



Reaching Consensus on Patient-Centered Definitions: a Report from the Patient-Reported Outcomes PCORnet Task Force

A PCORnet Patient Reported Outcomes Task Force White Paper

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Executive Summary

The [Patient-Centered Outcomes Research Institute](#) (PCORI) developed the [National Patient-Centered Clinical Research Network](#) (PCORnet) to catalyze efficient outcomes research and provide more evidence to the knowledge base to improve patient care. Eleven task forces were created, including the [Patient-Reported Outcomes \(PRO\) Task Force](#), to facilitate the incorporation of information provided by patients across the network to maximize data sharing and interoperability. In this paper, the authors delineate definitions for data contributed by patients with the intent to operationalize these terms within PCORnet.

The PRO Task Force assessed terminology usage across the 29 networks (including 11 clinical data research networks and 18 patient-powered research networks) that make up PCORnet and reviewed current literature to develop baseline definitions. The Task Force held four conference calls with approximately 50 attendees, which included representatives from each of the networks, PCORI staff, and patients to determine the terms and refine definitions. We have adopted and recommend the below three terms to describe the various patient-contributed data types collected across PCORnet. Consistent use of these terms for data contributed by patients will facilitate communication in patient-centered research.

Terms for Patient Contributed Data

PATIENT-REPORTED OUTCOME (PRO): a report that comes directly from the patient about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else.

PATIENT-CENTERED OUTCOMES: outcomes that matter to patients

PATIENT-GENERATED HEALTH DATA: health-related data (such as health history, symptoms, biometric data, treatment history, lifestyle choices, and other information) that are created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern. Patient-generated health data include patient-reported outcomes.



Introduction

In the past few decades, clinical care has shifted to be more patient-centered, resulting in improved outcomes, health status, and efficiency of care.¹ Now, the concept of patient centeredness is extending from health care delivery to clinical research; patients' unique perspectives have the potential to change and improve the way clinical research is conducted and to an even greater extent, influence the research questions asked.² Involving patients in decisions regarding the direction of research gives patients and their caregivers an opportunity to ask research questions that are meaningful to them, to participate in making informed health care decisions, and allow their voices to be heard in assessing the value of health care options and research prioritization.³⁻⁵

To support the mission of involving patients in research, the [US Patient Protection and Affordable Care Act of 2010](#) established the [Patient-Centered Outcomes Research Institute \(PCORI\)](#) to fund patient-centered [comparative effectiveness research \(CER\)](#). The focus of PCORI is to conduct research that answers questions relevant for care, but more importantly, to answer questions that are meaningful and valuable to patients and their families.

PCORI has invested more than \$100 million U.S. dollars to develop a national [Patient-Centered Outcomes Research Network \(PCORnet\)](#) to facilitate efficient clinical outcomes research and provide more evidence for better health care decision making. PCORnet, once fully developed, will operate as a “network of networks” by working directly with patients, clinicians, caregivers, and patient-advocacy organizations to develop and link networks that merge clinical research with the healthcare process. PCORnet will establish data interoperability and sharing across networks for CER⁶ to better respond to patient's priorities and speed the creation of new knowledge. These efforts translate to harnessing the capability to provide CER investigators with large standardized datasets in real time and from real-world data sources such as hospitals, clinics and health plans, and also from individual patients themselves. In an effort to establish PCORnet, PCORI has recruited 29 networks to participate in Phase 1 development of PCORnet including [11 clinical data research networks \(CDRNs\)](#) and [18 patient-powered research networks \(PPRNs\)](#). CDRNs are networks that originate from healthcare systems consisting of hospitals and/or clinics, where patient data are collected as part of routine patient care. PPRNs, alternatively, are disease-specific networks, which include specialty clinics, research organizations (e.g., Arbor Research Collaborative for Health) and patient advocacy organizations, such as the Crohn's and Colitis Foundation of America, that are engaging activated patients interested in sharing health data and participating in research. In addition to the networks, PCORI has formed a [Patient Council](#), an advisory body that provides feedback and recommendations regarding PCORnet policies, ensuring patient engagement on issues related to the protection of patient privacy, consent, and autonomy.



