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THE NATIONAL HEALTH COUNCIL PATIENT-CENTERED VALUE ASSESSMENT RUBRIC

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Objectives

Value assessments have emerged as important tools to help health care stakeholders assess the value of new treatments. To inform work in this area, the National Health Council (NHC), with patient and stakeholder input, created this Patient-Centered Value Assessment Rubric *(known as the Value Assessment Rubric)*. The purpose of the Value Assessment Rubric is to provide a tool that the patient community, physicians, health systems, health economists, and payers can use to evaluate the patient centeredness of value assessments and to guide value assessment developers on the meaningful incorporation of patient centeredness and engagement. Patients, caregivers, patient organizations, and other stakeholders who helped to create this document stated that because of their lived experience, value assessments must integrate the patient voice to have practical utility. With these views and patient input, six domains were identified as critical to a patient-centered value assessment. Examples of sufficient and insufficient patient engagement and patient-centeredness are outlined throughout the document.

The Value Assessment Rubric comprises two sections:

SECTION 1

Meaningful Patient Engagement in the Value Assessment Development Process

This section outlines characteristics of meaningful engagement in the value assessment development process.

SECTION 2

Patient-Centeredness Considerations in General

The second section focuses on activities that enhance patient centeredness as the assessment is being developed throughout the phases but may not be directly related to patient engagement.

The NHC Definition of Value

The **value of a treatment** is commonly viewed by health care payers (i.e., both public and private insurers) in terms of its **effectiveness** and **cost**. Generally, this considers the treatment's effects, both positive and negative, and the costs and cost savings associated with the treatment. From patients' perspectives, value is **individualized** and **disease dependent**, and can **evolve** with the disease trajectory or stage of a patient's life.

Domains of a Patient-centered Value Assessment

1 **PATIENT PARTNERSHIP**

Patients should be involved in every step of the value assessment development and dissemination process.

2 **TRANSPARENCY TO PATIENTS**

The assumptions and inputs used within each component of the value assessment should be disclosed to patients in an understandable way and in a timely fashion.

3 **INCLUSIVENESS OF PATIENTS**

The value assessment should reflect perspectives from a range of stakeholders, including the patient community.

4 **DIVERSITY OF PATIENTS POPULATIONS**

The value assessment should account for differences across patient subpopulations, trajectory of disease, and stage of a patient's life.

5 **OUTCOMES PATIENTS CARE ABOUT**

The outcomes integrated into the value assessment should include those that patients have identified as important and consistent with their goals, aspirations, and experiences.

6 **PATIENT-CENTERED DATA SOURCES**

The value assessment should rely on a variety of credible data sources that allow for timely incorporation of new information and account for the diversity of patient populations and patient-centered outcomes, especially those from real-world settings and reported by patients directly. The data sources included should reflect the outcomes most important to patients and capture their experiences.

Glossary

These terms are a snapshot derived from the National Health Council's Patient Engagement and Value Glossaries.

Comparative effectiveness research (CER)	CER compares the effectiveness of two or more treatment approaches or health care services, examining their risks and benefits.[23]
Direct cost	A cost that can be directly associated to something, such as a test, treatment, procedure, or service. The costs can be either "direct medical costs" *(e.g., cost of medication)* or "direct non-medical costs" *(e.g., transportation costs).*[24]
Family Caregiver	Someone caring for those with a medical condition(s). Their care recipients are dependent on the health care system after the diagnosis of a medical condition or disability. A caregiver's views on health issues, such as the benefit and risk of new treatments, will vary depending on the severity of the condition and personal circumstances of those they care for.[11]
Effectiveness	A measure of how well a treatment works in the real world *(e.g., Does it work outside a controlled trial?).*[25]
Health technology assessment (HTA) or Value Assessment	An interdisciplinary process to evaluate the social, economic, organizational, and ethical issues for a health intervention or health technology (such as a drug) and can involve a review of: · *clinical evidence compared to existing care,* · *cost effectiveness* · *social and ethical impacts on the health care system and the lives of patients.*[26,27] Assessments vary, but most look at the health benefits and risks of using the technology. They can also look at costs and any other wider impacts that the technology may have on a population or on a society, and/or look at the relationship between costs, benefits, and risks, and make recommendations about value and pricing.

Indirect cost	Costs incurred by society as a result of the impact of disease, illness, and treatments, excluding direct costs. They include things like the loss of ability to engage in normal daily activities, work, domestic responsibilities, volunteering, and social and recreational/leisure engagements.[24,28]
Meaningful engagement	Direct relationships and partnerships that are bidirectional, reciprocal, and continuous. Communications are open, honest, and clear. Engagement goals, participants, methods, desired impacts, and actual impacts are clearly outlined and transparent.
Patient	Someone having or at-risk of having a medical condition(s), who currently may or may not receive medicines or vaccines to prevent or treat a disease. They are dependent on the health care system after the diagnosis of a medical condition or disability. A patient relies on the health care system to feel better and to have a longer, healthier, and more robust life. An individual patient's views on health issues, such as the benefit and risk of new treatments, will vary depending on the severity of their condition and personal circumstances.[11]
Patient advocacy organization/patient organization	A 501(c)(3) organization that has a mission to combat a particular disease, disability, or group of diseases and disabilities, or to improve and protect the health of a particular group of people. It engages in programs, such as research, education, advocacy, and service to individuals and communities. It takes a holistic view of the conditions for the patients it represents and seeks universal support from stakeholders for its mission and programs. While a patient advocacy organization may advocate for patient access to care, they do not have prescribing authority; formulary control, responsibility, or decision-making authority; or make drug purchases.[11]
Patient centered	Any process, program or decision focused on patients in which patients play an active role as meaningfully engaged participants, and the central focus is on optimizing use of patient-provided information. Patient centered means doing things WITH—not FOR or TO—patients.[29]

