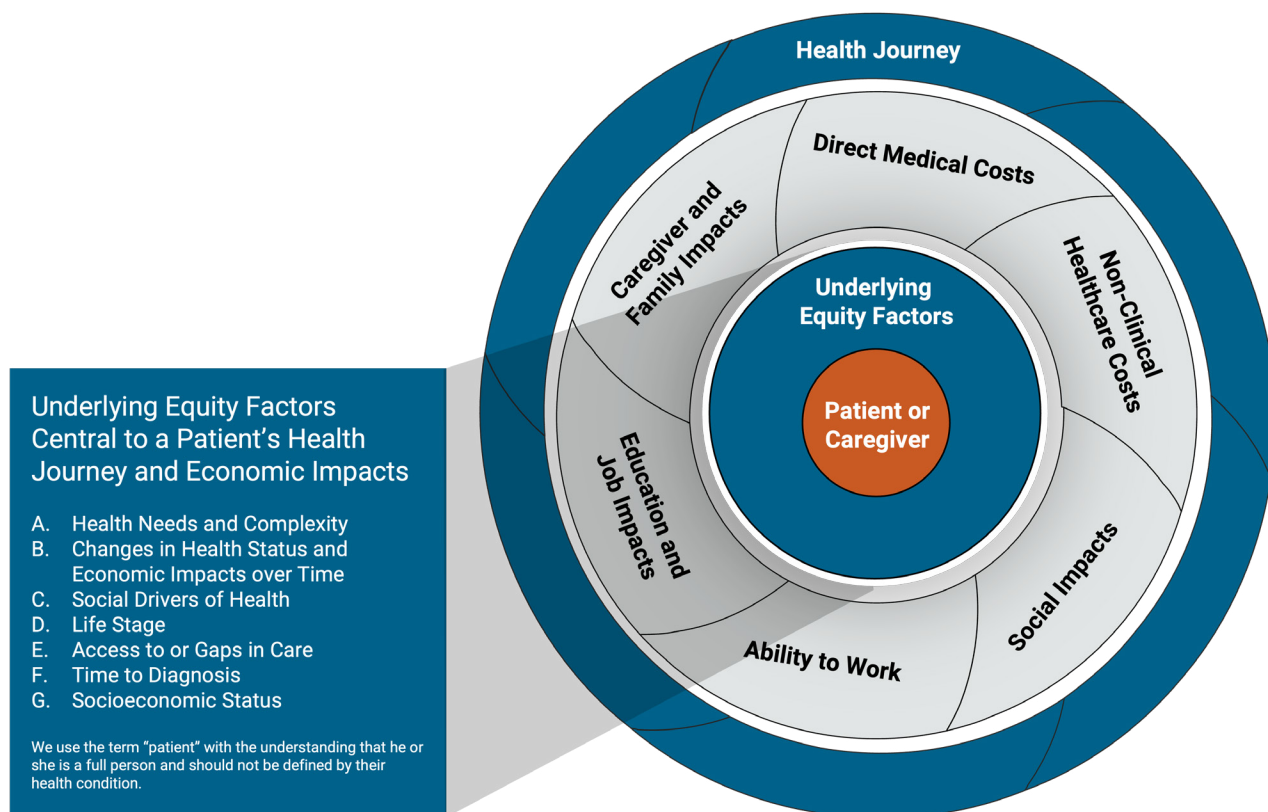
- Growing multi-stakeholder partnerships needed to expand data collection on a broader range of economic impacts,
- Driving culture change to orient researchers and decision-makers to patient-centered economic outcomes

that are outside of traditional measures,

- Collaborating to identify measures and data points that reflect economic outcomes that reflect the full range of economic impacts, and
- Engaging underserved and underrepresented communities as leaders to identify priorities and solutions.

This Framework and the Principles (see Page 6) that guide it are intended to encourage partnerships between the patient and caregiver community and researchers, and to broaden how we understand and measure the economic impacts on patients and caregivers. Please see the full report to review the detailed inputs for the Framework and potential applications.

Figure 1. An Interactive Framework to Understand Economic Impacts on Patients and Caregivers



FRAMEWORK PRINCIPLES

- **Invite patients, caregivers, and family members to serve as advisors, partners, and/or co-authors.** Connect with people representing the health areas of focus and people representing diverse perspectives.
- **Start with the whole person.** Patients and caregivers often feel dehumanized by the healthcare system. Authentic engagement should guide research question development, increase the specificity of research goals, and build ongoing partnerships with the patient community – especially from underrepresented groups.
- **Acknowledge the complexity of the health journey.** Any research study or project will not be able to fully capture all relevant economic impacts, but it can incorporate those that patients identify as most important. Consider using mixed methods research approaches to help fill these gaps.
- **Incorporate health equity throughout.** As IVI wrote in its recent report, there is “[no value without equity](#).” Design research goals or measurement strategies with a health equity lens. Incorporate an intentional health equity focus when planning the research, partnering with patients and caregivers, and identifying the research measures.
- **Clarify research goals.** Use patient and caregiver insights and the Framework to define research goals. Acknowledge the changing nature of the data and of the economic impacts over time.
- **Use the Framework and patient journeys to identify priorities.** In partnership with patients and caregivers, use the Framework to prioritize which economic impacts to include.

