A Blueprint for Patient-Centered Value Research

Partnering with Patients for Better Healthcare Decisions

Center for Innovation
& Value Research

Table of Contents

Our Mission

The Center for Innovation & Value Research (Center) is an independent non-profit research organization working to ensure all patients have access to the right care at the right time. Our mission is to advance the science, practice, and use of patient-centered **health technology assessment (HTA)** to support decisions that make healthcare more meaningful and equitable.

Our Work

The Center drives innovation in HTA through **patient-centered value research** and partnerships focused on patient preferences, novel value methods, and model development. We collaborate with patients, researchers, employers, and providers to define and assess value, serving as a laboratory for testing and refining patient-centered HTA methods.

Purpose and Scope of the Blueprint

The ***Blueprint*** defines the Center's approach to patient[1] collaboration in value research and provides a structured framework for integrating patient perspectives throughout the research process. It serves as a resource for stakeholders—including patients, patient advocacy organizations, researchers, payers, purchasers, healthcare providers, and life sciences manufacturers—who seek to embed meaningful patient engagement in their work.

Patients / Patient Advocacy Organizations

Researchers

Payers / Purchasers

Healthcare Providers

Life Sciences Companies

---

[1] We use the term "patient" to refer to a person who has had a significant encounter with the healthcare system that has lived experience 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 but use this term in recognition of their lived experience and the importance of this experience to improving the healthcare system.

Value Principles and Key Areas of Work

Since 2019, the Center has served as a learning laboratory, leading the conversation around advancing methods for HTA and value research. This Blueprint reflects the culmination of the Center's research and stakeholder engagement efforts to date, rooted in our value principles highlighted below.