Patient-centered health care	Care that is respectful of and responsive to individual patient preferences, needs, and values in context of their own social worlds. Patient centeredness is created by engaging, informing, and actively listening to people with conditions at every point of contact—from the research bench to the bedside and everywhere in between.[30,31]
Patient-centered outcome (PCO)	An outcome reported by patients as important to them in the way they experience a disease or treatment for that disease.[29]
Patient-centered outcomes research	A type of outcomes research that focuses specifically on the outcomes of interest to patients and stakeholders, and includes their perspectives throughout the entire research process.[23]
Patient-centered health technology assessment (HTA)/ value assessment (VA)	Patients are engaged, heard, understood, and respected throughout the entire HTA/VA process, and their input is incorporated and guides decision-making.
Patient engagement	Refers to "the active, meaningful, authentic and collaborative interaction between patients and other stakeholders across all aspects of the health ecosystem, where decision-making with regard to an activity or process is guided by patients' contributions as partners, recognizing their unique experiences, values and expertise." This definition is also applicable across stakeholders and engagement activities *(e.g., participation in an interview, focus group)*.[32]
Patient-generated health data	Health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern.[33]
Patient preference	When faced with different choices, patients have personal views of how desirable or undesirable those choices are. In health care, patient preference is a measure of that level of desirability of the alternatives or choice among health outcomes or treatments *(e.g., different drugs)*. There are various techniques used in research to measure patient preferences.[34,35]

Patient-provided information (PPIn)	Describes information a patient contributes directly at any point during the product lifecycle. The term broadly encompasses the entirety of information that can be collected from an interaction with a patient. The focus should be the patient's view on their disease(s)/condition(s), desired attributes for treatments, experiences with treatments, benefit- risk preferences, and desired goals and outcomes. It should not be primarily focused on any one product.[11]
Patient-reported outcome (PRO)	A subset of PPIn; an outcome measure based on a report that comes directly from the patient *(e.g., study subject)* about the status of the patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. A PRO can be measured by self-report or by interview provided that the interviewer records only the patient's responses.[29.36]
Patient voice	The "patient voice" is a metaphor that captures the belief that the health ecosystem must do a better job of listening to what patients *(individual and patient communities)* express about their experiences, needs, values, goals, priorities, preferences, and expectations related to having a disease and its management starting with their journey to diagnosis, symptoms, burden, and impacts, and perceptions regarding treatment-related benefits, risks, burden, tradeoffs, unmet need and access.
Perspective	The perspective or point-of-view in an economic analysis determines which types of costs and health benefits are included in the evaluation. Traditional perspectives evaluated include the health care system and societal.[38] An analysis based on a health care system perspective might only include costs incurred by the health system *(e.g., costs for medicine, administration, and monitoring)* and patient health outcomes. The societal perspective is broader and also includes things like a patients' loss of productivity due to the inability to work.

Representativeness	A sufficient number of and types of people are included in the engagement activity to ensure that those engaged can speak on behalf of the target population. It refers to “who” and “how many” individuals to include in an interaction in order to, as closely as possible, engage with individuals that represent the broader, target patient population.[38]
Utility	Utility values are intended to represent how patients value different states of health *(e.g., perfect health, having fatigue, being in pain, being unable to walk)*. States of health can be assigned a number—usually between 0 and 1, where perfect health is equal to 1 and death is equal to 0. To assign where the other health states *(e.g., fatigue or pain)* lie between 0 and 1, researchers ask patients and members of the general public to rate the desirability of these health states using methods that typically involve a questionnaire. Utility values are also known as “health state preference values” and are used when assessing quality of life.
Value	The value of a treatment is commonly viewed by health care payers *(i.e., both public and private insurers)* in terms of its effectiveness and cost. Generally, this considers the treatment’s effects, both positive and negative, and the costs and cost savings associated with the treatment and its impact. From patients’ perspectives, value is individualized and disease dependent, and can evolve with the disease trajectory or stage of a patient’s life.[39]
Value assessment framework	The guiding principles of organizations that conduct value assessments. Value assessments often include a comparison of clinical effectiveness, a cost-effectiveness analysis, a budget impact analysis, and other components. The value assessment frameworks detail the guiding principles behind each of these components that will drive each value assessment. Some value assessment frameworks are focused on shared decision making between a patient and a provider, while others are focused on population-level decision making such as coverage and reimbursement decision making.

Introduction

The U.S. health care system continues to undergo transformative changes in the way it delivers and pays for care. As the traditional fee-for-service payment system gives way to more value-based payment arrangements, understanding and defining the value of health care treatments and interventions has become a national priority.

VALUE ASSESSMENTS ARE IMPORTANT TOOLS TO HELP HEALTH CARE STAKEHOLDERS ASSESS THE VALUE OF NEW TREATMENTS.