Background and Rationale

Healthcare research studies that include costs to patients and families, or incorporate patient-centered economic measures, often rely on the evaluation of direct medical costs defined by healthcare payers (e.g., co-pays, co-insurance, deductibles, claims). However, people with serious or chronic health conditions, and those who care for them, experience a much wider range of economic impacts because of their health and healthcare. These impacts might include the time to navigate the healthcare system, non-covered costs for home-based care or remedies, costs of transportation to receive care, their ability to work, caregiver impacts, or behavioral concerns that may affect their overall health and economic status.¹ In addition, severity of disease, socio-economic status, race, gender, caregiver responsibilities, and other underlying social factors exert powerful influence on how patientsⁱ and caregivers experience these economic impacts. Stakeholders across the health ecosystem acknowledge that while there is agreement that these are important considerations, they are rarely or inconsistently addressed in research studies -- and therefore in policy and decision-making.

The importance of economic impacts on patients and families is increasingly at the heart

ⁱ 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.

of national conversations about quality, equity, and affordability for Americans. 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.² Populations of color and low-income populations experience more severe health burden and poorer health outcomes. A larger portion of Black adults (16%) report having medical debt as compared to White adults (9%). Adults who are low-income report having medical debt at a higher rate (12%) than adults with high incomes (4%). Low-income individuals are also more likely to report having significant medical debt.³ These economic impacts on patients are significant and wide ranging. For example, researchers have found that each year in the United States, there is:

- \$147 billion in lost productivity due to heart disease and stroke⁴;

We are asking, what are the gaps that are leading to why people are not accessing the treatment they need? When people do not access the treatment they need, then they often end up using the more expensive, more invasive, and possibly less effective treatment.

KEY INFORMANT INTERVIEWEE

- \$164 billion in lost earnings due to arthritis⁵; and
- \$997 billion in economic burden of rare disease patients and caregivers.⁶

At the same time, access to healthcare and social supports can improve both health outcomes and income, as well as other measures of socioeconomic status for patients and families.⁷

Understanding the economic factors that impact healthcare access, utilization, health disparities, and health outcomes is critical to informing strategies used to address healthcare cost and value. This can also create insights for addressing misalignment in incentives in the healthcare system.

As evidence of this growing attention, the 2019 reauthorization of the Patient-Centered Outcomes Research Institute (PCORI) involved expansion of the organization's charge to include an increased scope of research priorities and mandate to consider, when appropriate, "the full range of outcomes data, including the potential burdens and economic impacts of the use of medical treatments, items, and services for different stakeholders."⁸ Since that reauthorization, PCORI has provided guidance to researchers and other stakeholders on how to implement this directive. In November 2022, a PCORI-funded report was released that listed a range of stakeholder values to broaden their understanding of patient-centered value elements.⁹

The **Innovation and Value Initiative (IVI)** and **AcademyHealth** are committed to ensuring that patients and caregivers are full partners in healthcare research.¹⁰ Moreover, both organizations invest in improving how health researchers, value assessors, and decision-makers (e.g., payers, employer-purchasers) can improve how they measure and account for economic impacts on patients and caregivers through consideration of a broad range of costs, burdens, and benefits, including those that patients experience outside of the healthcare system. Building on this commitment, IVI and AcademyHealth partnered with a diverse stakeholder team to develop an Economic Impacts Framework (the Framework) to guide researchers and other stakeholders in accounting for the full range of economic impacts on patients and caregivers (see Figure 2). This evolving resource is intended to guide future research and measurement of a broader range of economic factors, and to inform decision-making that ultimately affects the design, delivery, and payment for value-based care.

We need to account for the compounding economic impacts and inequities that result from racism and sexism on patients and families.

KEY INFORMANT INTERVIEWEE






Framework Development

The Framework was developed as part of a Eugene Washington PCORI Engagement Award (EASCS-24274). Following an initial environmental scan, IVI and AcademyHealth invited thought leaders from across the industry to participate in a multi-stakeholder Steering Committee (see Appendix 1) to provide insight and recommendations in the development of the Framework. The environmental scans included a brief internet search to review definitions and research on the concept, “economic impacts,” as well as collecting resources recommended by project participants. In the fall of 2022, IVI and AcademyHealth held nine key informant interviews to refine the Framework (see Figure 1).

IVI and AcademyHealth convened an invitation-only roundtable discussion in February 2023 to further refine the visual image and to better understand the potential uses of the Framework and the guidance needed to apply the Framework. In March of 2023, IVI and AcademyHealth held a public webinar and a consensus meeting to finalize the guiding principles for the Framework and the potential applications. Table 1 shows the engagement activities and the participants.