CORE PRINCIPLES

Sustains Authentic Patient Centricity

Supports Health Equity

Advances Transparency

SUPPORTING PRINCIPLES

Focuses Value Discussion Across Treatment Interventions

Improves Clinical and Real-World Data

Facilitates Customizable Decision-Making

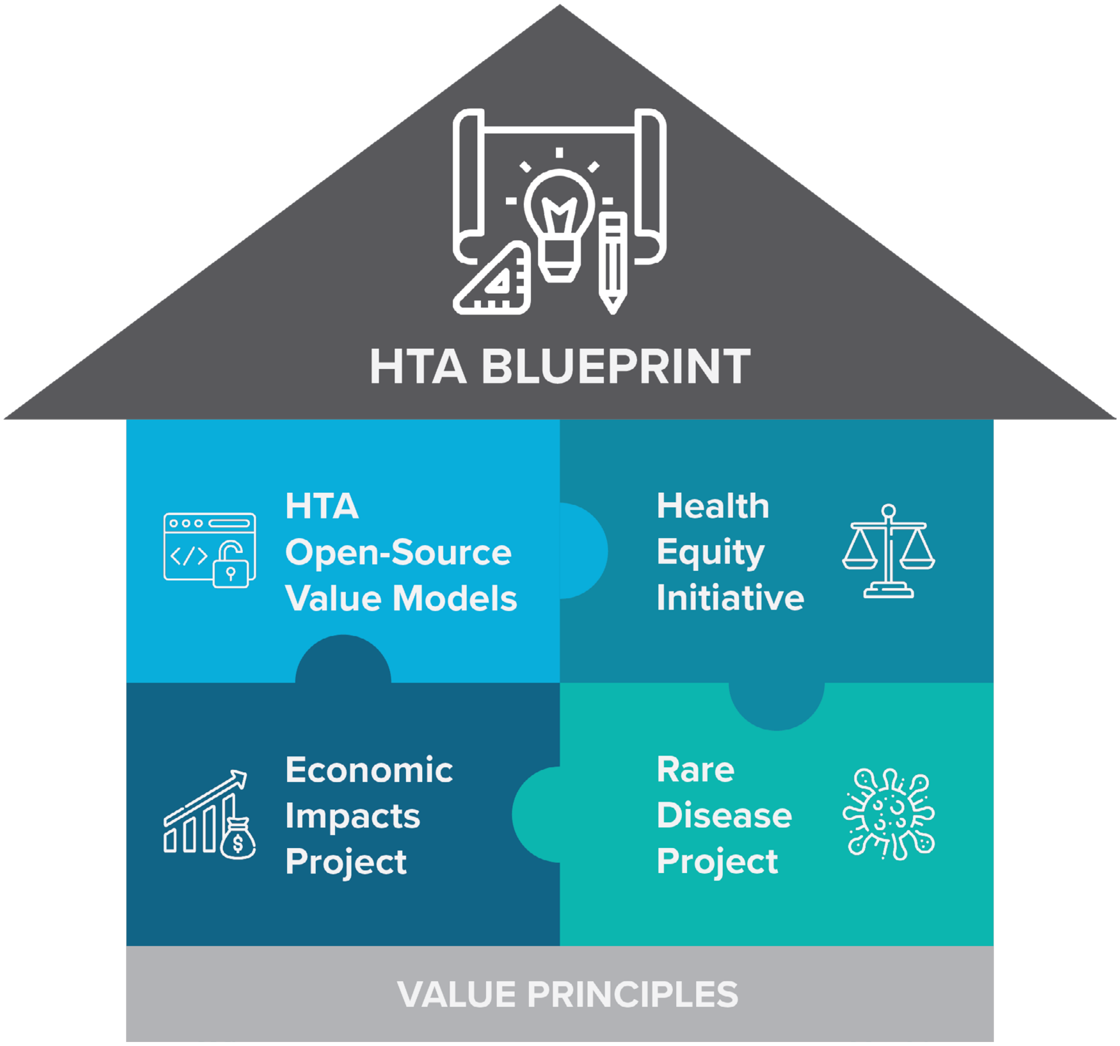
Adapts to and with Evolving Evidence

Cultivates Modernized Methods

Fosters Long-Run Innovation

These principles provide the foundation for the development of key projects and processes that underpin the Blueprint, including the HTA Open-Source Value Models, Rare Disease Patient-Centered Outcomes Project, Patient-Centered Economic Impacts Project, and our Health Equity Initiative (see Figure 1). As an ongoing process, the Blueprint also serves as a framework for new methods and approaches to patient-centered value research. We recognize that this is a continuous learning journey, and we remain committed to refining and improving our work.

Figure 1. Laying the Groundwork for the Blueprint



Conceptual Blueprint

How Patient-Centered Value Research Informs HTA

HTA, also known as value assessment, is an analysis of the clinical and economic value of a particular healthcare intervention using various factors such as cost, safety, and efficacy.[2] Employers, payers, life sciences companies, and policymakers, among others, use it to help determine how patients are treated and at what cost. **Patient-centered HTA** ensures that patients are engaged, heard, and respected throughout the HTA process, with their input directly influencing decision-making.[3]

The Center emphasizes the importance of ***patient-centered*** HTA, as characterized by:

- Core principles of patient-centricity, health equity, and transparency.
- Meaningful patient partnership throughout the HTA process, including co-leadership in strategy and governance.
- Incorporation of patient preferences, clinical and economic outcomes, and lived experiences into HTA, shaping research questions, model design, and evidence application.
- Facilitation of shared decision-making, empowering patients in healthcare decisions.

The Center defines **patient-centered value research** as a meaningful and impactful partnership between patients and researchers in the design and conduct of research. Patients are engaged at every stage of the research process—from conceptualization and design through execution, analysis, and dissemination (see Figure 2). This approach ensures that patient input directly shapes research priorities, methodologies, and outcomes, with the goal of generating insights that authentically reflect patient experiences, needs, and preferences.

In this document, we break down each stage of the Blueprint on pages 8 through 13, linking key activities to applied value principles and highlighting real-world examples of the Center's work in patient-centered value research.

