OS PCOR TF
OFFICE OF THE SECRETARY
PATIENT-CENTERED OUTCOMES
RESEARCH TRUST FUND
VISION 2029

Better Data
Stronger Evidence
Informed Decisions

2024

Annual Portfolio Report

Building Data Capacity for the Office of the Secretary Patient-Centered Outcomes Research Trust Fund

Administered by the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Office of the Secretary Patient-Centered Outcomes Research Trust Fund (OS-PCORTF) works to build data capacity for patient-centered outcomes research (PCOR) by coordinating a portfolio of projects developed, implemented, and coordinated in partnership with other United States (U.S.) Department of Health and Human Services' (HHS) agencies. OS-PCORTF aims to generate stronger evidence and foster informed decisions by promoting the availability and accessibility of high-quality data and improving federal, state, and researcher capacity for collecting, linking, and analyzing data to support comparative clinical effectiveness research (CER) and patient-centered outcomes studies.

ASPE | OFFICE OF
ASSISTANT SECRETARY FOR PLANNING AND EVALUATION | HEALTH POLICY

OS PCOR TF | OFFICE OF THE SECRETARY
PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND

Visit the OS-PCORTF website at https://aspe.hhs.gov/collaborations-committees-advisory-groups/os-pcortf.

Explore the OS-PCORTF project portfolio at https://aspe.hhs.gov/collaborations-committees-advisory-groups/os-pcortf/explore-portfolio.

MISSION

Build and strengthen data capacity for patient-centered outcomes research through coordination across agencies and federal programs.

VISION

Better data for patient-centered outcomes research to improve evidence generation, decision making, and health outcomes for all Americans.

The OS-PCORTF projects, federal agency consortia, and ASPE-led efforts collectively advance progress toward achieving the OS-PCORTF Strategic Plan goals[1] and enhance patient-centered outcomes research and CER across key national and HHS health objectives. The 2019 OS-PCORTF reauthorization funded the OS-PCORTF through 2029 and specified maternal mortality, intellectual and developmental disabilities, and economic burden outcomes as research priorities.[2]

Strategic Plan

GOAL 1
Data Capacity for National Health Priorities

GOAL 2
Data Standards and Linkages for Longitudinal Research

GOAL 3
Technology Solutions to Advance Research

GOAL 4
Person-Centeredness, Inclusion, and Equity

Read the OS-PCORTF Strategic Plan for 2020-2029 at https://aspe.hhs.gov/collaborations-committees-advisory-groups/os-pcortf/os-pcortf-strategic-plan-2020-2029.

This report describes the activities and accomplishments of the OS-PCORTF during Fiscal Year (FY) 2024, including from 42 active OS-PCORTF projects.[i] More information about the 42 FY 2024 OS-PCORTF projects, including detailed profiles of completed and newly funded projects, can be found in the accompanying 2024 Annual Portfolio Report Appendices. The OS-PCORTF website provides information on the entire **OS-PCORTF portfolio**, including past projects.

The report is organized in the following sections:

[i] For multi-agency OS-PCORTF projects, we count each project at the level of the funded agency (i.e., if an OS-PCORTF project funded two scopes of work with different HHS agencies, the project is counted twice).

The Breadth and Diversity of OS-PCORTF Projects

The OS-PCORTF brings together HHS agency leaders, informaticians, data scientists, and researchers around the shared interest in increasing data capacity for patient-centered outcomes research.

Administration for Children and Families (ACF)	Agency for Healthcare Research and Quality (AHRQ)	Office of the Assistant Secretary for Planning and Evaluation (ASPE)	Centers for Disease Control and Prevention (CDC)	Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC)
Centers for Medicare and Medicaid Services (CMS)	Food and Drug Administration (FDA)	Health Resources and Services Administration (HRSA)	National Institutes of Health (NIH)	

42 Projects in FY 2024

8 Completed Projects   **27** Continued Projects   **7** New Projects

HHS Interagency Partnerships and Stakeholder Engagement

OS-PCORTF projects leverage interagency partnerships and engage PCOR stakeholders and subject matter experts throughout the project planning and execution phases of their projects. These partnerships and stakeholder engagements improve the resulting data infrastructure resources, help ensure resources meet end user needs, and build data capacity for patient-centered outcomes research in areas of national importance.

Project teams synergize efforts across HHS. Several projects strengthen relationships among HHS agencies by collaboratively developing tools and resources that address common goals and priorities. For example, interagency partnerships are enhancing resources such as the Centers for Disease Control and Prevention

Cross-Agency Collaboration

95 percent of FY 2024 OS-PCORTF projects involve interagency partnerships

(CDC) **National Center for Health Statistics (NCHS) Data Linkage Program**[3] or the Agency for Healthcare Research and Quality (AHRQ) **Social Determinants of Health (SDOH) Database**.[4] Projects also work with experts to harmonize the use of data elements, value sets, definitions, and clinical terminologies across federal programs to improve data interoperability and capacity to link and compare data across HHS programs for patient-centered outcomes research. The relationships built through the OS-PCORTF often serve as the foundation for subsequent HHS projects or initiatives.