In addition to seeking out participants from a range of stakeholder groups, IVI also sought to include individuals representing diverse diseases, ages, genders, races, and geographic regions. Participants with patient,

Table 1. Engagement Activities

	 Steering Committee	 Key Informant Interviews	 Roundtable	 Consensus Meeting	 Public Webinar
Date	5 Meetings	Fall 2022	February 2023	March 2023	March 2023
Purpose	Provide ongoing expertise, guidance, and insight	Help define the framework and expand the list of inputs	Validate the framework and begin to explore when economic data should be collected	Prioritize principles to guide the framework and identify steps needed to put the framework into practice	Demonstrate the need for a better approach to economic impact and highlight early lessons learned
Participants	13 Members	9 Interviews	14 Participants	15 Participants	115 Registrants
Stakeholder Perspectives*	4 Patient/Caregiver 4 Researcher 2 HTA Researcher 2 Policy 1 Payer 1 Employer	6 Patient/Caregiver 3 Researcher 2 Policy 1 Payer 1 Employer	6 Patient/Caregiver 4 Researcher 1 Payer/Researcher 1 Employer 2 Industry	8 Patient/Caregiver 5 Researcher 2 Industry	28 Patient/Caregiver 36 Industry 21 Researchers 30 Other (payer, employer, not reported)

*Some stakeholders brought multiple perspectives so there may be more perspectives than participants.

caregiver, and researcher perspectives were heavily emphasized. For each engagement activity, participants were asked to provide feedback on the draft visual aid, reflect on their perspectives deriving from experiencing economic impacts and/or measuring such impacts, and explore potential applications of the Framework. Following each engagement, IVI revised the Framework and identified additional considerations and revisions to support the usability and implementation of the Framework by PCORI (as a funder of such research) and a wider range of stakeholders, including researchers, patient- and family-focused organizations, and other entities that use such inputs as part of system-level analysis and decision-making, including payers, employer-purchasers, and health delivery systems.

Using the Term “Patient”

Throughout this project, participants wrestled with the use of the word “patient.” Several individuals urged IVI and AcademyHealth to use person-first language – encounters with the healthcare system can be dehumanizing and people may feel that the term “patient” reduces them to a disease rather than a full, complex person with considerations outside the healthcare system. At the same time, others argued that using the term “patient” is important because it has specific reference to considerations of people within the healthcare system, and using the term, “person,” may cause confusion. In the end, we chose to continue using the term “patient” for the initial Framework, but to also include a specific reference that patients are more than their disease and should be treated as such.

The Framework Principles

The purpose of the Framework is to:

- Offer guidance to researchers and other stakeholders on the full range of economic impacts on patients and caregivers;
- Help empower patients and caregivers articulate priorities and experiences to researchers and other decision-makers; and
- Provide insights to payers, employers, and other decision-makers to better capture currently unmeasured or inconsistently measured costs.

From the first meeting with the Steering Committee to the final convening of the project, every participant emphasized the importance of changing our approach to understanding the economic impacts on patients and caregivers. The Framework is designed as a guide to reframe the prioritization of traditional health systems to one that accounts for factors that matter most to patients and caregivers.

As researchers and other stakeholders consider potential applications of the framework, the first and most important consideration is that **patients and caregivers, with their complex and varied experience, need to be put at the center of understanding economic impacts.** This requires authentic engagement of patients and caregivers in the research process, right from the start.

FRAMEWORK PRINCIPLES

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- **Clarify research goals.** Use patient and caregiver insights and the Framework to define research goals. Acknowledge the changing nature of the data and of the economic impacts over time.
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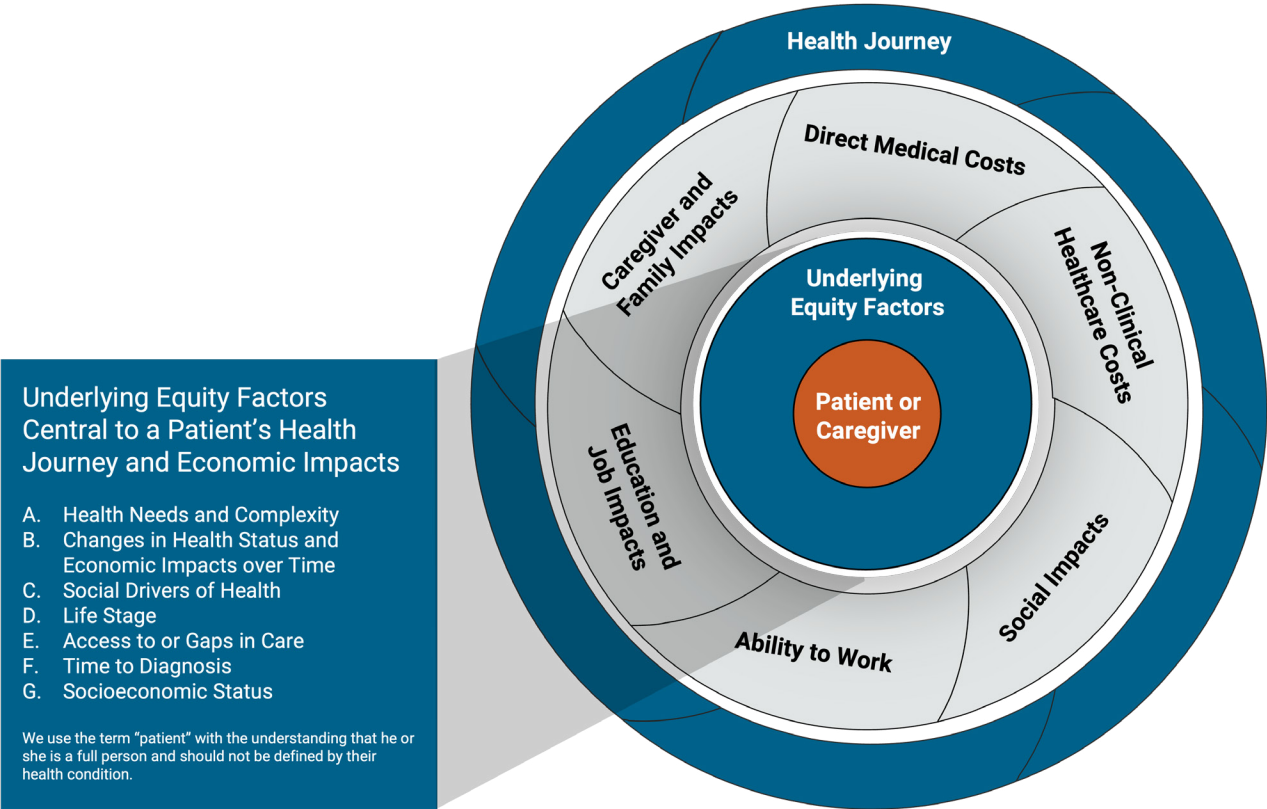
The Framework