By 2015, four organizations—the American Society of Clinical Oncology (ASCO), the Institute for Clinical and Economic Review (ICER), the National Comprehensive Cancer Network (NCCN), and Memorial Sloan Kettering Cancer Center—released frameworks that developers have described as intended to support physicians and/or payers *(public and private insurers)* in assessing the value of treatments.[1-4] In general, there are various types of value assessment frameworks, but this Rubric is intended to focus on value assessment frameworks to support population-level decision making.[15]

WHILE THE SUBJECT OF THESE ASSESSMENTS ARE TRADITIONALLY PHARMACEUTICALS, HEALTH CARE SERVICES AND PROCEDURES CAN ALSO BE EVALUATED.

These assessments continue to grow in prominence. ICER's website notes that from 2017–2019, more than 75% of private insurers and [pharmacy benefit managers], and multiple employer coalitions—[used] ICER's assessments to inform formulary decisions, coverage criteria and price negotiations."[16] In recent years, these assessors have also created several tools and opportunities that support patient engagement in value assessment.[40-43]

THE PATIENT COMMUNITY, LIKE OTHER STAKEHOLDERS, IS EAGER TO TAKE A GREATER PART IN THE VALUE DISCUSSION.

Individual patients or patient organizations must be engaged throughout the creation of these frameworks and throughout the conduct of these assessments from their inception. Patient engagement in value assessment has improved since 2015, however there is still work to be done.

Patient perspectives on value can differ significantly from that of physicians, drug manufacturers, and payers, often integrating considerations beyond clinical outcomes and cost, such as a treatment's ability to help patients achieve personal goals.[5]

To have true utility, value assessments must incorporate these other value- influencing factors, and the only way to achieve this is by having robust processes in place to incorporate the patient voice. Such action is particularly important if payers look to value assessments to inform reimbursement and coverage decisions that can affect the treatment options accessible to a patient.

To inform work in this area, the National Health Council (NHC), with patient and stakeholder input, created this Patient-Centered Value Assessment Rubric.

The purpose of the Value Assessment Rubric is to provide a tool that the patient community, value assessors, physicians, health systems, health economists, and payers can use to evaluate the patient centeredness of value assessments and to guide value assessment developers on the meaningful incorporation of patient centeredness and engagement throughout their processes.

Assessing Patient Engagement in Value Assessments

On February 1, 2016, the NHC held a multi-stakeholder roundtable with the objective of creating a Value Assessment Rubric capturing the characteristics of a patient-centered value assessment. During the roundtable, participants discussed recent patient advocacy experiences with value assessments, reviewed other patient-engagement rubrics, and considered the hallmark characteristics of patient centeredness in assessments of value. In 2023 and 2024, the NHC updated this document with the expertise and advice of its Value Work Group *(comprised of patient organizations)* and a health economist with firsthand experience conducting value assessments.

THE PATIENT COMMUNITY REPRESENTS A BROAD RANGE OF VOICES

In this rubric, “patient community” broadly encompasses individual patients, family caregivers, and the organizations that represent them. For the purposes of the rubric:

Individual Patients are those who have or are at risk of having a medical condition(s) whether or not they currently receive medicines or vaccines to prevent or treat a disease.

Family caregiver is defined as an individual who provides unpaid care to a family member or friend who needs assistance with everyday activities.[6]

Patient organizations are comprised of individuals, both lay and professional, and their mission is to combat a particular disease, disability, or group of diseases and disabilities, or to improve and protect the health of a particular group of people. Some patient organizations may or may not collect data from their members and review policy goals with their patient constituency so additional direct input from patients and family caregivers unaffiliated with patient organizations may be beneficial.

Patient-centered health care is respectful of and responsive to individual patient preferences, needs, goals, and values in context of their own social worlds. Patient centeredness is created by engaging, informing, and actively listening to people with chronic conditions at every point of contact—from the research bench to the bedside and everywhere in between.[7,8]

The patient community is diverse and heterogeneous and brings to the value discussion different perspectives that have been informed by their experiences, trajectory or stage of disease, level of expertise, and many other factors.

It is important to note the distinction between patients and consumers in this context. Certainly, patients and consumers share many concerns but their perspectives on health issues can differ. A person with a chronic disease and/or disability relies on the health care system to enable a longer, healthier, and more robust life. A consumer is a generally healthy individual who will move in and out of the health care system as their needs could change over time. This difference may lead to perspectives on the value of new treatments that vary in important ways.

PATIENT-CENTERED VALUE

Value means different things to different people. Establishing a definition of value that is broadly supported across the health care system has been elusive. However, for consistency, the NHC uses the following definition:

VALUE

The **value of a treatment** is commonly viewed by health care payers (i.e., both public and private insurers) in terms of its **effectiveness** and **cost**. Generally, this considers the treatment's effects, both positive and negative, and the costs and cost savings associated with the treatment. From patients' perspectives, value is **individualized** and **disease dependent**, and can **evolve** with the disease trajectory or stage of a patient's life.