The [PCORnet Patient-Reported Outcomes \(PRO\) Task Force](#) is one of eleven task forces assigned to assist these networks in realizing collaborative data sharing and integration into PCORnet. The PRO Task Force is comprised of representatives from the PPRNs and CDRNs; PCORnet staff; clinicians with experience collecting, analyzing, and using the data; patients and caregivers who either contribute data or facilitate collection as part of an advocacy group; and researchers with expertise in the methodological design, theory and policies surrounding the collection and standardization of patient-generated data. The mission of the PRO Task Force is to provide technical assistance to networks. Specifically, the Task Force is committed to providing and developing strategies, tools, and resources related to the measurement, collection, and analysis of patient-generated health information, including patient-reported outcomes data. Additionally, the PRO Task Force serves PCORnet aims by facilitating the use of patient-reported information and outcomes in the clinical setting as well as in planned research. As a first step in realizing these goals, the PRO Task Force collaborated with the PCORnet networks and patient representatives to develop a common set of definitions for use across PCORnet. The purpose of this paper is to delineate definitions for data contributed by patients in order to facilitate data sharing and interoperability.

Background

Each network within PCORnet is expected to collect and share patient-generated data, including information that comes directly from the patient and their caregivers, who may serve as proxies. In the early conversations among the PRO Task Force members, it became clear that in order to establish a standardized data structure on the scale of PCORnet, the group would need to codify terms and vocabulary to facilitate conversations and ultimately data sharing. For example, the types of data collected widely varied across networks, and the terms used to describe the data were used interchangeably and lacked distinction and clarity. Data collected from patients encompass an array of information ranging from vital signs (e.g., blood pressure) to self-reported health-related quality of life (HRQOL), symptoms, physical function, satisfaction with care, adherence to prescribed medications or other therapy, and perceived value of treatment. Information originating from proxy reports, social networks and wearable mechanical devices may also be considered as being collected from the patient. When the intent of collecting these data is not only to inform clinical care but also to contribute quality data to clinical research (e.g., CER), standardization of terms is critical for interoperability and data sharing across networks. Cataloging of metadata regarding the source and origin of the data (i.e., a patient report or a wearable device) is also necessary. The PRO Task Force determined that during Phase 1 of PCORnet, the CDRNs and PPRNs needed a consistent and cohesive framework for defining patient-reported outcomes, patient-centered data, and patient-generated health data.

The PRO Task Force held four conference calls with representatives from each of the CDRNs and PPRNs, PCORI staff, and patients (approximately 50 attendees). These calls



were used to review terms and definitions that were being used across PCORnet and in the published literature, in order to arrive at a consensus on terminology and definitions for PCORnet.

Assessment of Existing Terminology and Usage

Early in the process, we assessed task force members' applied definitions of the terms *patient-generated data*, *patient-reported outcomes*, and *patient-based outcomes* and solicited how these terms were defined and used within the context of their networks. Respondents replied on the phone or over email. While we did not assess the terms *measure* and *instrument*, we believe they are used consistently across the networks. An *instrument* is a device used to quantify a physical property or concept. An instrument includes all necessary materials for measurement (e.g., a PRO instrument would include the questionnaire, scoring instructions, and validation work). The term *measure* is often used synonymously with *instrument* when referring to patient-reported outcomes.

The assessment revealed that the three patient-centered terms—*patient-generated data*, *patient-reported outcomes*, and *patient-based outcomes*—were being used interchangeably and lacked clear distinction across networks. The networks were collecting patient-generated data (e.g., activity levels) in various forms, ranging from lab values to self-reported survey data to activity monitoring devices, yet little cohesiveness existed to distinguish the nuances of the data being collected. This lack of consistency was also found in the literature.⁷⁻⁹

Patient Generated Data (PGD)

Across the networks, the definition of *patient-generated data* varied substantially as shown in **Table 1** and included: substantial non-health information such as insurance status, socioeconomic background, risk perception/assessment of patient values, and evaluation of healthcare providers; and health-related data (health history, symptoms, biometrics, etc.) that are created, recorded, or collected by patients (or their caregivers). They also included PRO data.

Patient-Reported Outcomes (PRO)

Task Force members reported that the term *patient-reported outcomes* was being defined within the networks to include: data that are generated by patients/parents (not by doctors or researchers), any patient response to questions about their health or experience of care, any patient-reported data about how treatments affect them (e.g., health-related quality of life), survey responses using standard instruments and nonstandard instruments, reports of patient health status that come directly from the patient (functional

status, quality of life, symptom scales, etc.), and outcomes that are actively reported by the patient and that cannot be assessed any other way.