The Framework principles invite researchers to fully partner with patients and caregivers prior to the point of developing any research design and questions. They encourage addressing health equity considerations in the research planning and to incorporate methods that include both qualitative and quantitative measures.

The Framework (see Figure 2) offers an organizing guide for researchers and decision-makers to better capture economic impacts on patients and caregivers. The patient or caregiver are at the center of the visual representation to demonstrate how important these individuals and their families are to the Framework.

The Framework offers a visual representation and organizing construct of a wide range of economic impacts, but some of these concepts do not fit into neat categories and may overlap across domains. We acknowledge that the intersection of lived experience, the social system, and health needs of the person will drive how patients and caregivers experience economic impacts. We recommend starting any initiative that includes economic impacts with a health journey mapping exercise, roundtable discussions, and/or patient and caregiver interviews to better understand the range of economic impacts that patients and caregivers experience.^{11,12,13,14}

Figure 2. An Interactive Framework to Understand Economic Impacts on Patients and Caregivers



Domains

Each of the six domains (illustrated in gray in Figure 2) represent a broad category of economic impacts. These domains may overlap or intersect, reflecting the many ways that patients and caregivers experience economic burdens in the context of their lives. As one roundtable participant said, for the patient or the caregiver, **“it all comes from one wallet.”**

The domains include:

- **Direct Medical Costs:** Patient or caregiver costs paid to a healthcare provider or healthcare system.
- **Non-Clinical Healthcare Costs:** Costs that are a direct result of seeking treatment but are not paid into the healthcare system.ⁱⁱ
- **Social Impacts:** Economic impacts that may have less obvious measures but have downstream impacts like time spent negotiating with insurance companies, compounding financial impacts, or access to social services.
- **Ability to Work:** Traditional work measures like productivity, sick days, and days off from work.
- **Education and Job Attainment:** Impacts such as career choice or educational attainment.ⁱⁱⁱ

ⁱⁱ These are often listed as indirect costs. Participants in the initiative made the case that “indirect” implies these costs are less significant or impactful, which they believed to be false.

ⁱⁱⁱ This domain was separated from ability to work to highlight its importance.

- **Caregiver and Family Impacts:** These are the economic impacts that caregivers experience because of the primary patient’s illness or health condition.

Table 2 expands on these domains to list the inputs or subcategories that would define each of these domains.

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

Discussions with stakeholders throughout the project focused on the need to understand economic impacts from the lens of the lived experience of patients and caregivers. Often, researchers collect data on an economic impact without understanding how social drivers of health influence how these economic impacts result in different outcomes for different populations.

The Framework can help tell the story faithfully, but realistically, that patients and caregivers are made better off when providers and payers make good decisions with actionable [patient] insights and research.