---

[2] Goodman CS. HTA 101: Introduction to Health Technology Assessment. Bethesda, MD: National Library of Medicine (US); 2014.

[3] https://nationalhealthcouncil.org/wp-content/uploads/2024/10/NHC_Patient_Voice_Value-Assesment_v5.pdf

Figure 2. A Blueprint for Patient-Centered Value Research

Why Involve Patients? The Impact and Meaning of Patient-Centered Value Research

Patient engagement, once described as the “blockbuster drug of the century,”[4] is a critical component of value-based healthcare. It underscores the important shift towards patient-centered care that prioritizes active involvement of patients in their healthcare journey. By putting patients at the center and collaborating with them in research to inform decision-making, we can improve health quality, health outcomes, and ultimately, lower costs.

---

[4] Dentzer, S. (2013). Rx for the “blockbuster drug” of patient engagement. Health Affairs, 32(6), 202. https://doi.org/10.1377/hlthaff.2013.0037.

INITIATION

KEY ACTIVITY

Co-Develop Research Questions

Collaborate with patient partners to create research questions that directly address patients' needs and priorities.

APPLIED PRINCIPLE

Sustains Authentic Patient-Centricity

Includes diverse patient voice to reflect community and population needs.

REAL-WORLD EXAMPLE

Health Equity Initiative

Developed research questions with input from community representatives to address economic and access disparities in healthcare.

KEY ACTIVITY

Establish Multi-Stakeholder Advisory Groups

Form advisory groups that include patients, caregivers, healthcare providers, and researchers to incorporate diverse perspectives.

APPLIED PRINCIPLE

Supports Health Equity

Engage patients from diverse backgrounds to shape questions relevant to their experiences.

REAL-WORLD EXAMPLE

Major Depressive Disorder Model

Created an advisory group involving patient advocates, employers, players, life sciences companies, researchers, and clinicians to provide holistic input on model goals and applicability.

KEY ACTIVITY

Explore the Patient Journey

Map out the patient journey to identify key points, challenges, and unmet needs related to treatment and care pathways over time.

APPLIED PRINCIPLE

Improves Clinical and Real-World Data

Capture detailed patient perspectives to inform authentic journey mapping.

REAL-WORLD EXAMPLE

Economics Impacts Project

Developed report on how to use patient journey mapping to reveal the full spectrum of economic burdens faced by patients and caregivers.

PLANNING

KEY ACTIVITY

Seek Input on Patients' Priorities

Engage patients to define what outcomes are most meaningful, such as symptom relief, daily function, and overall quality of life.

APPLIED PRINCIPLE

Facilitates Customizable Decision-Making

Align outcome priorities with what matters most to individual patients.

REAL-WORLD EXAMPLE

Major Depressive Disorder Model

Focused on patient-defined priorities, such as daily functionality and symptom management, for treatment model outcomes.

KEY ACTIVITY

Contribute to Data Exploration and Feasibility

Work with patients to assess what data should be collected and the best methods to ensure it accurately reflects their experiences.

APPLIED PRINCIPLE

Advances Transparency

Engage patients in data methods to ensure data integrity and transparency.

REAL-WORLD EXAMPLE

Economic Impacts Project

Collaborated with patient representatives to understand a broad range of economic impacts that would best represent the cost burdens on patients and caregivers.

KEY ACTIVITY

Review Study Protocols

Develop and review study protocols with patient partners to ensure that the study aligns with the needs and priorities of patients.

APPLIED PRINCIPLE

Cultivates Modernized Methods

Patient feedback informs accessible innovative protocols that reflect real-world needs.

REAL-WORLD EXAMPLE

Major Depressive Disorder Model

Review study protocols with patient advocates to ensure inclusivity and accessibility in study design and execution.

EXECUTION

KEY ACTIVITY

Employ Mixed Methods

Use both quantitative and qualitative methods, such as surveys and interviews, to provide a comprehensive view of patient outcomes and preferences.