Patient-Based Outcomes

The definition of *patient-based outcomes* was more consistent across networks, with the term being used to refer to outcomes of particular relevance/importance to patients (as determined by patients). The terms *patient-based outcomes* and *patient-centered outcomes* were often used interchangeably.

Table 1. Initial definitions proposed by the CDRNs and PPRNs	
Patient-Generated Data	Patient-Reported Outcome
Substantial non-health information such as insurance status, socioeconomic background, risk perception/assessment of patient values, and evaluation of healthcare providers	Data that are generated by patients/parents (not by their doctors or researchers)
Health-related data (health history, symptoms, biometrics, etc.) that are created, recorded, or collected by patients (or their caregivers)	Any patient response to questions about their health or experience of care
PRO data...but would also include other types of data that fall outside the PRO definition	Any patient-reported data about how treatments affect them”(e.g. QOL)
	Survey responses using standard instruments and nonstandard instruments.
	Reports of patient health status that come directly from the patient (functional status, quality of life, symptom scales, etc.)
	Outcomes that are actively reported by the patient and that can't be assessed any other way

Literature Review

During our discussions of the three terms and associated definitions, we uncovered additional synonyms being used to describe the contribution of health data by patients. Based on feedback from the task force members, we searched PubMed and Google for all the terms that were discussed in our initial assessment of usage and compiled a list of definitions for the following terms: *patient-reported outcomes*, *patient-reported outcome measures*, *patient-generated data*, *patient-generated health data*, *patient-centered outcomes*, *patient-based outcomes*, *patient-based outcomes measures*, *proxy-reported outcomes*, and *patient data*.

We gathered definitions from published material^{1, 7-14} federal agencies and other organizations, including Food and Drug Administration (FDA),¹⁵ the NIH Collaboratory PRO Core,¹⁶ National Quality Forum and National Committee for Quality Assurance,^{10,17} and the Consolidated Standards of Reporting Trials (CONSORT) PRO extension.¹⁸ We assimilated predominant and overlapping concepts that emerged and developed a working set of definitions for discussion.

The working set of definitions derived from the identified candidate constructs is shown in **Table 2**. Proposed definitions were submitted to and discussed by the group and can be seen in **Table 1**.

Table 2. Existing Definitions from the Literature Search

Patient-Generated Health Data	
Office of Policy and Planning Office of National Coordinator for Health Information Technology ¹⁹	... health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern.
Patient-Reported Outcomes	
FDA ¹⁵	... 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.
NIH	Many argue that a key feature of PRO data is that they are not

Collaboratory PRO Core ¹⁶	interpreted by a clinician or any other person; although this may be the ideal scenario, there are times when documented PRO data may incorporate interpretation by a clinician, caregiver, or other person. For this reason, recording the reporter of the information can be an important facet of a PRO dataset.
National Quality Forum ¹⁷	...any report of the status of a patient's (or person's) health condition, health behavior, or experience with healthcare that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else. "PRO" has become an international term of art; the word "patient" is intended to be inclusive of all persons, including patients, families, caregivers, and consumers more broadly. It is intended as well to cover all persons receiving support services, such as those with disabilities.
CONSORT PRO Extension ²⁰	An outcome reported directly by patients themselves and not interpreted by an observer; include assessments of health status, quality of life, satisfaction with care or symptoms, adherence to medication
Basch et al. ²¹	The concept of any report of the status of a patient's health condition that comes directly from the patient (or in some cases a caregiver or surrogate), without interpretation of the patient's response by a clinician or anyone else. An example is the concept of depression.
Proxy Reported Outcomes	
FDA ¹⁵	A measurement based on a report by someone other than the patient reporting as if he or she is the patient. A proxy-reported outcome is not a PRO. A proxy report also is different from an observer report where the observer (e.g., clinician or caregiver), in addition to reporting his or her observation, may interpret or give an opinion based on the observation. We discourage use of proxy-reported outcome measures particularly for symptoms that can be known only by the patient.
Patient-based Outcomes	
Center for Clinical Health Policy Research ²²	... any questionnaire, interview schedule and other related method that assesses the patient's health, illness and benefits of health care interventions from the patients perspective
Sabatini <i>et al.</i> ; ¹¹ Michaud <i>et al.</i> ¹²	Some references in the literature use the term patient-based outcomes to describe questionnaires completed by either the patient or parent/proxy