CONSENSUS MEETING PARTICIPANT

Table 2. Considerations and Inputs of the Economic Impacts

Domain	Identified Inputs within Each Domain	Considerations for Research and Measurement
Direct Medical Costs	Insurance Costs <ul style="list-style-type: none"> Co-insurance & co-payments (medications, doctor visits, emergency costs, hospital stays, ambulance, etc.) Insurance premiums Deductibles 	<p>What direct medical costs do patients encounter as part of accessing care or completing treatment plans?</p> <p>What are the implications when patients have more than one health condition that requires treatment or other medical care, supports, or resources?</p>
	Device Costs (test strips, needles, etc.)	
	Durable Medical Equipment and Medical Supports (wheelchairs, walking aids, prosthetics, assistive clothing, etc.)	
	Care Navigation Assistance	
	Non-Covered Medical Costs (new healthcare innovations and tests, out-of-network costs, etc.)	
	Downstream/Domino Healthcare Costs <ul style="list-style-type: none"> Misdiagnosis/diagnostic journey Side effect costs Co-occurring health conditions Cost of delayed care 	
Non-Clinical Healthcare Costs	Transportation (gas, parking, public transit, airfare, etc.)	<p>What costs do patients encounter that are related to accessing care, but are not directly tied to the healthcare system?</p> <p>How do geographic factors (e.g., rural vs. urban) affect costs to patients?</p>
	Housing/Vehicle Assistive Modifications	
	Childcare/Eldercare	
	Technology/Devices/Clothing/	
	Non-Traditional Healthcare (CBD, acupuncture, medical foods, meditation, fitness services, etc.)	
	Clinical Trial Costs (cost of participating in trial)	
Social Impacts	Access to Social Services (food, housing, transportation, prescription drug programs)	<p>What trade-offs do patients make in order to afford their care?</p> <p>How does access to/lack of access to social support services impact a patient's ability to engage in their healthcare?</p> <p>How much time do patients spend navigating the health delivery system(s) and/or coordinating across providers and payers?</p> <p>What are existing measures or initiatives to capture social drivers of health data?</p>
	Compounding Financial Impacts <ul style="list-style-type: none"> Loss of savings, bankruptcy, dependent care costs, legal fees Ability/Inability to obtain life insurance Ability to pay for rent/mortgage/ utilities Ability to pay for food, clothing 	
	Quality of Network/Access to Providers	
	Time (Time Toxicity)* <ul style="list-style-type: none"> Care coordination time Insurance navigation time Travel time 	

* Gupta, A., Eisenhauer, E.A., and Booth, C.M. "The Time Toxicity of Cancer Treatment." *Journal of Clinical Oncology* 2022 40:15, 1611-1615. Available: <https://ascopubs.org/doi/10.1200/JCO.21.02810>

Domain	Identified Inputs within Each Domain	Considerations for Research and Measurement
Social Impacts (continued)	Psychosocial Impacts <ul style="list-style-type: none"> Psychosocial a result of health condition Financial stress 	How do patients' ability to access high quality providers impact downstream treatment costs?
	Social Costs <ul style="list-style-type: none"> Lack of social capital Social isolation Relationship loss Quality of life 	
Ability to Work	Lost Wages	<p>What effect does the health condition or healthcare have on a patient's ability to work?</p> <p>How does ability to work factor into clinical and economic outcomes important to patients and families?</p> <p>How does increased sick days or decreased productivity affect decision-making by employers? By patients and caregivers? By payers?</p>
	Sick Days (Short- and Long-Term)	
	Disability	
	Productivity	
	Presenteeism	
	Adequacy of Health Insurance Coverage	
	Unemployment Benefits	
	Social Security Benefits	
Employment and Education Impacts	Educational Attainment (high school, two-year college, trade school, military, college, graduate school)	<p>How does the health condition or healthcare affect a patient's career, job choices, and/or educational attainment?</p> <p>What estimates of such opportunity costs have relevance for evaluating quality of care or the value of interventions?</p>
	Job Choice	
	Employment Options	
	Job Re-Training	
	Retirement Savings	
	Limitations on Employment Choice	
Caregiver and Family Impacts	Travel/Transportation	<p>How does caregiving affect an individual's ability to maintain their own health and healthcare, their career, or education? What are the quantifiable costs for this caregiving?</p> <p>What are the economic impacts of the emotional health burden on caregivers and family?</p>
	Cost of Delaying or Forgoing Care	
	Insurance/Care Navigation Time	
	Ability to Work	
	Sick Days	
	Lost Wages	
	Forced Early Retirement	
	Job Choice	
	Job Retaliation	
	Sibling Educational Attainment	
	Psychosocial Impacts	
Injury or Illness as a Result of Providing Care		

Examples raised during engagements include:

- **A narrow view of the patient may underestimate impacts.** Individuals with multiple health conditions may have greater economic burden that might not be captured with a single disease focus because the intersection of multiple diseases or disorders may have compounding economic impacts.
- **The magnitude of impacts will differ.** Individuals with lower incomes may experience higher relative economic burden than those with higher incomes.
- **Economic impacts may change over time.** For individuals who have long-term health conditions and/or must change their work status because of their illness, the economic impacts of the treatment will go up as their income goes down.
- **Caregiver and family costs are key factors in understanding overall economic impacts.** Caregiver burden must account for the challenges that families face when balancing both childcare and caregiving.
- **Access to care impacts health status and outcomes; it also may influence economic impacts over a patient's lifetime.** Economic impacts may interact and compound over time.

Stakeholders recognized that environmental, social, life cycle, and political factors create an underlying ecosystem within which individual patient and caregiver experiences and economic impacts exist. These factors are further compounded by racism, sexism, access and quality of health insurance/coverage, geography, age, and severity and complexity of health conditions.

Throughout the project, stakeholders emphasized the methods for evaluating the compounding economic impacts over time and acknowledge the complexity of building meaningful measures to evaluate economic impacts. Table 3 defines these underlying factors.

How do you take the entirety of a person and their life journey into one bucket? You can't group a 17-year-old and an 80-year-old and expect them to have the same economic impacts even if they have the same disease.