PATIENT PERSPECTIVES

Eliciting patient feedback in a meaningful and comprehensive way is necessary because patient perspectives and experience of "value" is unique from other perspectives. One study of patients with metastatic breast cancer showed that more patients emphasize value in terms of their personal benefit *(such as being able to maintain good relationships with family members)* rather than in economic terms.[10] Organizations like the Society for Women's Health Research (SWHR) have highlighted the value considerations for female populations. SWHR has published principles on how value assessors can include specific female populations when they may have been historically excluded from data sets or research *(i.e., lactating or pregnant patients)*. They found that life stages and events like menopause or breastfeeding may change the value of a treatment intervention. These are examples of the unique experience and heterogeneity of value that patients can inform.[19]

The Value Assessment Process

The value assessment process can be broken down into five distinct phases:

SCOPING STAGE

During which the assessment's purpose and goals are established *(e.g., the question(s) the assessment is intended to help answer)*

DRAFTING STAGE

Including subsequent refinements to present the evidence to support the question(s) of the assessment

DELIBERATION STAGE

Discuss the findings and policy implications with stakeholders

DISSEMINATION STAGE

Share the findings and policy implications with stakeholders and a broader audience

UPDATE STAGE

Reflect changes or new knowledge in the disease, treatment, and evidence landscapes as well as to revisit the overall methodology

> **At each stage of the process, there are opportunities and touch points for reaching out and involving patients, family caregivers, and patient organizations. Throughout this document, reference to the development process includes the stages described above.**

VALUE ASSESSMENT METHODOLOGY/EXISTING ASSESSMENTS

The methods within a value assessment may differ from organization to organization, but core components may exist across organizations.

For example, the comparative clinical effectiveness is an evaluation of the evidence on the comparative clinical effectiveness of one treatment versus another and involves comparing the benefits and harms of each treatment. Some value assessment organizations include a cost-effectiveness analysis as part of their value assessment. A cost-effectiveness analysis considers the costs in relation to the clinical benefits of one treatment versus another and usually involves extrapolating data beyond that reported in the randomized controlled trial or available evidence source. Some value assessment organizations may also conduct a budget impact analysis to assess the short-term financial impact of a new treatment.

CONSIDERATIONS OF VALUE ASSESSMENT IN THE FEDERAL GOVERNMENT

Due to the passage of the Inflation Reduction Act (IRA), 2022, the Secretary for the Department of Health and Human Services (HHS) must now "negotiate maximum prices for select brand-name drugs that are covered under Medicare Part B [starting in 2028] (physician-administered drugs) and Part D [starting in 2026] (retail prescription drugs)."[17]

Pharmaceutical companies must send HHS details on these products, including development costs, subsidies they receive from the government, comparative effectiveness research done on other treatments, and more comprehensive economic data. To solicit feedback from the wider community on this change the Centers for Medicare and Medicaid Services (CMS) held 10 listening sessions (one for each of the newly negotiated drugs) in 2023. These sessions were designed to gather input from a broad range of stakeholders, including patients, caregivers, health care providers, and researchers. Patient organizations whose constituents were affected by the negotiated drugs started collecting information and recruiting patient advocates when the listening sessions were announced. Methodological approaches differed among patient organizations with some holding public webinars to discuss the questions while others surveyed approximately 1,000 patients to gather data for the listening sessions. Numerous organizations put together patient statements based on the advocates' stories and CMS' discussion topics. Others submitted data to CMS about the negotiated drugs' and their therapeutic alternatives' impacts on patients. While many patient advocates noted concerns about the format of CMS' efforts to incorporate patient input, they were encouraged that CMS committed to improve the processes moving forward.[18]

The involvement of patient organizations was critical in the effort to bring the patient voice to CMS, ensuring that the real-world impacts of drug pricing decisions were considered in the negotiation process.

DOMAINS OF A PATIENT-CENTERED VALUE MODEL

Roundtable participants agreed that because perceptions of value to patients are likely to differ significantly from perceptions of value to payers, providers, and consumers, value assessments must integrate the patient voice to have practical utility. The participants also agreed that any value assessment must be constructed with six key domains in mind:

1. **Patient Partnership**
   Patients should be involved in every step of the value assessment development and dissemination process.
2. **Transparency to Patients**
   The assumptions and inputs used within each component of the value assessment should be disclosed to patients in an understandable way and in a timely fashion.
3. **Inclusiveness of Patients**
   The value assessment should reflect perspectives from a range of stakeholders, including the patient community.
4. **Diversity of Patients/Populations**
   The value assessment should account for differences across patient subpopulations, trajectory of disease, and stage of a patient’s life.
5. **Outcomes Patients Care About**
   The outcomes integrated into the value assessment should include those that patients have identified as important and consistent with their goals, aspirations, and experiences.
6. **Patient-Centered Data Sources**
   The value assessment should rely on a variety of credible data sources that allow for timely incorporation of new information and account for the diversity of patient populations and patient-centered outcomes, especially those from real-world settings and reported by patients directly. The data sources included should reflect the outcomes most important to patients and capture their experiences.

The NHC Patient-Centered Value Assessment Rubric

The Value Assessment Rubric described below is intended to be a living document or tool to be refined over time based upon feedback from the patients, patient organizations, value assessors, and other stakeholder user experiences.

The rubric will require maintenance, updating, and enhancement as experience and knowledge is collected on its performance. It should be considered a guide for patient-centeredness best practices.

The Value Assessment Rubric comprises two sections:

SECTION 1

Meaningful Patient Engagement in the Value Assessment Development Process

This section outlines characteristics of meaningful engagement in the value assessment development process.

SECTION 2

Patient-Centeredness Considerations in General

The second section focuses on activities that enhance patient centeredness as the assessment is being developed throughout the phases but may not be directly related to patient engagement.

