Engaging Patients to Enhance Data for Health Outcomes Research

To help patients make informed choices about their care, the United States Department of Health and Human Services (HHS) is improving the quality and accessibility of data needed to determine which treatments and care options work best. Resources from the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS-PCORTF) support HHS data infrastructure projects that engage patients and improve the collection of data from patients about their care. Using these data in health outcomes research helps ensure the evidence generated reflects patient preferences, needs, goals, and values.

The following highlights OS-PCORTF project activities to engage patients, project accomplishments, and potential future work to enhance data for research.

Incorporating Patient Perspectives in Evidence Generation Supports Research that Reflects What Matters Most to Patients[1,2]

OS-PCORTF projects have strengthened the inclusion of patient perspectives in health outcomes research to help ensure that the evidence generated reflects the treatment outcomes that are important to patients. Researchers can use this evidence to improve resources, such as care and wellness plans, that are developed for patients and their care teams to make evidence-informed decisions.

HHS agencies enhanced collection and representation of patient perspectives and experiences in medical device registries for use in future research.

- Patients were engaged in stakeholder meetings to provide input on critical data to include in a coordinated registry network (CRN) of three medical device registries.
- The project helped improve the quality of registry data available to study and compare the long-term safety and effectiveness of medical devices used in the treatment of women's health conditions.
- The project was expanded to enhance 12 additional CRNs in different clinical areas. These enhancements included capturing patient-reported outcomes data and patient preferences in the registry data.

Learn more: *Developing a Strategically Coordinated Registry Network (CRN) for Women's Health Technology* **(FDA, NIH, and ASTP/ONC)**
Bridging the PCOR Infrastructure and Technology Innovation through Coordinated Registry Networks (CRN) Learning Community **(FDA)**

The CDC collected input from people with intellectual and developmental disabilities (ID/DD) to improve research on interventions and treatment outcomes for this population.

- The project team sought patient feedback to develop a tool that helps clinicians collect information from people with ID/DD during medical visits. This tool helps ensure that people with ID/DD are better represented in administrative datasets used for research focused on improving ID/DD care.
- Individuals with ID/DD and their caregivers provided input to the project team on the most relevant information to capture at the point of care.

Learn more: ***Engaging People with Intellectual and Developmental Disabilities to Enhance Functional Disability Representation in Point of Care Settings*** **(CDC)**

Looking Ahead To promote patient-centeredness in the research process, researchers should engage patients early. For example, patients can be involved in advisory groups to ensure that data on relevant patient outcomes are collected and the evidence generated is meaningful to patients. Additionally, researchers can encourage patient engagement by simplifying data collection tools to make it more efficient for patients to contribute information.

Collecting Standardized Patient-Centered Outcomes Data Allows Patients to Share Information about their Health Experiences

OS-PCORTF projects have improved the collection and use of patient-reported data to support more personalized care. Collection of patient-reported data that reveals how they feel about their treatment, symptoms, quality of life, and outcomes can complement information from clinical data when used in health outcomes research. Clinicians can then use these data to tailor treatment plans to individual patients.[3]

HHS agencies partnered to make it easier to collect patient-reported outcomes (PRO) data from patients.

- The project teams developed a standards-based implementation guide to consistently collect, integrate, and exchange PRO data between different health care organizations with different electronic health records (EHRs).
- Patients were interviewed to provide feedback on the usability and perceived helpfulness of a PRO data collection app.

Learn more: ***Advancing the Collection and Use of Patient-Reported Outcomes (PRO) through Health Information Technology*** **(AHRQ and ASTP/ONC)**

The NIH developed and tested data standards that help guide researchers on how to incorporate patient-reported health data into health care effectiveness studies.

- Patient representatives participated in reviewing the proposed patient-reported data elements to assess their quality and appropriateness for inclusion. By including data reported directly by patients, researchers can more comprehensively assess the effectiveness and safety of medication prescribed to patients with cardiovascular disease.

- The project team also developed a method to quickly and efficiently evaluate the reliability of patient-reported data compared to EHR data, further improving the proper use of patient-reported health data. Researchers can use these methods to incorporate patient-reported data into studies on many different diseases and conditions.