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ROUNDTABLE PARTICIPANT

Table 3. Underlying Factors

Factor	Consideration
Health Needs and Complexity	This refers to the level of care an individual needs. This may reflect severity of disease, presence of one or more co-occurring health conditions, type(s) of treatment needed or even whether treatment(s) are known and available
Changes in Health Status and Economic Impacts Over Time	This refers to how health status will change the level of economic impacts and the time horizon relevant to such shifts. If a person's health improves, economic impacts may decrease. If a person's health worsens, the economic impacts may increase significantly.
Social Drivers of Health	Social drivers of health (SDOH, also known as social determinants of health), are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.*
Life Stage	Individuals may experience economic impacts of disease differently depending on life stage.
Access to or Gaps in Care	Geographic area, changes in public and private insurance, and changes in employment status may affect a person and family's access to care services and the economic impact of changes in coverage.
Time to Diagnosis	This refers to the amount of time and health care encounters required before receiving an accurate diagnosis. Longer time to diagnosis is associated with higher level of disease severity and higher economic impacts.**
Socio-Economic Status	An individual's (or support network or community) level of income influences the level of economic burden of disease.

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

** McGarvey, N., Gitlin, M., Fadli, E. et al. Increased healthcare costs by later stage cancer diagnosis. *BMC Health Serv Res*, 22, 1155 (2022). <https://doi.org/10.1186/212913-022-08457-6>.

First-Hand Perspectives: Understanding Economic Impacts on Patients and Caregivers*

Danielle is 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 student health center multiple times in the past two months but had been told it was just menstrual cramps. During the evaluation, the physicians identifies a mass in her abdomen, and she is diagnosed with uterine cancer, which is rare for someone her age. Danielle and her family experience a series of significant economic impacts over the course of her treatment.

Initially, Danielle remains on her parents' health plan, but she takes a leave of absence from school and her mother takes significant time off from work to care for her. Ultimately, Danielle's mother leaves her job to focus on caregiving and navigating insurance and care. The entire family switches to another health insurance with more limited benefits and higher co-insurance. The specialist is over an hour away, and required multiple tolls, parking, and babysitting for Danielle's younger brother for every visit. After recovery from her cancer treatment, Danielle must go to work full time to maintain health insurance and can only take part-time evening classes through the local university. Danielle is labeled as having a pre-existing condition and faces a lifetime of higher insurance rates. In addition to the physical and psychological suffering from the illness, the uncertainty about her health condition and the shifts in insurance coverage have long-term consequences for Danielle and her entire family.

- Direction Medical Costs: ED visit, treatment co-pays
- Non-Clinical Healthcare Costs: Ambulance services, tolls and parking
- Social Impacts: Social isolation, travel time, compounding financial impacts, stress
- Education and Job Impacts: Uncertainty about future job options
- Caregiver and Family Impacts: Lost wages, insurance/care navigation, switching job-based insurance, cost of childcare

*This story is for illustration of the framework and is not based on an actual patient.

Framework Applications

This project underscores the importance of investment in research to build a more robust data ecosystem that defines and captures economic impacts for patients and families. Some elements of the Framework domains lack adequate measures to support their evaluation or incorporation of data into comparative effectiveness or health technology assessments. **Prioritization of which inputs or domains should be considered must be based on the research needs, health condition of focus, and experiences of patients and caregivers.**

IVI and AcademyHealth encourage PCORI and other research funders to incorporate the Framework into its future research prioritization and evaluation criteria. Doing so will increase accountability of research partners across the ecosystem to systematically identify and prioritize the capture of economic impact data as part of comparative effectiveness, clinical effectiveness, implementation studies, community-base participatory research, and other projects. Over time, the shared learning supported by such improved research can support translational and implementation initiatives that demonstrate improvements in both clinical and quality of life outcomes for patients and families. Ultimately, improvement in the practice and consistency of such evidence generation will universally benefit decision needs of health systems, payers, purchasers, and policy makers.

As part of the capstone consensus dialogue for this project, participants explored ways the Framework could be applied by various stakeholders. Table 4 outlines potential applications of the Framework by stakeholder group. Users of the Framework should consider the following questions:

- What steps should stakeholders take to partner with patients or caregivers to strengthen the research questions and process?
- What economic impacts from the Framework domains are most salient to the research/project goals?
- How can measures be identified to capture both the cost data inputs and the downstream impacts of those costs?

As a researcher, we struggle with this tension. There's no way research can capture every patient's sort of experience. On the other hand, that's our job and our goal.

ROUNDTABLE PARTICIPANT

Table 4. Potential Applications of the Framework and Challenges

Stakeholder Perspective	Potential Applications
Patient and Caregiver Advocates and Organizations	<ul style="list-style-type: none"> • Guide burden of disease and other real-world evidence studies and registry development • Inform patient-centered core-impact studies • Help articulate the range of costs and trade-offs that patients and caregivers make
PCORI and Other Research Funders	<ul style="list-style-type: none"> • Validate and incentivize mixed methods research approaches • Utilize in research requests • Embed in evaluation criteria for research awards
Researchers	<ul style="list-style-type: none"> • Use as a guide in partnerships with patients and caregivers to elicit specific insights about economic impacts • Reference when developing research questions and methodology • Expand the range of economic impacts included in proposed and published research
Health Technology Assessment Organizations	<ul style="list-style-type: none"> • Shift approaches to capturing the “societal perspective” in economic evaluations • Demonstrate that the full range of costs – direct and indirect – are impactful for healthcare decision-makers, patients, and caregivers • Discuss whether all important costs have been included and considered in economic evaluations, and explicitly point out where there are gaps.
Policy	<ul style="list-style-type: none"> • Incentivize data collection efforts to broaden understanding of economic impacts
Employers	<ul style="list-style-type: none"> • Improved understanding of impact of insurance policies on broader costs • Drive data collection initiatives and requests for studies and data quality on benefits and outcomes
Payers	<ul style="list-style-type: none"> • Inform internal research approaches • Potentially demonstrate cost areas across traditional silos (pharmaceutical, hospital, etc.)

