

Improving Patient-Centered Outcomes Research through Better Collection and Use of Participant-Provided Information

Participant-provided information (PPI) has emerged as a key data source in research on patient-centered care, as PPI provides an essential perspective into patients' symptoms and experiences that is often not captured in the regular course of clinical care.² PPI is also an important data source for addressing health inequity as it considers the conditions under which people live, such as socioeconomic status, education, and employment.³ These social determinants of health (SDOH) include systemic issues such as racism and discrimination and reflect the primary drivers of health inequity.⁴ Likewise, PPI can inform multiple aspects of the care process—from prevention and diagnosis to treatment and long-term care, and can also inform researchers' interpretation of clinical trial results as well as support effective drug and device surveillance. The term PPI has evolved over the years and can include patient-generated health data (PGHD), such as data from wearables and medical devices, and patient-reported outcomes (PRO) data such as scales of pain intensity or physical function.^{5,6}

"Periodic data collection that happens within the clinical delivery system only offers a snapshot into a patient's disease. Linkage of patient-reported data to clinical data will lead to stronger evidence to support patient-centered outcomes research."¹

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From these diverse sources of PPI, there is a wealth of valuable health information available and an ever-growing number of digital health tools to collect it (see Exhibit 1). However, it is challenging to use PPI data in patient-centered outcomes research (PCOR). Key data infrastructure challenges include the need to: 1) develop and disseminate standards to support PPI data collection and analysis; 2) improve mechanisms to promote the collection of these data among both patients and clinicians; and 3) integrate PPI into the electronic health record (EHR).⁷ OS-PCORTF projects across HHS agencies are working to expand data capacity or data infrastructure for the collection and use of PPI specifically around these challenge areas.

Exhibit 1. Patient-Provided Information (PPI) Sources and Information Flow



Development and Dissemination of Standards to Support PPI

Collection & Analysis. A lack of standards, inconsistent application of existing standards, and data quality issues among PPI limits its usability in PCOR. Although it is a rich potential data source, these quality and consistency issues mean that similar types of data collected from different sources or in different formats cannot be easily aggregated or compared. Standardizing PPI data and ensuring it is recorded consistently in the EHR is an important step in making it broadly usable, as this provides assurance to providers, researchers, and others who would like to incorporate PPI into care and research.

Use of the ADAPTABLE Trial to Strengthen Methods to Collect and Integrate Patient-Reported Information with Other Data Sets and Assess Its Validity

The NIH project, *Use of the ADAPTABLE Trial to Strengthen Methods to Collect and Integrate Patient-Reported Information with Other Data Sets and Assess Its Validity*, began in 2016 to build upon ADAPTABLE, the first major randomized comparative effectiveness trial to be conducted by the National Patient-Centered Clinical Research Network (PCORnet). Given that ADAPTABLE relied on patients to report key information at baseline and throughout follow up, it provided a unique opportunity to develop, pilot, and evaluate methods to validate and integrate PPI with data obtained from EHRs. The team developed, piloted, and evaluated data standards for PPI to describe the completeness, consistency, and fitness-for-use of patient-reported health data. They also evaluated the face validity of patient-reported data through systematic comparison to EHR data, and identified approaches to resolve inconsistencies between patient-reported and EHR-derived data.

KEY PRODUCTS

- Tools: The Patient-Reported Data Assessment Tool and technical and user documentation are publicly available on [Github](#)
- Key Data Elements: These have been added to the [NIH CDE Repository](#)
- Publication: Findings from a literature review describing the [data standards and metadata standards for patient-reported health data](#) was published in a report along with recommendations for [new patient-reported element Logical Observation Identifiers Names and Codes \(LOINC\) terms](#) that were released for trial use.

PROJECT AGENCIES: NIH

Improved Mechanisms to Promote the Collection of PPI. The collection of PPI is dependent on the participation of both patients and clinicians. Thus, efforts to improve collection of these data must be centered on making it easier for patients to report outcomes and easier for clinicians to use PPI data by integrating it in the clinical workflow.