National Institute for Health Research, Health Technology Assessment Programme ¹³	... an array of questionnaires, interview schedule and other related method that assesses the patient's health, illness and benefits of health care interventions from the patients perspective
Patient-Centered Care	
Institute of Medicine (IOM) ²³	... providing care that honors the needs, wants, values, and preferences of an individual patient
Patient-Centered Outcomes	
PCORI ²⁴	<p>Outcomes that matter to patients</p> <p><u>Answers these questions:</u></p> <ul style="list-style-type: none"> • "What should I expect will happen to me" • "What are my options and what are the potential benefits and harms of those options"? • "What can I do to improve the outcomes that are most important to me"? • "How can clinicians (and care delivery systems) help me make the best decisions about my health and healthcare"?

Consensus Development

Based on the initial assessment, literature review, and subsequent discussion to build consensus, we narrowed the list of terms to the three most widely used in the U.S. literature and having previously found federal or national adoption. We held a final call to reach consensus on the adoption or adaptation of the terms. The proposed terms and their definitions were submitted to the PRO Task Force for a member vote of accept/do not accept and subsequently adopted.

The PRO Task Force recommends the terms *patient-generated health data (PGHD)*, *patient-reported outcomes (PRO)*, and *patient-centered outcomes (PCO)* to describe the various patient-contributed data types collected across PCORnet (**Table 3**). The details of how the Task Force reached consensus on the definitions and attributes of each term are described in more detail below.

Table 3: Final definitions adopted by the Task Force

<p>Patient-generated health data</p>	<p>As defined by ONC:¹⁹ “health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern.”</p>
<p>Patient-reported outcomes</p>	<p>As defined by FDA:¹⁵ “A measurement based on a report that comes directly from the patient about the status of a patient’s health condition without amendment or interpretation of the patient’s response by a clinician or anyone else.” However, the PRO TF also includes proxy-reports as PROs in circumstances where communication via proxy is sole method of communication with patients.</p>
	<p>As defined by PCORI:²⁴ “outcomes that matter to patients”</p>

Patient-Generated Health Data (PGHD)

“Patient-generated health data” is an umbrella term that reflects information of all types that is sourced from the patient. PGHD has been formally defined by the Office of National Coordinator’s (ONC) Federal Advisory Committees (the Health IT Policy Committee [HITPC] and the Health IT Standards Committee [HITSC]) as: “health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (i.e., care partners or those who assist them) to help address a health concern.”¹⁹ The Technical Expert Panel (TEP) on Patient-Generated Health Information (PGHI) convened by National eHealth Collaborative (NeHC) also adopted this definition.²⁵

The PRO Task Force adopted the term “patient-generated health data” as defined by the ONC instead of the less specific term “patient-generated data” because the Task Force is focused on health-related data for incorporation into the overall PCORnet shared data network. This term emphasizes the patient as the responsible party for capturing and recording the data as well as directly sharing data with health care providers and other stakeholders. However, the term does not distinguish the mode of collection, such as whether data came from a wearable device or a survey, and metadata will be necessary to capture this sort of information.

Patient-Reported Outcome (PRO)

The term “patient-reported outcome” (PRO) typically refers to information that is reported by the patient, and includes health-related quality of life (HRQOL), symptoms, side effects, function, and satisfaction. Although valued as outcomes by patients, the PRO data can include descriptive, explanatory, or prognostic concepts.¹⁴ More characteristically, PROs are questionnaires or surveys that assess areas of health concern (i.e. “domains”) such as pain, fatigue, emotional distress, physical functioning, and social role participation.

PRO data capture a patient’s perception of health, which has relevance in clinical care as well as research. In health care settings, the data can help guide clinical decision-making and enhance clinician-patient communication. When consistently collected, the data can give clinicians insight into a patient’s symptom burden or highlight other concerns like underlying depression or drug abuse. Collected properly, these data can contribute to comparative effectiveness research (CER) as well as provide valuable information about hospital performance and health care utilization.