The two sections of the Value Assessment Rubric include a set of characteristics that correspond to the six domains of a patient-centered value assessment, as outlined above. Examples of the type of activities that represent high or low activity within the domain are also included.

Section 1 → MEANINGFUL PATIENT ENGAGEMENT IN THE VALUE ASSESSMENT DEVELOPMENT PROCESS

This section provides characteristics of meaningful engagement that illustrate efforts for incorporation of the patient voice. While a clear understanding of "meaningful" may be evasive, for this document:

MEANINGFUL ENGAGEMENT

Direct relationships and partnerships that are **bidirectional, reciprocal,** and **continuous**. Communications are **open, honest,** and **clear**. Engagement goals, participants, methods, desired impacts, and actual impacts are **clearly outlined and transparent**.[11,12,13,14]

**Please note that the examples provided here are only intended to be illustrative of the characteristic. These examples are not intended to be exhaustive.*

1 Patient Partnership

👍 **HIGH** – Meaningful patient engagement in the process
👎 **LOW** – Low or no meaningful patient engagement in the process

CHARACTERISTICS OF MEANINGFUL PATIENT ENGAGEMENT	Examples of Patient Partnership*	
	👍 HIGH	👎 LOW
Patients are recognized as partners and integrated in all aspects of assessment development phases	Patient input was specifically sought and incorporated throughout the process, from scoping to updating the assessment	Patient input was not specifically sought and was only received as part of a public comment period
Patient partners are supported to enhance participation and capacity to engage	Patient partners were provided with training and user-friendly/ health literate materials, with adequate time to review	No patient-specific resources were developed or provided
Direct input is collected from a wide range of patients through mixed methods as suited to the disease, population, and context ***(surveys, focus groups, structured interviews, shadowing, real-world evidence, etc.)***	Processes were established for conducting a patient survey, interviews of disease-specific patient group staff, and use of a disease-specific registry	Processes only included use of data from randomized controlled trials reporting aggregate clinical outcomes

2 Transparency to Patients

CHARACTERISTICS OF MEANINGFUL PATIENT ENGAGEMENT	Examples of Transparency*	
	👍 HIGH	👎 LOW
The process for selection of patient representatives is transparent	The specific criteria used to identify, select, and invite patient representatives were disclosed, along with a rationale	No systematic process and/or criteria for selecting patient representatives was provided
The patient community has early opportunities for review of and comment on assessment reports.	Patients were given at least three opportunities to review and provide comments without undue limitations as to length *(e.g., word count limits)* or time to respond *(e.g. one month or more)*. Patients may have also been given the opportunity to comment through a two-way dialogue during a live webinar	Patients were given one opportunity to provide input after the draft was fully developed with strict word limits and less than five business days to respond
Health literate tools are available to patients to help them understand all aspects of the assessment and to communicate the assessment to other patients	A work group, with patient participation, crafted a communication strategy for patients including a lay audience friendly summary of the assessment	No patient-specific communication materials were developed
A clear distinction is made in public communications that are accessible to patients about the model development stage *(e.g., draft versus finalized)*	The call for comments was sent directly to relevant patient organizations, was easily accessible to patients, and clearly described that the assessment was still in its drafting stage	The call for public comment was difficult for patients to find on the website and did not disclose stage of assessment or if there would be additional opportunities to comment
Developer responses to public comments are made public to allow the patient community to understand how its input has or has not been used	Each new draft includes a section explaining how patient community comments were addressed	No information was provided on how public comments informed revisions

3 Inclusiveness of Patients

CHARACTERISTICS OF MEANINGFUL PATIENT ENGAGEMENT	Examples of Inclusiveness*	
	👍 HIGH	👎 LOW
Representatives from the patient community are involved throughout the process, as required or expected given the demographics of the condition/population	A rationale was provided for the patient community perspectives that were sought and incorporated throughout the process. Representation and inclusion of patient subpopulations in the process beyond race/ethnicity *(e.g., female, pregnant patients, geographic location, low health literacy, etc.)* among other subpopulations	Input was sought from stakeholders without consideration of the type of stakeholders that would be most appropriate given the condition/population. Value assessors sought perspectives of patients easiest to reach
Assessment results are translated into usable and meaningful information for patients	User-friendly tools were developed with patient input and made available to patients and families for other uses such as shared decision making with clinicians. The tools were successfully tested with the users before public release and are health literate and numerate	The model was intended for shared decision making between patients and providers, but no tools for the patient community were provided

4 Diversity of Patients/Populations

CHARACTERISTICS OF MEANINGFUL PATIENT ENGAGEMENT	Examples of Diversity*	
	👍 HIGH	👎 LOW
Diversity of the patient population from historically and underrepresented and marginalized or minoritized communities is acknowledged and considered	Thoughtful consideration was given to differences in patient experience across relevant patient subpopulations, including populations at-risk and those with early- and late-stage disease	The model assumed the patient population is homogeneous and takes a 'one-size-fits-all' approach
Diverse/historically underrepresented and marginalized or minoritized patient and caregiver perspectives and data are included in the assessment	Diverse and historically underrepresented and marginalized or minoritized patient data are incorporated and delineated in assessments *(e.g., female, rural, Native American patients etc.)*. Researchers may have also needed to increase rates of inclusion of these populations to assess important differences even if that inclusion is larger than the proportionality of those affected in the population. If data is unavailable, then value assessors have created a plan to find or incorporate that data at a later date	The value assessors simply noted that "representativeness" was a limitation but did not make a plan for incorporating more diverse representation or data

