NORC
at the University of Chicago

Expanding Patient Reported Outcomes and Patient Generated Health Data across PCORnet®

Executive Summary

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Presented to:
Patient-Centered Outcomes Research Institute (PCORI)

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The Patient-Centered Outcomes Research Institute (PCORI®) is undertaking a multi-step assessment process as it considers data infrastructure enhancements to PCORnet®, the National Patient-Centered Clinical Research Network. PCORnet ("the Network") is a distributed research network with a national scope, including Clinical Research Networks (CRNs) patient partners, and a Coordinating Center. These partnerships allow researchers to query millions of clinical, claims, and registry records to support efficient, high-impact comparative clinical effectiveness research (CER) within a secure, privacy-preserving structure.

One of the resources PCORnet uses to enhance the usability and "research readiness" of Network data is the PCORnet common data model (CDM), which standardizes data from the numerous Network Partners into a consistent format. PCORI is considering enhancements to the CDM, as well as other data infrastructure improvements that would increase data availability and accessibility across PCORnet in the short-term, mid-term, and long-term.

PCORI has identified three areas of interest for data infrastructure enhancements:1) social determinants of health (SDOH); 2) patient-reported outcomes (PROs) and other patient-generated health data (PGHD); and 3) Centers for Medicare & Medicaid (CMS) claims data. Under a contract from PCORI, NORC at the University of Chicago is conducting an assessment of opportunities in these three areas.

This paper articulates NORC's findings on the current state of PROs and PGHD collection within PCORnet, challenges for expanding PCORnet infrastructure to increase the availability and accessibility of PROs and PGHD within the Network, and opportunities for data infrastructure expansion. These findings are based on a survey of health systems participating in PCORnet; a literature review; and key informant interviews (KIIs) with stakeholders associated with PCORI, PCORnet, and those with expertise in data infrastructure for the collection and standardization of PROs and PGHD.

For the purposes of this paper, PRO and PGHD are defined as follows:

- **PRO**: A measurement based on a report directly from the patient (or their designated proxy) about the status of a patient's health condition without amendment or interpretation of the patient's response.

- **PGHD**: Health-related data created, recorded, or gathered outside a clinical setting— through a mobile application, device, or patient portal—by or from patients (or family members and other caregivers).

Current State. The survey provided insights into the current landscape of PRO and PGHD collection and use among 53 of the 75 health systems participating in PCORnet.

- Most health systems that completed the survey reported that they are collecting PROs as part of clinical care. However, the extent to which there is a single common PRO measure used across health systems is unclear. While the majority of health systems collecting PROs are using PROMIS measures, aggregately health systems indicated they were collecting nearly 500 distinct PROs, with limited overlap in measures used.
- Integration of PRO data into the electronic health record (EHR) greatly varies across health systems. Nearly half of health systems that currently collect PRO data reported

they have full EHR integration (i.e., PRO data are fully integrated with other data within the EHR and can be plotted along with other data).

- Over half of health systems who completed the survey stated that they were planning to expand PRO collection. These plans included expanding PRO collection to all clinical specialties and improving processes for collecting PRO data to reduce patient burden on tasks like filling out forms.

- For many health systems, PGHD collection is still at an early stage, with limited EHR integration. Health systems that are collecting PGHD are primarily focused on collecting biometric data, symptoms, and health history. These data are most commonly collected through the patient portal. Multiple health systems report having plans to expand PGHD collection within the next 2-4 years.

Opportunities. Based on the current state of the PCORnet data infrastructure and the existing PRO data and PGHD within the Network, challenges and opportunities for expansion and investment were identified in four areas:

- *Leveraging PRO Data Collected as Part of Routine Clinical Care*
  - ► Conduct additional surveillance to identify commonly used PRO questionnaires and measures: The extent to which there are common PRO measures collected across the Network is unclear. Given that PRO collection is often dictated by policy initiatives and incentives, commonly collected measures may exist within certain disciplines or clinical areas (e.g., orthopedics, oncology, behavioral health). Additional surveillance efforts could identify the full range of PROs collected by CRNs to determine common measures. (Short-term)
  - ► Standardize a subset of commonly used PRO measurement instruments across PCORnet CRNs: PRO measures are often validated and standardized; however, health systems may use different versions of the same instruments. Conducting pilots to examine the extent to which question and response strings differ across sites for commonly used PRO measures would inform the standardization of a subset of PRO instruments across PCORnet CRNs. (Short-term)
  - ► Identify use cases to develop processes and workflows for standardizing PRO measures within the CDM: Capturing PRO data from EHRs into the CDM requires local development of processes to extract, transform, and load (ETL) data. ETL processes for PRO data are often developed by sites on a study-specific basis. Supporting the development of processes and workflows for standardizing PRO measures for specific use cases (e.g., oncology, orthopedics, behavioral health) within the CDM would build capacity for PRO data capture. (Mid-term)
  - ► Enhance PCORnet data curation processes to ensure that existing PRO data are "research ready": Current quarterly PCORnet data curation processes do not include the limited PRO data included in the CDM. Therefore, quality checks for "research readiness" do not occur until a relevant query (i.e., research question) is submitted to CRNs. The "research readiness" of available PRO data may be limited as there are differences in the latency of PRO data, the use of item-level scores or summary scores, and where PRO data elements are stored within the CDM. Additional steps can be taken

to ensure the data are research ready such as: 1) using test queries to proactively assess data quality; 2) providing instruction regarding the inclusion of item-level responses and summary scores; 3) reducing the latency of PRO data submitted by participating sites. (Mid-term)

- *Facilitating the Loading and Use of PRO Data Collected During Research*
  - ► <u>Develop a repository of PRO questionnaires for sites to use</u>: CRNs serve as venues for prospective collection of PRO data as part of research. For research studies, PRO data are often collected via platforms such as REDCap, with research teams developing study-specific data dictionaries and PRO instruments. This introduces heterogeneity in how PROs are collected. Supporting the development of a repository of PRO instruments— initially focusing on a small set of measures that are used frequently across research studies— that are importable within survey platforms would help reduce the heterogeneity of PRO data collected for research. (Mid-term)
  - ► <u>Identify data infrastructure supports both locally (i.e., for participating health systems) and centrally (i.e., across the Network) for PRO data collection for PCORnet Studies</u>: PRO data collected as part of research are not routinely loaded into the PCORnet CDM because researchers are used to their existing workflows and developing site-specific ETL processes is resource intensive. Supporting and bolstering local infrastructure, such as developing a plugin for a subset of survey/data collection platforms that would support simultaneous updates of instruments across sites, would advance standardized collection of PRO data. (Short-term) A centralized approach, such as establishing or leveraging an existing centralized platform for data collection in PCORnet designated studies, would standardize PRO collection and support the seamless ETL of data into the PCORnet CDM. (Long-term)

- *Engaging Stakeholders around PRO Data Priorities for the PCORnet CDM, Clinical Care, and Research*
  - ► <u>Address variation in mapping of PRO data elements in the CDM</u>: Researchers may have different interpretations of how PRO data should be mapped to fields in the CDM. Reconciling mapping for each individual study can be time consuming and create delays in research completion. Convening Network stakeholders, potentially through a workgroup, to better define PRO data mapping in the CDM and to determine if revisions are needed to the PRO CDM table would reduce the need for reconciliation during individual research efforts. (Short-term)
  - ► <u>Define meaningful measurement for PROs</u>: To be valuable in research, PRO data must be meaningful to patients and other stakeholders, including health system leadership. Identifying meaningful PRO measures will require engaging stakeholder groups to identify opportunities for improving PRO collection and use in a way that is mutually beneficial. These conversations may be an opportunity to identify PRO measures that are both primed for standardization and meaningful to patients and other stakeholders. (Mid-term)

- *Enhancing the PCORnet Data Infrastructure to Load and Leverage PGHD for Research*
  - ► <u>Pilot modifications to the PCORnet CDM specification that support the capture of certain types of PGHD</u>: The survey found that several health systems within CRNs see increased capacity for the capture and integration of PGHD as a broader goal for their system. Currently, the PCORnet CDM does not support the capture of PGHD collected from patient portals, wearable devices, and medical devices. Gaining buy-in from Network Partners and piloting modifications to the PCORnet CDM would support the capture of PGHD data—starting with the inclusion of dedicated fields for promising use cases (e.g., home blood pressure machines, glucometers) and, in the longer-term, developing and piloting a separate PGHD CDM table. (Mid- and long-term)

Next Steps. These opportunities will be discussed as part of a public-facing webinar on December 14, 2021, presented in collaboration by NORC, PCORI, and five technical and industry experts. These experts will provide context and perspective on the four opportunity areas above and engage the audience in a discussion to draw out further suggestions for PCORnet data infrastructure improvements.