……

APPLIED PRINCIPLE

Improves Clinical and Real-World Data

Use a blend of data to accurately capture and respect diverse patient perspectives.

……

REAL-WORLD EXAMPLE

Major Depressive Disorder Model

Utilized mixed methods, such as surveys and interviews, to understand a wide range of patient-reported treatment preferences and to design model's user interface.

KEY ACTIVITY

Conduct Analyses

Analyze data together with patient partners to evaluate outcomes that reflect the patient-centered goals established during planning, focusing on patient-defined priorities.

……

APPLIED PRINCIPLE

Adapts to and with Evolving Evidence

Use analyses that can evolve to incorporate new findings and patient input.

……

REAL-WORLD EXAMPLE

Rare Disease Project

Addressed outcomes data focusing on quality of life and healthcare access issues specific to rare disease patients.

KEY ACTIVITY

Provide Feedback on Preliminary Results

Share early results with patient partners for feedback and validation to ensure findings align with their experiences and perspectives.

……

APPLIED PRINCIPLE

Advances Transparency

Early and open sharing fosters trust and public accountability.

……

REAL-WORLD EXAMPLE

Economic Impacts Project

Shared initial economic impact recommendations with patient and caregiver partners to validate results. Revised the framework based on their feedback.

MONITORING

KEY ACTIVITY

Determine Relevance of Study Results

Assess how results apply to the broader patient community and identify potential implications for healthcare practice and policy.

APPLIED PRINCIPLE

Supports Health Equity

Tailor findings to increase accessibility and relevance for diverse patient groups.

REAL-WORLD EXAMPLE

Health Equity Initiative

Used findings to develop recommendations for equitable access to healthcare services in underserved communities.

KEY ACTIVITY

Conduct Regular Feedback

Host regular check-ins with patient partners to discuss progress, challenges, and any necessary adjustments to the research process.

APPLIED PRINCIPLE

Sustains Authentic Patient-Centricity

Regular patient input ensures alignment with evolving patient needs.

REAL-WORLD EXAMPLE

Major Depressive Disorder Model

Held quarterly sessions with mental health advocates to discuss model development and address any research barriers or areas needing adjustment.

DISSEMINATION

KEY ACTIVITY

Hold Public Comment Periods

Provide an opportunity for public input and feedback.

....

APPLIED PRINCIPLE

Advances Transparency

Enable community validation through public input and open access.

....

REAL-WORLD EXAMPLE

Major Depressive Disorder Model

Shared preliminary findings with the public and held three public comment periods to gather diverse stakeholder feedback to ensure transparency.

KEY ACTIVITY

Present Findings to Diverse Audiences

Include plain language summary for all reports that is easy to read and understand by all audiences, including patients.

....

APPLIED PRINCIPLE

Focuses Value Discussion Across Treatment Interventions

Make findings accessible and clear for all stakeholders.

....

REAL-WORLD EXAMPLE

Rare Disease Project

Presented findings on diagnostic challenges to patient advocacy groups and healthcare providers with accessible, plain language summaries.

KEY ACTIVITY

Co-Author Reports and Publications

Invite patient partners to co-author reports and/or publications, giving them recognition for their valuable input and partnership.

....

APPLIED PRINCIPLE

Sustains Authentic Patient-Centricity

Give due credit to patient partners, reinforcing the value of patient collaboration in research.

....

REAL-WORLD EXAMPLE

Economic Impacts Project

Invited all steering committee members to serve as co-authors in poster presentation for the PCORI Annual Meeting.

ASSESSMENT

KEY ACTIVITY

Discuss Recommendations for Future Research

Collaborate with patient partners to identify gaps in the current research and suggest directions for future studies that address remaining questions.

……

APPLIED PRINCIPLE

Facilitates Customizable Decision-Making

Enable research to adapt and address patient-identified areas of need.

……

REAL-WORLD EXAMPLE

Health Equity Initiative

Engaged patient advocates to identify additional research needs in policy applications for health equity.