5 Outcomes Patients Care About

CHARACTERISTICS OF MEANINGFUL PATIENT ENGAGEMENT	Examples of Outcomes*	
	👍 HIGH	👎 LOW
Outcomes important to patients are identified and incorporated into the assessment, such as: • **Functional status *(mental/ physical/societal)*** • **Health-related quality of life** • **Well-being** • **Clinical Measures** • **Survival** • **Productivity** • **Goals, expectations, aspirations** • **Financial stress**	A clear link was described between the outcomes incorporated into the assessment and their importance to patients	Only clinical outcomes were considered in the assessment without the context or ranking of importance to patients
Other non-medicals factors that are important to patients are considered in value assessment such as: • **Geographics and preferences** • **Other Social Drivers of Health** • **Delineating direct vs. indirect costs** • **Other non-cost related factors**	Value assessors take into account preferences patients have that are based on non-medical factors. For example, rural patients may have a more difficult time accessing infusions and would prefer self-administered treatments. Infusions may also lead to more indirect costs such as to time driving, missed work opportunities, and concerns over care coordination	Value assessors do not take into account these preferences or needs

6 Patient-Centered Data Sources

CHARACTERISTICS OF MEANINGFUL PATIENT ENGAGEMENT	Examples of Data Sources*	
	👍 HIGH	👎 LOW
Existing sources of patient- generated health data* ***(e.g., patient registries or patent- reported outcomes)*** **are identified and considered**	Data on patient-reported outcomes were used, and the sources well described/ transparently communicated in the methodology of value publications or comment periods	No effort was made to identify sources of patient-reported data on physical function, though this was identified by patients as the outcome of highest priority
Data related to the use of apps, devices, wearables etc., is patient centered, and are considered.	Data from patient-centered real-world studies are used in a value assessment. Patient-centered outcomes were considered, and patients were involved at the outset of the study to provide qualitative insights into the results and publications	A real-world study is conducted on patients but does not capture critical data. The wearable device is more commonly used by certain patients than others and this is not noted in the data

*Please note that not all validated patient-reported outcomes and other sources of data are patient-centered. A data source that includes patient-reported data does not automatically mean that the data is patient-centered, especially if the outcomes being measured are not important to patients.

Section 2 → PATIENT-CENTEREDNESS CONSIDERATIONS IN GENERAL

Section II outlines considerations to enhance the patient centeredness of the model in general. Patients, providers, and payers can apply this section to evaluate the extent to which additional steps, beyond engagement efforts, have been taken throughout the development of the value assessment to involve patients. These considerations enhance the patient centeredness of the assessment and the development processes, though patient engagement may not always be direct *(i.e., how to incorporate patient registry information which may not include patient engagement methods).* These are critical considerations when relevant. But if deemed not relevant, a clear rationale should be provided.

**Again, the examples provided below are not intended to be exhaustive.*

1 Patient Partnership

👍 **HIGH** – Meaningful patient engagement in the process
👎 **LOW** – Low or no meaningful patient engagement in the process

PATIENT-CENTEREDNESS CONSIDERATIONS	Examples of Patient Partnership*	
	👍 HIGH	👎 LOW
Rationale to substantiate the adequacy of the ratio of patient to non-patient participants is provided	Of a 10-member advisory committee, 20% of members were patients and 10% of members were a family care-giver, and rationale was provided for stakeholder composition	Of a 15-member team, 0% of members were patients and no transparent rationale was provided for stakeholder composition
Patients are engaged in providing technical assistance to model end-users on implementation	A patient-informed implementation plan was provided	The implementation plan was reviewed by patients after it was constructed by others
Patient engagement in the development process is evaluated, including an assessment of whether patient expectations have been met and if patients realize/see the impact of their engagement	The value assessors learned upon evaluation that patient partners reported: an adequate level of engagement; the assessment reflected patient input; and improvements in engagement processes were offered	No evaluation was conducted to assess patient engagement

2 Transparency to Patients

PATIENT-CENTEREDNESS CONSIDERATIONS	**Examples of Transparency***	
	HIGH	**LOW**
The purpose, goals, and methodology, of the assessment are made clear to patients ***(including the intended audience and use)*** **and are well-defined** ***(includes caution on how the assessment should not be used)***	The goals of the assessment are clearly represented and understandable to patients. The methodology has been communicated in a health literate way	The goals of the assessment are not clear to patients and do not include implications for patients. Details of methodologic limitations were not disclosed to patients until after the assessment was drafted
All assumptions and inputs used are articulated in an understandable, patient-friendly way	The assessment's assumptions and inputs were provided in a publicly accessible table, in a way a layperson can understand	The assessment's assumptions and inputs were described in technical terms and are not easily retrievable
Inputs considered but not used are described with the rationale for exclusion that patients can understand	Methods described why certain patient data were excluded from the assessment	Methods did not acknowledge existing patient data that was excluded from the assessment
Processes for updating and maintaining the assessment are clear and accessible to the patient community	The report explicitly listed factors that result in updates outside of routine maintenance, including new data on patient outcomes	The process for updates outside of routine maintenance were not described
Assessment evaluates unintended consequences for patients	Unintended consequences for patients were considered and publicly addressed	The assessment process missed significant unintended consequences for patients