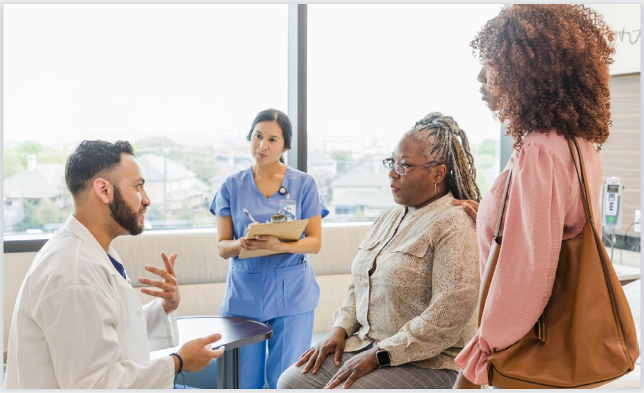
Learn more: *Use of the ADAPTABLE Trial to Strengthen Methods to Collect and Integrate Patient-reported Information with Other Data Sets and Assess Its Validity* **(NIH)**

Looking Ahead To improve the quality of the evidence from real-world ("pragmatic") clinical trials, researchers need to better understand how well EHR data captures all relevant patient health outcomes and they require tools to better identify patient-reported health data for use in these trials. To promote more efficient collection, exchange, and use of PRO data in clinical care and research, work is needed to: 1) enhance data exchange standards; 2) develop artificial intelligence tools that efficiently analyze PRO data to help clinicians use the data in patient care decisions; and 3) increase awareness among patients and care teams of the value of PRO data to promote shared decision-making, patient self-management support, and tailored care planning, goal setting, and goal attainment.

Empowering Patients as Partners in Health-Related Decision-Making Improves their Active Engagement and Experiences with Care[4]

OS-PCORTF projects have empowered patients to be more involved in activities that facilitate care decision-making. Patient-centered health outcomes research focuses on collecting data from patients about outcomes that matter most to them, which can inform decisions about benefits and risks for a given individual. Patients can feel empowered to use this information in discussions with their clinicians about which care options will be best for them.

HHS agencies collaborated to develop an interoperable, electronic care plan (eCare Plan) app and implementation guide for care coordination of multiple chronic conditions across EHRs, providers, and care settings.



- The eCare Plan app makes data available to patients, researchers studying real-world health outcomes, and providers and health systems striving to improve quality and safety.
- The patient-facing eCare Plan app empowers patients to access and update their eCare Plan information and submit patient-reported data and other data important to patients, such as functional status and goals, to their providers.
- Patients were engaged as partners in developing the eCare Plan app and tested the patient-facing tools to ensure usability.

Learn more: *Data Capacity for Patient-Centered Outcomes Research through Creation of an Electronic Care Plan for People with Multiple Chronic Conditions* **(AHRQ and NIH)**
Data Capacity for Patient-Centered Outcomes Research through Creation of an Electronic Care Plan for People with Multiple Chronic Conditions 2.0: Development of the Patient-Facing Application **(AHRQ and NIH)**

The FDA expanded the CURE ID platform, designed to collect and share real-world data on the treatment experiences of patients affected by diseases that have few known cures.

- Patients provided input on which health outcomes collected in the CURE ID database were important and meaningful to them.
- A patient and caregiver advisory group for CURE ID meets monthly to guide the program and provided feedback on how to make the platform more accessible to non-clinicians.
- The new CURE ID platform allows patients to submit data about their treatment experiences directly to CURE ID, providing more comprehensive data for clinicians and researchers to use in identifying potential treatment options for diseases that are hard to treat. Nearly 600 patients and care partners have submitted data to CURE ID.

Learn more: ***CURE ID: Aggregating and Analyzing COVID-19 Treatment from EHRs and Registries*** **(FDA)**

Looking Ahead To promote adoption among patients, researchers should consistently utilize user-centered design practices and place emphasis on user design requests driven by patient care needs. To improve patient-centeredness, future care planning tools should focus on supporting the capture of patient-reported information. For example, health goals can be tracked and updated over time to determine how attainment of these goals affect patient-centered outcomes.

Patient engagement is essential for building a stronger data infrastructure for research and practice. OS-PCORTF project teams work collaboratively with patients to identify meaningful data, develop accessible tools, and ensure the nation's research is driven by their perspectives. This approach benefits patients as well as researchers, clinicians, and decision makers. By involving patients, these groups can better understand patient experiences to inform interventions and improve health outcomes.

For more information about the OS-PCORTF projects described in this report, please reach out to **OSPCORTF@hhs.gov**

References

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