KEY ACTIVITY

Maintain Ongoing Feedback Loop

Assess what worked well and what could be improved throughout the research by asking for feedback from the team, including patient partners.

……

APPLIED PRINCIPLE

Adapts to and with Evolving Evidence

Foster adaptability and improvement based on real-time patient feedback.

……

REAL-WORLD EXAMPLE

Major Depressive Disorder Model

Collected ongoing feedback from stakeholders on barriers and successes, ensuring an iterative improvement process for the model.

KEY ACTIVITY

Evaluate Research, Policy, and Coverage Recommendations

Assess the impact of research findings on policies and coverage decisions, ensuring they support patient needs and priorities.

……

APPLIED PRINCIPLE

Fosters Long-Run Innovation

Align findings with policy changes that support patient-centered care and access.

……

REAL-WORLD EXAMPLE

Inflation Reduction Act Initiative

Actively engaged with the Centers for Medicare & Medicaid Services, provided guidance comments, and organized a policy symposium to inform and shape health policy.

Resources for Patient Partnership in Research by Stage

The list below provides a selection of key resources for each stage of the Blueprint. Resources may apply to multiple stages of the Blueprint, but are not repeated. In addition, the list is not exhaustive, but is a starting point for organizations looking to partner with patients and caregivers on patient-centered value research.

Across All Stages

- Patient-Centered Outcomes Research Institute (PCORI) Foundational Expectations for Partnerships in Research
- Center for Innovation & Value Research Patient-Centered Economic Impacts Framework
- The Council of Medical Specialty Societies (CMSS) and Patient-Led Research Collaborative (PLRC) Patient-Led Research Scorecards
- National Health Council (NHC) Rubric to Capture the Patient Voice and Value Classroom
- Patient-Focused Medicine Development (PFMD) Patient Engagement Management (PEM) Suite
- European Patients' Academy of Therapeutic Innovation (EUPATI) Open Classroom
- Institute for Patient- and Family-Centered Care: A Toolbox for Creating Sustainable Partnerships with Patients and Families in Research

Initiation

- NHC Patient Experience Mapping Tools
- NHC Patient Compensation Tools
- Orphan Drug Development

Planning

- SPIRIT-PRO Extension: Protocol checklist for planning patient-reported outcomes in clinical trials

Execution

- The HTAi Patient and Citizen Involvement Group: Best practices for executing patient-centered HTA
- Co-Design Methodologies: Guides on co-developing research protocols with patients
- Tools like REDCap or Dedoose for managing qualitative data from patient input

Monitoring

- Council for International Organizations of Medical Sciences (CIOMS): International Ethical Guidelines for Health-related Research Involving Humans

Dissemination

- Agency for Healthcare Research and Quality (AHRQ) Publishing and Communication Guidelines
- Frameworks such as RE-AIM: Guidance for disseminating and scaling HTA findings effectively
- Plain Language Summary Resources: Templates and tools for creating accessible content

Assessment

- Evaluation of Patient Engagement in Medicine Development
- National Pharmaceutical Council Current Landscape: Value Assessment Frameworks
- Frameworks for FDA's Real-World Evidence Program: Guide assessing outcomes in real-world applications

Glossary

Term	Definition
Health Technology Assessment (HTA)	HTA is a process of looking at new medical treatments, devices, or procedures to see if they are safe, work well, and are worth the cost. It helps doctors and health systems decide which treatments should be offered to patients.
Patient-Centered HTA	This approach focuses on making sure that the needs and experiences of patients are at the center of the decision-making process. It ensures that new treatments or technologies help improve the quality of life and health outcomes for patients.
Patient-Centered Value Research	Patient-centered value research is a collaborative partnership between researchers and stakeholders, particularly patients, to ensure that every stage of the research process—from design to dissemination—is shaped by the experiences, needs, and preferences of those most impacted, aligning priorities and outcomes to generate meaningful and actionable insights.

Center for Innovation
& Value Research

www.valueresearch.org