

Welcome

The National Health Council (NHC), in partnership with the University of Maryland School of Pharmacy and Tufts Medical Center, is excited to invite you to contribute to developing good–practice recommendations, research and training priorities to assist researchers in developing more patient-centered value/health technology assessments (V/HTA). The project is part of a collaboration including two Value Assessment Centers of Excellence: the Patient-Driven Values in Healthcare Evaluation ([PAVE](#)) and Tufts Center for Enhanced Value Assessment ([CEVA](#)).

Purpose of Study

The purpose of the study is to derive a set of methods recommendations, patient-centered data elements, and research and training priorities related to patient-centered V/HTA. Patient-centered V/HTA exists when patients are engaged, heard, understood, and respected throughout the entire V/HTA process, and their input is incorporated and guides decision-making. A V/HTA can be considered patient-centered when individual patients sit down with a final V/HTA report and believe it reflects the multi-dimensionality of their experiences, the burden of disease, and recognizes the different ways a disease manifests.

Purpose of Comment Period

As an employee of a member of the National Health Council, you are being asked to provide feedback on the draft recommendations before they move onto the next phase of our study, an eDelphi survey. Please feel free to submit suggestions related to the language or content within the draft recommendations.

Perspectives on Draft Recommendations

Table 1. Definitions

<p>Scope of the Evaluation - describes the population, interventions, comparators, outcomes, settings, and analysis inputs (e.g., costs) that will be the basis of a value/health technology assessment. The scope guides researchers when they are structuring their assessment and looking for data and evidence to include in an economic model or evaluation based on primary data.</p>
<p>Perspective of the Evaluation - point of view adopted when deciding which types of costs and health benefits are to be included in an economic evaluation</p>
<p>Patient and Caregiver Engagement</p> <ul style="list-style-type: none">• Timing of input: Patient input should be gathered prior to and throughout a V/HTA to maximize its impact.• Scope of input: Patient input and patient experience data are important aspects of economic evaluations. As a result, in addition to other elements, economic evaluations should reflect the natural history of the disease, diversity of patient populations and their experiences, real-world treatment and care patterns, out-of-pocket costs, and outcomes important to patients.• Financial support from the entity commissioning a V/HTA (e.g., V/HTA body) should be provided to patients and patient organizations assisting with data-gathering efforts and other contributions throughout a V/HTA (e.g., interpretation, scoping).
<p>Economic Evaluations & Data Inputs</p> <ul style="list-style-type: none">• Out-of-pocket costs incurred by patients and their caregivers (e.g., home modifications, unpaid caregiver costs) should be included in all patient-centered economic evaluations.• The availability of relevant data and evidence (e.g., randomized controlled trials, real-world data/evidence) to support a V/HTA and economic evaluation should guide the framing, scope, and timing of initial V/HTAs and updates.• Data gaps identified while developing economic evaluations should be clearly communicated to data vendors, research funders, and the patient community, along with any biases it may create in the results.• When time and resources permit, patient organizations should collaborate with researchers to fill data gaps by fielding surveys or extracting data from registries in advance of or during a V/HTA.• Once collected by patient organizations, these data collected represent the best available evidence, and the lack of peer-review should not be a barrier to use in that V/HTA.• The patient community can assist in evaluating the quality and representativeness of potential data inputs.
<p>Communicating V/HTA, Models & Assessing Quality</p> <ul style="list-style-type: none">• Researchers should communicate results and limitations of assessments in plain language and provide justification for the use of certain data inputs, the gaps in data that hindered the analysis, and the target audience.• Policies outlining when and/or under which conditions reassessments will take place should be clearly communicated.• Interactive models (e.g., dashboard) should be released alongside reports to allow stakeholders to modify models for their own uses and test assumptions. These models allow for greater transparency.• A variety of stakeholders, including a diverse set of patients and social scientists, should be invited to review V/HTA reports prior public release.• There should be sufficient time built into processes to allow stakeholder feedback to be incorporated before releasing reports publicly.• To promote shared learning and transparency, examples of how patient input and patient experience data guided a V/HTA and the development of economic evaluations should be published alongside reports.• A standardized reporting template could be developed to communication how patient input and patient experience data guided a V/HTA.

Perspectives on Draft Research & Data Gathering

To what extent do the following topics require additional research or dialogue to advance the patient-centricity of health economics and outcomes research?

Model Perspective
<ul style="list-style-type: none">Value/health technology assessment bodies, payors, or others often prioritize economic models that take a healthcare sector perspective, which focuses on costs to the health system (e.g., costs to the health care system only). This is often at odds with a desire to develop models that take a societal or patient-/caregiver- perspective, which consider costs more holistically, including things patients often say are important, such as the impact on careers (e.g., presenteeism), time, unpaid caregiver time costs, etc. Additional research and stakeholder dialogue regarding expectations on the perspective used in models commissioned on behalf of patients and healthcare beneficiaries are needed.
Research Methods & Data Inputs
<ul style="list-style-type: none">Patient experience data is often qualitative, collected directly from patients and caregivers. There is a need to provide guidelines and illustrative examples of how qualitative data can be used to guide economic evaluations.A U.S. national strategy is needed to collect and make available data to inform patient-centered economic evaluations. Examples of data needed include:<ul style="list-style-type: none">Time costsProductivityOut-of-pocket costsHealth state utility data collected at different time points and across different patient and caregiver groups in different settingsOther societal impacts (e.g., education, social services, criminal justice)Measurement tools that more comprehensively capture health-related quality of life should be co-developed with representative groups of patients according to best practices for survey development.Methods for collecting spillover effects, including on family members, peers, and broader society, and incorporating these estimates into economic evaluations. Spillover effects are “impacts or costs that extend beyond a health intervention or program's targeted recipient (the patient) to unintentionally impact other recipients either in a positive or negative way.” For example, lessening caregiver responsibilities or anxiety.Research about how to quantify costs and benefits, such as those incurred in the education system (e.g., cost associated with special education, school absenteeism, and various educational professionals), is needed.

Comments: [free text](#)

Perspectives on Educational Resource Development Priorities

<ul style="list-style-type: none">Resources about approaches to incorporating patient experiences into economic model development, including illustrative examples.Resources that clarify to stakeholders that patient and clinician perspectives are unique and often differ from one another. There is a significant body of literature documenting how patient and clinician perspectives differ. However, we identified disagreement on whether patients and clinicians provide the same information. Training is needed to address this confusion.Resources related to patient-reported data terminology, data collection methods, and potential applications are needed. Our interviews identified confusion about qualitative and quantitative patient-reported data. For example, data collected using patient-reported outcome measures was referred to as “qualitative data.” While qualitative interviews guide the development of patient-reported outcome measures/questionnaires, data collected using an existing patient-reported outcome measure is typically quantitative. Patient experience data can be collected qualitatively (e.g., interviews) or quantitatively (e.g., preference survey).