Throughout the project, stakeholders emphasized the importance of using health journey maps, focus groups, interviews, roundtables, and ongoing partnerships to improve understanding of the lived experience of patients and caregivers. Patients focused their comments on the importance of ongoing engagement and full partnership rather than single encounters that may not improve trust in the process or the right level of specificity in engagement.

Challenges

Throughout this project, participants saw the Framework as having great potential to improve how we understand and capture economic impacts on patients and caregivers. At the same time, participants emphasized that the real shifts proposed in this Framework are complex and challenging. For patient and caregiver organizations, they shared how challenging it has been to have a full voice in the research

process. Patient organizations raised concerns that their data collection efforts were often disregarded or considered not rigorous enough to be fit for purpose. Many patient organizations reported that they were over-burdened in collecting this kind of data without adequate funding or resources.

IVI conducted this project to offer a resource to researchers when they are seeking to include a broader range of economic impacts on patients and caregivers in their research, knowing that this is a challenging prospect. Some of the challenges identified in discussions include:

- Lack of clarity in how to translate economic impacts into meaningful measures;
- Lack of data sources;
- Uncertainty in connecting economic impacts to treatment effects;
- Need for additional methods for analysis of the data;
- Need for methods to account for intersection of impacts and changes in impacts over time; and
- Lack of methods for measuring costs and impacts that are outside of claims or other healthcare data sources.

Throughout the discussions, participants emphasized the importance of the Framework as an opportunity to foster conversations and partnerships between patients, caregivers, and researchers that, while challenging, could have the potential to move towards a more patient-centered research approach.

The [economic] impact is personal first. The impact on your non-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.

ROUNDTABLE PARTICIPANT

Next Steps

This Framework reflects a consensus-driven process to help stakeholders, especially researchers, capture the full range of economic impacts on patients, families, and caregivers. With commitment and wide-spread consensus for a patient-centered focus, this Framework offers a first-stage guide for defining and considering economic impacts in a wider range of research and measurement initiatives. Such progress offers the opportunity to improve a data ecosystem that supports broad clinical and policy decision-making, as well as to drive improvements in global research endeavors to ensure they capture a robust, more complete picture of the patient experience. Multiple questions and opportunities for ongoing learning remain, such as:

1. How do users of the Framework operationalize the collection of these novel data points?
2. What are the first areas for the development of measures?
3. What are the priority data gaps to address via research investment?

This initiative demonstrates broad support for investing in efforts to standardize the collection and application of a fuller range of economic impacts on patients and families. The Framework helps to capture the domains of such economic impacts. Researchers and other stakeholders will benefit from this dynamic framework, which supports further

dialogue between researchers and patient communities, challenges payers and clinical systems to improve their data collection of economic impacts, and supports the creation of accountability – by research funders, payers, and purchasers – for acknowledging, measuring, and evaluating the economic outcomes on patients and families.

WAYS TO TAKE ACTION

- Grow multi-stakeholder partnerships needed to expand data collection on a broader range of economic impacts.
- Drive culture change to orient researchers and decision-makers to patient-centered economic outcomes that are outside of traditional measures.
- Engage underserved and underrepresented communities as leaders to identify priorities and solutions.



Appendix

Acknowledgments	23
Key Terms	25
Endnotes	27

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Name and Affiliation	Steering Committee	Key Informant Interview	Roundtable Participant	Webinar Speaker	Consensus Meeting
Alan Balch, PhD (Patient Advocate Foundation and National Patient Advocate Foundation)					X
Kelly Barta (Coalition of Skin Diseases)			X		X
Mata Charokopou, PharmD, MBA, MSc (UCB, Inc.)			X		
Elizabeth Cope, PhD, MPH (AcademyHealth)	X		X		
Gwen Darien (National Patient Advocate Foundation)	X			X	X
Kate Davidson, LCSW (Learning and Diffusion Group at the Center for Medicare and Medicaid Innovation)	X				
Olivia Dieni, MPH (Cystic Fibrosis Foundation)			X		X
Margo Edmunds, PhD, FAMIA (AcademyHealth)	X		X		X
Omar Escontrias, DrPH, MPH (National Health Council)	X				
Elizabeth Franklin, PhD, MSW (Sanofi)		X			
Robert Friesel (National Psoriasis Foundation)		X			
Paul Fronstin, PhD (Employee Benefit Research Institute)		X			
Katherine Gallagher-Robbins (National Partnership for Women and Families)		X			
Janaera Gaston (Northeast Business Group on Health)			X		
George Gondo (National Psoriasis Foundation)		X			
Jason Harris (National Psoriasis Foundation)		X			
Leah Howard (National Psoriasis Foundation)		X			
Candace Henley (Blue Hat Foundation)		X			
Maureen Hensley-Quinn (National Academy for State Health Policy)	X				
Tom Hubbard (Network for Excellence in Healthcare Innovation)	X				
Annie Kennedy (EveryLife Foundation for Rare Diseases)		X		X	X
Karen Mancera-Cuevas, DrPH, MPH, MS, CHES (National Health Council)					X