Within a regulatory context, the FDA has defined “patient-reported outcome” as: “A measurement based on a report that comes directly from the patient about the status of a 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 response.”¹⁵ The FDA distinguishes between PROs and “proxy-reported outcomes,” which they define as “a measurement

based on a report by someone other than the patient reporting as if he or she is the patient.” The FDA states that a “proxy-reported outcome” is also different from an observer report where the observer (e.g., clinician or caregiver), in addition to reporting his or her observation, may interpret or give an opinion based on the observation.¹⁵ The FDA discourages use of proxy-reported outcome measures, particularly for symptoms that can only be known by the patient.¹⁵

The FDA’s definition of PROs has become widely accepted. The NIH Health Care Systems Research Collaboratory and the National Quality Forum have both adopted this definition.^{16,17} The National Quality Forum goes further to expand its definition, stating that PRO domains encompass HRQOL (including functional status), symptom and symptom burden, experience with care, and health behaviors. They also state that the word “patient” is intended to be inclusive of all persons, including patients, families, caregivers, consumers, and all persons receiving support services, such as those with disabilities.¹⁷

The CONSORT (Consolidated Standards of Reporting Trials) group similarly defines a patient-reported outcome as: “an outcome reported directly by patients themselves and not interpreted by an observer; PROs may include patient assessments of health status, quality of life (QOL), satisfaction with care or symptoms, or patient-reported adherence to medication.”¹⁸ CONSORT also makes the distinction between outcomes reported by patients and proxies, and states that proxy reports from caregivers or clinicians cannot be viewed as PROs.

Lastly, the European Medicines Agency defined PRO as “any outcome evaluated directly by the patient himself and based on patient’s perception of a disease and its treatment(s).”²⁶ It is proposed as “an umbrella term to cover both single dimension and multi-dimension measures of symptoms, health-related quality of life (HRQOL), health status, adherence to treatment, satisfaction with treatment, etc.”

Because the FDA’s definition is widely used and well established and was most similar to the definitions used by the CDRNs and PPRNs, the PRO Task Force adopted the term patient-reported outcomes as used by the FDA. However, we are expanding the definition to allow support in reporting by caregivers or people who support the patient. Our interpretation of PROs accepts reports from non-clinician caregivers as PROs in instances where patients are incapable of direct communication via self-report (e.g. parent reports for neonatal patients). Because data capture through wearable and other mechanical devices is included in our definition of PGHD, our definition of PRO excludes these types of data, although we include PROs collected through social media. The collection of additional metadata is necessary to make data harmonization, aggregation, and eventually sharing possible. This includes storing information regarding who is answering the PRO questions (e.g., patient), where the data were collected (e.g., home), and when the data were collected (e.g., 6-month follow-up appointment).

Patient-Centered Outcomes (PCO)

Patient-based or patient-centered outcomes refer to measures that are of direct importance to patients; the focus on PGHD and PROs has arisen out of the need to be more patient centric and to address concerns of the greatest importance to patients. Some references in the literature have used the term “patient-based outcomes” to describe questionnaires focused on issues of concern to the patient, completed by either the patient or proxy.^{11,12} The United Kingdom’s National Health Service’s Health Technology Assessment Programme uses the term “patient-based outcome” to refer to an “array of questionnaires, interview schedule and other related method that assesses the patient’s health, illness and benefits of health care interventions from the patient’s perspective.”¹³ This definition is similar to our definition of a PRO because outcomes are measured based on questionnaires, interviews, and other modes of assessment that are reported directly from the patient. In a report in 2001, the Institute of Medicine defined the analogous term “patient-centered care” as “care that honors the needs, wants, values, and preferences of an individual patient.”²³ Most recently, PCORI has defined patient-centered outcomes research as “the evaluation of questions and outcomes meaningful and important to patients and their caregivers.”² PCORI points out that this definition “rests on the axiom that patients have unique perspectives that can change and improve the pursuit of clinical questions.”²

The members of the Task Force emphasized the importance of patient-centered outcomes to be “outcomes of particular relevance/importance to patients,” therefore the PRO Task Force has adopted the term “patient-centered outcomes” and definition from PCORI, which is “outcomes that matter to patients” (**Table 2**).