Collection of Patient-Provided Information through a Mobile Device Application for Use in Comparative Effectiveness and Drug Safety Research

The FDA's *Collection of Patient-Provided Information through a Mobile Device Application for Use in Comparative Effectiveness and Drug Safety Research* project, funded in 2015, developed the widely-applicable MyStudies app. The app was designed to link PPI with claims and EHR data from Sentinel's participating partners. While initially piloted among pregnant women, the app can be reconfigured for diverse patient populations and utilized across a vast range of health-related research topics, allowing for a novel level of flexibility in healthcare research. For example, the FDA has leveraged the MyStudies app to build the COVID MyStudies app,⁸ which allows investigators to send informed consent forms directly to patients. Having a secure electronic option for patient consent safeguards clinical trials and other health research from disruption and delay during the pandemic.

KEY PRODUCTS

- The [MyStudies app](#) is built using the [ResearchStack \(Android\)](#) framework and [Apple's ResearchKit \(iOS\)](#) framework, allowing researchers to easily customize the flow and content as well as integrate other data sources.
- The source code for the app is publicly available on [GitHub](#) so that developers can improve on its capabilities.
- The [user documentation and a report summarizing the development of the menu-driven query tool](#) is on the NIH Collaboratory Living Textbook.
- Two publications discuss using patient-reported health data in clinical trials: [Rockhold et al. JAMIA 2020](#) and [Bennett et al. Healthcare 2020](#).

PROJECT AGENCIES: FDA

The Crohn's & Colitis Foundation has also built upon the FDA MyStudies Mobile App through an integration that enables their research information exchange platform, IBD Plexus, to transfer information to the app and trigger patient surveys. These surveys are used to fill important information gaps critical to advance research. Use of the app has also enhanced the ability to capture patient experience data beyond the clinical care system to establish a comprehensive picture of patients' disease journeys.

Integration of PPI into EHRs. Integrating PPI into EHRs facilitates the use of these data during clinical visits and makes it easier to combine PPI with robust clinical data within the EHR to be used for PCOR. Three active OS-PCORTF projects are seeking to improve integration of PPI into EHRs.

Advancing the Collection and Use of Patient-Reported Outcomes through Health Information Technology

The AHRQ and ONC project, *Advancing the Collection and Use of Patient-Reported Outcomes through Health Information Technology*, began in 2017 to standardize the integration of PPI in EHRs and support the use of this information at the point of care. When accessible to the provider, PPI can be used to inform shared decision-making and patient-provider communication, care planning, and goal setting. Shared decision-making is a promising strategy for improving health equity as it helps better engage patients in their healthcare.⁹ This project developed implementation specifications and applications to enable standardized collection and use of PRO to make the data more available for research and healthcare delivery.

KEY PRODUCTS

- The **PRISM app** developed through the **AHRQ Step Up App Challenge competition**.
- Implementation Guide: **The PRO Fast Healthcare Interoperability Resources (FHIR) Implementation Guide (IG) (and Pilot Test)**
- A **final report** on the project accomplishments
- **Webinar slides** describing the FHIR PRO Implementation Guide

PROJECT AGENCIES: AHRQ AND ONC

Capstone for Outcomes Measure Harmonization

To facilitate the standardized collection, linking, and use of PPI data, a 2018 AHRQ project, *The Capstone for Outcomes Measure Harmonization* project, assisted providers with the collection of harmonized depression outcome measures in EHRs. The team assessed the feasibility of collecting standardized depression measures using routinely captured clinical and patient-reported data from EHRs and transferring those data to existing patient registries. It also assessed the potential for registries to share information back to the clinical sites. Three different entities participated in testing the data PRO collection methods, transfer of information, and integration of the data into their EHRs. The goal was to increase the data available for use in diverse research settings, including clinical research, patient-centered outcomes research, and quality improvement and implementation research, and to do so in a way that fit into provider workflows.

KEY PRODUCTS

- The FHIR **Outcome Criteria Framework Implementation Guide**
- An **article** highlighting AHRQ's Outcome Measures Framework
- A **white paper** describing the technical approach used to prepare the Standardized Library of Depression Outcome Measures
- **Findings** from the multi-stakeholder panel including the 10 standardized outcome measures

PROJECT AGENCIES: AHRQ

Data Capacity for Patient-Centered Outcomes Research through Creation of an Electronic Care Plan for People with Multiple Chronic Conditions

A 2019 project from AHRQ and National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases (NIH/NIDDK), *Data Capacity for Patient-Centered Outcomes Research through Creation of an Electronic Care Plan for People with Multiple Chronic Conditions*, is developing an interoperable clinician-facing electronic care (eCare) plan. This tool provides standardized information that clinicians can use to collect patient health concerns, preferences, interventions, and health status over time—and allows patient-centered data to be aggregated from diverse data sources.

