

KEY CONCEPTS IN PATIENT-CENTEREDNESS, PATIENT ENGAGEMENT, AND PATIENT-REPORTED OUTCOMES

In June 2019, the National Health Council (NHC) released *The National Health Council Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem*.^{vii} The rubric may be useful to registry staff as it includes useful definitions and sections on Meaningful Patient Engagement Processes and General Patient-Centeredness Considerations. The NHC defines “patient-centered” as “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.”^{viii}

There are varying definitions of patient engagement, as well as varying levels of patient engagement in our health care system. Some levels of patient engagement are more clinically focused and could be considered a partnership between the patient and the clinical team. At another level, patients could be engaged in the broader health care process. The following definition is intended to focus on patient engagement more holistically, at the patient to clinical team level:

- ▶ **Patient Engagement:** Partnering with clinicians and the broader care team in exploring, decision-making, and planning health care. Patients can also be engaged in the clinical system through research, registries, quality improvement, etc., which could be separate activities from health care decisions.

Additional concepts in patient engagement and patient-centeredness include:

- ▶ **Patient Activation:** refers to a patient’s knowledge, skills, ability, and willingness to manage his or her own health and care.^{ix}
- ▶ **People First:** People-first language is used to speak appropriately and respectfully about an individual with a disability or condition. People-first language emphasizes the person first, not the disability. For example, when referring to a person with a disability, refer to the person first by using phrases such as “a person who ...,” “a person with ...,” or “a person who has”^x
- ▶ **Shared Decision-Making (SDM):** A process of communication in which clinicians and patients work together to make optimal health care decisions that align with what matters most to patients. SDM requires three components:
 - Clear, accurate, and unbiased medical evidence about reasonable alternatives—including no intervention—and the risks and benefits of each;
 - Clinician expertise in communicating and tailoring that evidence for individual patients; and
 - Patient values, goals, informed preferences, and concerns, which may include treatment burdens.^{xi}

The NHC rubric is paired with a glossary intended to help patients, patient advocates, and other health care stakeholders understand what common terms mean and ensure that everyone collaborating to make health care more patient-centric is speaking the same language. Following are excerpts from the glossary that are important for distinguishing terms and meanings in patient-centeredness and patient engagement.

Key Concept Definitions (Adapted from: <https://www.nationalhealthcouncil.org/resources/glossary-patient-engagement-terms>)

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), whether or not they currently 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 his or her condition and personal circumstances.

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 chronic conditions at every point of contact—from the research bench to the bedside and everywhere in between.

Patient Community: broadly encompasses individual patients, family caregivers, and the organizations that represent them. The patient community is 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.

Patient Engagement in Research: refers to “the active, meaningful, authentic, 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 unique experiences, values, and expertise.”* While this definition refers specifically to research, it is also applicable across stakeholders and engagement activities (e.g., participation in an interview, focus group).

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.

Patient-Reported Outcome (PRO): a subset of Patient Provided Information (PPI); 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.

Patient Information: broadly means all information regarding a patient from any source, such as patient-provided information as well as other medical information about a patient, including but not limited to: test results (e.g., genetic, pathology, imaging), identifying information, family history, provider opinion, and any other information in a patient's medical records.

* ISPOR Patient-Centered SIG. Defining Patient Centeredness and Engagement in HEOR: Proposed Definition and Stakeholder Response. Published May 21, 2018. Accessed April 15, 2019. https://www.ispor.org/docs/default-source/presentations/1388.pdf?sfvrsn=ccb5658d_1.

Integration of Patient-Reported Outcomes

Collecting patient-reported outcomes (PROs) and other patient-provided information (PPI) is often a goal or objective of patient engagement activities. The National Health Council definitions, provided above, offer important differentiations for registries to consider in the development and integration of PROs. It is essential to engage patients, families, and caregivers in projects and activities for identifying outcomes of importance, interest, and meaningfulness to patient stakeholders. However, merely including a PRO questionnaire that fits the needs of an organization and including it in registry data collection does not equal patient-centeredness or ensure that patients are engaged in the registry. According to an article in *Value in Health* titled “Assuring the patient-centeredness of patient-reported outcomes: content validity in medical product development and comparative effectiveness research,” not all patient-reported outcomes are patient-centered and not all patient-centered outcomes are patient-reported. The authors state:

The essential characteristic of a patient-centered approach to outcome measurement is that it assesses concepts (i.e., health-related phenomena) that are considered most important by members of a given target population, based on direct input from representatives of that population. Concepts for measurement should not be selected based solely on convenience or interest to investigators.

Key items for investigators who are developing a new PRO measure, or selecting an existing measure for use in a new study, are to 1) describe all of the concepts reported as important by patients in the target population or in a closely related population, and 2) provide a rationale for which concepts were included or excluded. ... It is critical to remember that research to inform care of patients – and to be understood and interpreted by patients – is one of the targets of Comparative Effectiveness Research; hence patient-centered PRO measures need to be consistently understandable and meaningful to patients themselves, and this generally requires patient input up front.^{xii}

This guidance aligns with the qualitative information from key stakeholders gathered during this project; the best practices suggested include:

1. Prior to PRO implementation, involve patients in PRO selection and implementation decisions
2. Assess how the process of including patients and capturing data is working periodically, not just when issues arise
3. Use various patient-generated data collection methods (e.g., tablet input in office, online survey or questionnaire)
4. Identify how data will be shared with patients and providers, with patient input on how they want to receive information

Patient Engagement Framework

There are many aspects to meaningful patient engagement that are useful to consider when designing approaches to patient inclusion, as well as understanding opportunities for involvement. Figure 1 suggests a framework for patient engagement in their own health and health care in the broader sense.

Figure 1: Framework for Patient Engagement in Health and Health Care^{xiii,xiv}