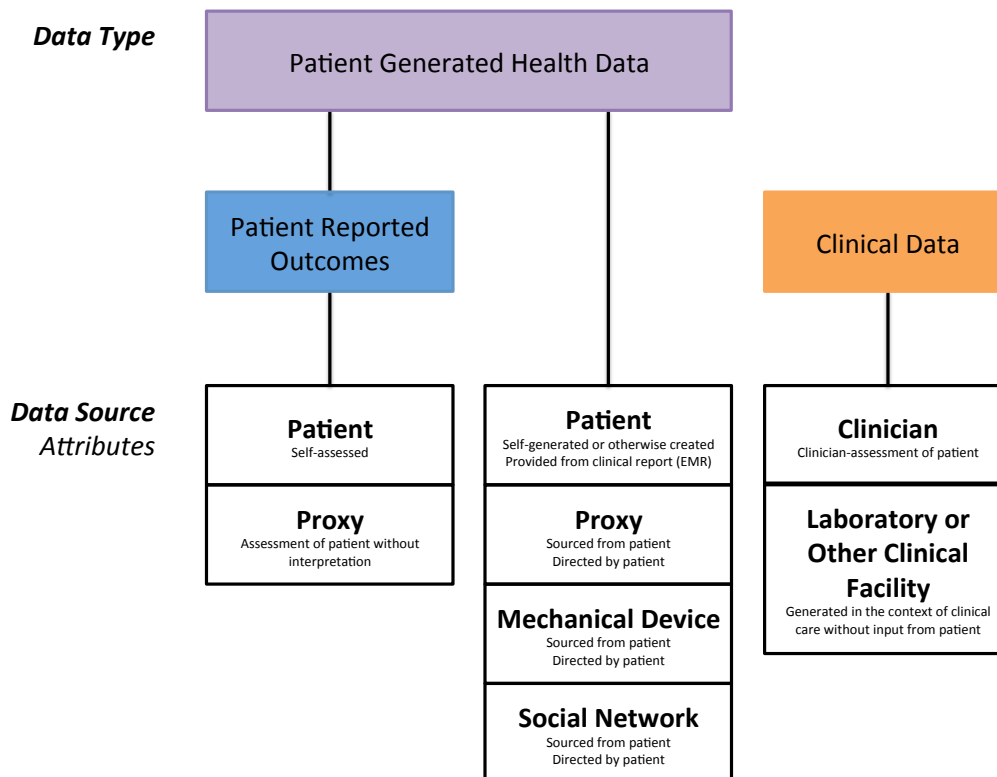
Overlap Between the Terms

Together, these three terms help define the larger picture of patient-centered care. *Patient-centered outcomes* is the most general term (any outcome that matters to patients), and *PGHD* are the data that go into measuring a patient-centered outcome and include vital signs measured/recorded by the patient or proxy; self-reported data on symptoms, functioning, or quality of life (typical PRO data); and information from biometric sensors or home glucose monitoring. Within this context, PROs are just one type of PGHD. However, PGHD are distinct from other data generated in clinical settings in two ways: 1) patients, not providers, are primarily responsible for capturing or recording these data; and 2) patients decide how to share or distribute these data to health care providers and others.¹⁹ For example, PGHD recorded by pedometers may be for personal use or may be used by a clinician as part of care, but the decision to share that information would be the patient’s. PRO measures, conversely, are typically self-reported questionnaires collected at home or in the clinical setting using a validated instrument at the request of a patient’s clinician or as part of a research study. With both PROs and PGHD, the data may not always be included

in the medical record, but often reside in a registry or other database housed by the clinic or research team.

After adopting and refining terms and related attributes for each, the Task Force developed a taxonomy of terms (**Figure 1**). The chart allows PCORnet investigators to easily classify data collected within their networks into one of three categories: PGHD, PROs, and clinical data; patient-centered outcomes data can be represented by any of these data types. The chart includes multiple data source attribute options because understanding the data source—patient-generated health data or clinician data—will enable researchers to extract insights and meaning from what the patient has experienced, and also compare across several networks and even conditions.

Figure 1: Working Phylogeny Chart of Patient-Generated Health Data Terms



Discussion

PRO measures allow for the reporting of patient experiences, without interpretation, rather than in clinical language. For example, where patients may explain that they are

experiencing stomach upset or discomfort, clinicians would translate that to words such as dyspepsia that are less meaningful to patients. Future work will focus on recommendations for common PRO measures that could be adopted across the PPRNs and CDRNs to assess patient-reports broadly across PCORnet, and the need for additional data fields housing metadata that describes the environment in which the data were collected. These tools facilitate the collection of research quality data.

As PCORnet expands and matures, so too will its data structure. To the PRO Task Force, this means thinking critically about the patient-generated health data and ways to standardize the process of data collection and sharing, while ensuring that there are methods in place to study outcomes that are meaningful to patients. In the near term, our objective is to codify the language we are using within our task force to start these discussions.

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