2 Transparency to Patients *(continued)*

PATIENT-CENTEREDNESS CONSIDERATIONS	Examples of Transparency*	
	HIGH	LOW
Results of any evaluation are made public	Evaluation reports were posted to a website publicly accessible by the patient community	Evaluation reports were only distributed to a small group that excluded patients
Patient partners are acknowledged as contributors/authors to the assessment	The report provided a list acknowledging all contributors, and the patient partners are listed among them with roles	The report did not identify patient partners, leading to questions regarding any patient involvement
All potential conflicts of interest and funding sources are disclosed, including those of patient partners	Potential conflicts of interest and funding sources for work group members were explicitly acknowledged and posted to a publicly accessible website that the patient community could access	Potential conflicts of interest and funding sources for work group members were not publicly available for patients to access

3 Inclusiveness of Patients

PATIENT-CENTEREDNESS CONSIDERATIONS	Examples of Inclusiveness*	
	HIGH	LOW
A role for patients affected by the treatment is considered	Including a patient who had been affected by the treatment on the team was discussed, and the rationale for or for not including one was provided in the assessment report	Inclusion of a patient was not mentioned in supporting documents
Patient partners are engaged to support the deliberation and dissemination of the assessment	Patient partners are active in deliberation and support dissemination efforts	Patient partners have not been involved in the deliberation or dissemination of the assessment

4 Diversity of Patients/Populations

PATIENT-CENTEREDNESS CONSIDERATIONS	Examples of Diversity*	
	👍 HIGH	👎 LOW
Differences in patient perceptions of value, that shift over time as patient circumstances change, are acknowledged and considered *(reflects expected stages over time)*	The assessment accounted for differences over time/disease progression	Consideration was not given to patient-reported shifts in perceptions of value based on disease progression
Applicability and limitations across patient subpopulations and disease trajectory are acknowledged and considered	Information was provided on the assessment's limitations *(for example, younger adults and adolescents were not part of the data used in the assessment)*	The assessment's limitations were not stated; it is assumed incorrectly that assessors sought diverse population input
Processes are included for identifying and incorporating new knowledge regarding patient subpopulations and disease trajectory in different demographics	A mechanism was described that allows patients and other stakeholders to suggest when an assessment update is necessary due to new or changing information about diverse populations	No mechanism was offered for patients to suggest when an update is needed
Patient advisory boards were created to drive better institutional patient practices	The advisory board is made up of a diverse and representative set of patients and caregivers. Patients come from an array of backgrounds *(e.g., insurance type, demographic region, linguistic tradition, gender identity/sex, race and ethnicity, income level etc.)*	Patients with the highest levels of health literacy and proximity are chosen to be on a patient advisory board. Patients may have dual roles and are also health economists or medical doctors

5 Outcomes Patients Care About

PATIENT-CENTEREDNESS CONSIDERATIONS	Examples of Outcomes*	
	👍 HIGH	👎 LOW
Economic inputs are considered in the context of a patient's experience	The model incorporated costs from a variety of stakeholder perspectives, including patient out-of-pocket costs	Only cost issues from the payer perspective were included without rationale for exclusion of patient costs
Processes are in place for identifying and incorporating emerging information on outcomes of importance to patients	A mechanism was described that allows patients and other stakeholders to suggest when an assessment update is necessary due to new or changing information *(i.e., ongoing public comment pages on assessor websites)*	No mechanism was offered for patients to suggest when an assessment is needed

6 Patient-Centered Data Sources

PATIENT-CENTEREDNESS CONSIDERATIONS	Examples of Data Sources*	
	HIGH	LOW
Data beyond randomized controlled trials are considered *(e.g., natural history of disease, patient views, outcomes and/or treatments, patient experiences, patient preferences regarding outcome or treatment characteristics)*	The report described all data sources used, including relevant data outside of randomized controlled trials *(e.g., patient registry data)*	The assessment only included clinical trial data submitted to FDA as part of a new drug application
Rationale for the inclusion or exclusion of available data sources is provided and information is provided in a patient-friendly way	Supporting documents clearly included a discussion of the work group's decision to exclude a data source on patient-reported outcomes	No rationale was provided for why a specific data source was excluded from the assessment

Conclusion

Value assessments can help advance the national dialogue on value in health care, but only if these frameworks incorporate the patient voice. Value assessments must provide enough information such that patients and other stakeholders can assess the assessment's patient-centeredness in order to determine if the assessment can be factored into health care decision making.

The National Health Council Value Assessment Rubric can assist all stakeholders, especially the patient community, in assessing the level of patient centeredness and engagement in a given value model. It is also designed to support value assessors in conceptualizing plans for meaningfully engaging patients. This Value Assessment Rubric is the first step in structuring truly patient-centered value assessments that patients and their families can rely on.

The National Health Council invites use of this Rubric by health care stakeholders and welcomes comments based on use experiences that can help us strengthen the Value Model Rubric.

Appendix I

HOW PATIENT ORGANIZATION INPUT CAN AFFECT AN ASSESSMENT

Many patient organizations have been involved in the value assessment process since 2015. As part of their effort to have their constituents' perspectives represented alongside those of payers, clinicians, and health economists, disease-specific patient organizations have created guiding principles and recommendations for their populations. The following is an excerpt from the Arthritis Foundation's work in value assessment.