Data aggregation is particularly important and challenging for people with multiple chronic conditions (MCC), who have complex health needs handled by diverse providers, across multiple settings of care. PCOR is needed to better understand optimal care for these complex patients, yet comprehensive data enabling the study of factors influencing outcomes across multiple conditions and disease states in real-world settings are largely unavailable. The clinician-facing eCare plan app will also allow for the collection of SDOH data such as food insecurity, poverty, and homelessness. This information is particularly useful in advancing health equity as it provides insights on barriers that a patient may face adhering to their care plan so that the care team can support them.

A companion project, *Data Capacity for Patient-Centered Outcomes Research through Creation of an Electronic Care Plan for People with Multiple Chronic Conditions 2.0* will focus on building a patient-facing version of the eCare app. Like its counterpart, the patient-facing eCare app will focus on improving data collection for individuals with MCCs; specifically, chronic kidney disease (CKD), cardiovascular disease (CVD), diabetes, and/or chronic pain with or without opioid use disorder (OUD). By working in concert with the clinician-facing app, the patient tool will enrich current understanding of the complex care requirements and outcomes of high-need patients.

KEY PRODUCTS

- **Collaboration Website:** To manage tasks, share documents, and facilitate discussions
- **Draft IG:** To implement the eCare Plan software application:
- **Draft App:** The clinician-app code and materials.
- **HL7 Connect-a-thon materials:** Documents the testing of the app and the IG
- **MCC Clinical Information Model for CKD** is available on the project website.

PROJECT AGENCIES: AHRQ AND NIH/NIDDK

Looking to the Future. All of these projects fill technical and non-technical gaps in the PCOR landscape. By addressing technical aspects of standardizing PPI for exchange and integration, these projects will inform new and innovative ways to leverage this valuable data for research. The projects are exploring ways to make it easier to both collect and use PPI to improve care and advance health equity.

In December 2019, Congress reauthorized the PCORTF for 10 additional years, which will allow for additional OS-PCORTF-funded projects over the next decade. Future directions may include efforts to address data privacy and security issues, create core data elements from digital health sources, as well as further improvements to integrate PPI into clinical practice. Keeping pace with this rapidly evolving digital health landscape requires a continued coordinated effort. OS-PCORTF is uniquely positioned to support synergies both within and across federal and state institutions as well as outside of the government through private/public collaborations. Through the OS-PCORTF portfolio, ASPE has successfully fostered collaborative efforts across multiple agencies that improve the collection, integration, and standardization of valuable PPI data, creating enhanced opportunities for patient-centered outcomes research.

ADDITIONAL OS-PCORTF FUNDED PROJECTS

- The 2015 ONC project *Conceptualizing a Data Infrastructure for the Capture and Use of Patient-Generated Health Data* created a policy framework for the use of PPI in research and care delivery, then pilot tested the concepts and implementation of the framework.
- In the NIH's *Emergency Medicine Opioid Data Infrastructure: Key Venue to Address Opioid Morbidity and Mortality* project, begun in 2018, the project team is assessing the feasibility of using certain opioid use disorder (OUD)-specific Common Data Elements (CDEs) to capture PPI in emergency departments.
- Since 2017, the FDA, NIH/NLM, and ONC have collaborated on *Developing a Strategically Coordinated Registry Network to Support Research on Women's Health Technologies* to create a coordinated registry network for women's health technologies that collects and links standardized patient-reported outcomes.
- In 2018, the FDA completed the *Source Data Capture from Electronic Health Records: Using Standardized Clinical Research Data* project, creating tools and methods to automate the flow of EHR data into clinical trial data collection systems. OneSource focused on data elements related to large adaptive clinical trials for breast cancer, including biomarkers and PROs, but its tools are appropriate for broader use; for example, OneSource has been deployed for electronic clinical trial consent processes during COVID-19.

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