Name and Affiliation	Steering Committee	Key Informant Interview	Roundtable Participant	Webinar Speaker	Consensus Meeting
Jessica Mason (National Partnership for Women and Families)		X			
Laura McClung, PhD (UCB, Inc.)	X				
Jackie McRae, PharmD, MS (PhRMA)					X
Justin McGinnis, PhD (EMD Serono)			X		
Robert Nordyke, PhD, MS (National Pharmaceutical Council)	X				
Laura Pizzi, PharmD, MPH (ISPOR)	X				X
Elridge Proctor, MPA (GO2 for Lung Cancer)	X	X			
Casey Quinn, PhD (PCORI)		X			X
Abby Sears, MBA (OCHIN)	X				
Erin Mackay, MPH (National Partnership for Women and Families)		X			
Juan Marcos González Sepúlveda, PhD (Duke University, School of Public Health)	X			X	
Kistein Monkhouse, MPH (Patient Orator)			X	X	
Dianne Munevar, MPP (NORC, University of Chicago)			X		
Cheryl Neslusan, PhD (Janssen)					X
Elizabeth Oehrlein, PhD, MS (Applied Patient Experience, LLC)			X		X
Urvashi Patel, PhD, MPH (Evernorth)		X			
Mary Reed, PhD (Kaiser Permanente)			X	X	
Beverly Rogers (Patient Advocate)			X		X
Shannan Sharp (XLH Network)			X		
Mark Schlesinger, PhD (Yale School of Public Health)			X		
Anna Sinaiko, PhD (Harvard TH Chan School)			X		
Cristie Travis (HealthCareTN)	X				
Gretchen Wartman (National Minority Quality Forum)	X			X	X
Tiffany Westrich-Robertson (AiArthritis)					X
David White (Kidney Warrior, Patient Advocate)			X		

Key Terms

Term	Definition
Affordability	An assessment of a person's ability and willingness to pay. It is an interaction of spending, income, and judgments about the value of something relative to its price. ⁱ
Comparative Effectiveness Research (CER)	The generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy-makers to make informed decisions that will improve health care at both the individual and population levels. ⁱⁱ
Cost-Effectiveness Analysis (CEA)	A method to examine both the costs and health outcomes of one or more interventions. It compares an intervention to another intervention (or the status quo) by estimating how much it costs to gain an additional unit of some health outcome, such as a life-year gained or a case prevented.
Co-Insurance	The percentage of costs of a covered health care service you pay (20%, for example) after you've paid your deductible. ⁱⁱⁱ
Co-Payment or Co-Pay	A fixed amount (\$20, for example) you pay for a covered health care service after you've paid your deductible. ^{iv}
Cost-Sharing	The share of costs covered by your insurance that you pay out of your own pocket. This term generally includes deductibles, co-insurance, and co-payments, or similar charges, but it doesn't include premiums, balance billing amounts for non-network providers, or the cost of non-covered services. Cost-sharing in Medicaid and CHIP also includes premiums. ^v
Deductible	The amount you pay for covered health care services before your insurance plan starts to pay. With a \$2,000 deductible, for example, you pay the first \$2,000 of covered services yourself. ^{vi}
Economic Burden	In medicine, a term used to describe problems a patient has related to the cost of medical care. Not having health insurance or having a lot of costs for medical care not covered by health insurance can cause financial problems and may lead to debt and bankruptcy. Economic burden can also affect a patient's quality of life and access to medical care. For example, a patient may not take a prescription medication or may avoid going to the doctor to save money. Cancer patients are more likely to have economic burden than people without cancer. Also called economic hardship, financial burden, financial distress, financial hardship, financial stress, and financial toxicity. ^{vii}
Financial Burden	Healthcare financial burden is defined as the proportion of total OOP medical expenditures divided by total income for each family. ^{viii}
Health Economic Modeling	A set of analytic approaches in health economic analysis that synthesize clinical, epidemiological, and economic evidence from different data sources into an evaluation framework that will enable researchers or decision-makers to generate estimates for specific outcomes of interest. Models are usually a simplified representation of the real world to inform decision-making by characterizing uncertainty in projecting outcomes. ^{ix}
Health Economics and Outcomes Research (HEOR)	HEOR research focuses on measuring and valuing the outcomes of healthcare interventions with a particular focus on the effect of these interventions on patients. By bringing the fields of health economics and outcomes research together, researchers can use data and insights for healthcare decision-makers. ^x

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x <https://www.ispor.org/heor-resources/about-heor>

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

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Innovation and Value Initiative
917 Prince Street
Alexandria, VA 22314

www.thevalueinitiative.org