Arthritis Foundation Principles on Patient-Centered Value Assessment

"Many people with arthritis have co-morbidities that impact their treatment choices and care. And the lifetime considerations of health costs and outcomes cannot be measured in isolated episodes or short-term windows of time.

A good example comes from 2016 data as part of an RA drug review by the Institute for Clinical and Economic Review (ICER).

- Survey responses showed that patients on average had to try between 2 and 3 drugs before finding one that worked for their disease. And often patients found the drug to be less effective over time, prompting an additional round of treatment changes.
- Anecdotal evidence sheds light on what happens when patients have disruptions in their treatment: symptoms often worsen, leading to the need for further intervention and treatment, and sometimes hospitalization."
- This data was critical to inform the ICER review process and led to recommendations in the final report about the inappropriate nature of step therapy in some cases."[20]

Example of a Comment letter from Arthritis Foundation to ICER with Associated Changes

Arthritis Foundation Comments

March 2017[21]

"Further, we continue to seek clarity on the inclusion of comorbidities in the model. Many patients with arthritis also suffer with comorbidities such as cardiovascular disease, mental health conditions, infections, and malignancies. Of adults diagnosed with arthritis, 47% also have at least one of the previously listed conditions and as many as 40% of people with rheumatoid arthritis (RA) experience significant symptoms of depression . These symptoms can lead to more physical function problems, higher disease activity, physical and social inactivity, poorer health overall, and an increased need for medical care. We urge ICER to revise and incorporate how comorbidities are accounted for in the incremental costs outcome measures."

Final Rheumatoid Arthritis Evidence Report–ICER

April 2017[22]

"Feedback received during the public comment period indicated additional subpopulations or stratifications of interest, including (e) presence of comorbidities *(e.g., cardiovascular, psychiatric, malignancy)*; (f) both "early" *(i.e., within 2 years of symptom onset)* and established RA; (g) seropositivity for prognostic markers such as anti-cyclic citrullinated peptide (CCP) antibodies; (h) geography, in particular U.S.-based versus non-U.S. settings; and (i) study funding *(i.e., industry-sponsored vs. other funding sources)*."

Appendix II

THE NATIONAL HEALTH COUNCIL THANKS THE FOLLOWING ORGANIZATIONS FOR PROVIDING THEIR ASSISTANCE AND EXPERTISE WITH THIS INITIATIVE.*

American Cancer Society Cancer Action Network, Inc.

Aetna Inc.

American Society of Anesthesiologists

Amgen Inc.

Arthritis Foundation

Asthma and Allergy Foundation of America

Bristol-Myers Squibb Company

Cancer Support Community

Crohn’s & Colitis Foundation

Eli Lilly and Company

Epilepsy Foundation

FH (Familial Hypercholesterolemia) Foundation

Mental Health America

National Consumers League

National Multiple Sclerosis Society

National Patient Advocate Foundation

Parent Project Muscular Dystrophy

Patient-Centered Outcomes Research Institute (PCORI)

Sanofi

Society for Women’s Health Research

**The list of participants will be continuously updated on the National Health Council website.*

Appendix III → HELPFUL RESOURCES

PUTTING PATIENTS FIRST
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Value Assessment
Get-Ready Checklist
FOR PATIENT ORGANIZATIONS

Companion piece to the Patient-Centered Value Assessment Rubric

Updated August 2024

Original publication September 2016

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NHC Value-Assessment Get-Ready Checklist for Patient Organizations

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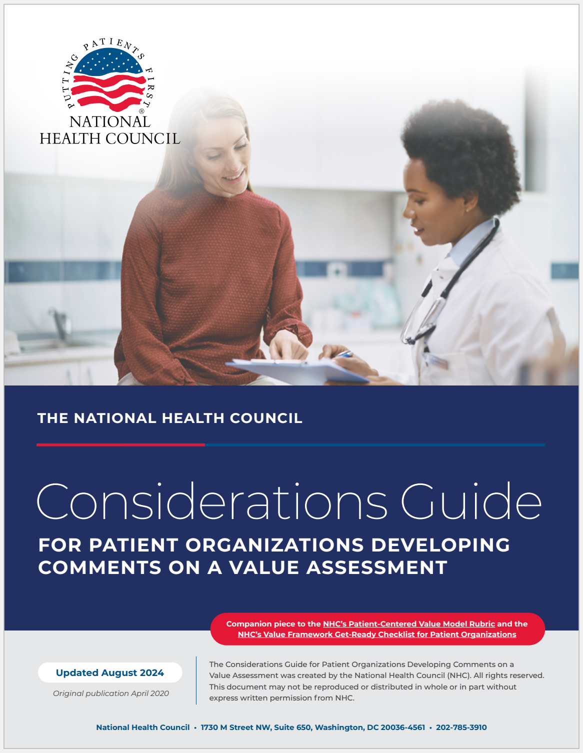

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Considerations Guide
FOR PATIENT ORGANIZATIONS DEVELOPING COMMENTS ON A VALUE ASSESSMENT

Companion piece to the NHC's Patient-Centered Value Model Rubric and the NHC's Value Framework Get-Ready Checklist for Patient Organizations

Updated August 2024

Original publication April 2020

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NHC Considerations Guide for Patient Organizations

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