OS-PCORTF projects extend the work of broader federal initiatives. The portfolio's interagency collaborations support goals of the HHS Health Information Technology (IT) Alignment Policy which seeks to promote greater alignment of health IT-related activities across HHS.[5] OS-PCORTF projects also address objectives of several executive orders and initiatives issued in recent years, including the Cancer Moonshot initiative,[6] the 2019 Executive Order on Advancing American Kidney Health,[7] the 2021 Executive Order on Advancing Racial Equity and Support for Underserved Communities,[8] the Maternal Health Blueprint,[9] and the HHS Action Plan to Improve Maternal Health in America.[10]

Building on OS-PCORTF Foundational Work

50 percent of all FY 2024 projects leverage the work of prior OS-PCORTF projects

Gathering end user input improves data resources and helps ensure usability in real-world settings. Projects use various mechanisms to engage end users in the design and development of data resources. These mechanisms include engagement with end user collaboratives and communities of practice, key informant interviews and focus groups, workshops, public comments, surveys, and technical expert panels (TEPs). Many OS-PCORTF projects also consult with external professional organizations (e.g., Health Level Seven [HL7®], the REDCap Consortium, and the Maternal Health Research Collaborative for Minority Serving Institutions) and subject matter experts for additional input on project activities and resources. Additionally, several projects pilot test data resources to assess their implementation feasibility and usability in health systems, health information exchanges (HIEs), public health departments, and patient/disease registries.

End User Engagement

88 percent of all FY 2024 projects engaged end users

SPOTLIGHT

Using OS-PCORTF Resources to Support Real-World Patient-Centered Outcomes Research

Data Capacity for Patient-Centered Outcomes Research through Creation of an Electronic Care (eCare) Plan for People with Multiple Chronic Conditions 2.0: Development of the Patient-Facing Application. The open-source, Fast Healthcare Interoperability Resources (FHIR®)-based app developed through this project is currently being pilot tested through two Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) Leading Edge Acceleration Projects in Health Information Technology (LEAP) projects. One LEAP project pilot tested a modified eCare plan app to support care coordination between a health care organization and community-based organization for individuals experiencing homelessness,[11] while another LEAP project is adapting the eCare Plan app for three behavioral health use cases.[12] Additionally, the NIH-funded Multiple Chronic Conditions: Multiple Data Sources (MC COMPARE) project,[13] implemented by the Oregon Health & Science University, will use the eCare Plan app to

incorporate social needs data to improve outcomes for people with hypertension and other chronic conditions.[14] *Agency Leads: AHRQ & National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases (NIH/NIDDK)*

Small-Area Community SDOH Data: Enhancements and Linkages to Inform Action. The initial **AHRQ SDOH Database,**[15] has been downloaded over 36,000 times and has been used in 51 published research articles. PCORnet®, the National Patient-Centered Clinical Research Network, funded by the Patient-Centered Outcomes Research Institute (PCORI) is also using the AHRQ SDOH Database to develop tools to enable linkages to the database to identify treatment variations based on socioeconomic factors. The Michigan Value Collaborative[16] also used the database in a regional equity analysis of barriers to care for heart failure patients.[14] *Agency Lead: AHRQ*

OS-PCORTF projects collaborate through topic-focused interagency consortia. Three consortia were launched in FY 2024 to build capacity in maternal health, health equity, and Medicaid data. These consortia bring together 48 members across 11 federal agencies and offer opportunities to exchange ideas and collaboratively problem solve complex issues.

Across 24 convenings, the three consortia:

- Conceptualized areas of future OS-PCORTF projects about maternal health, health equity, and Medicaid data.
- Refined the scope of cross-agency OS-PCORTF projects.
- Shared project progress and updates on relevant federal initiatives in their areas of focus.
- Provided substantive feedback on OS-PCORTF technical papers.
- Discussed strategies to disseminate OS-PCORTF resources with a focus on reaching early career investigators.

SPOTLIGHT

OS-PCORTF Consortia

Supporting Goal 1: Maternal Health 2.0 Consortium consists of 26 members representing 10 HHS agencies. Building on prior year activities, the Consortium focused on improving data infrastructure to conduct longitudinal PCOR studies to assess maternal health outcomes in the postpartum period. The participating OS-PCORTF projects have contributed to achieving Consortium objectives that align with the 2019 OS-PCORTF reauthorization priority to address maternal mortality. These activities include developing and testing new data standards and analytic tools; expanding the use of electronic health record (EHR), Medicaid, and birth records data through linkages; and developing a maternal health research agenda and potential research topics for federal agencies and private organizations.

Supporting Goal 4: Health Equity Consortium consists of 18 members representing seven HHS agencies. In FY 2024, the Consortium identified SDOH data infrastructure needs, and opportunities for leveraging HHS data initiatives and building on OS-PCORTF work to enhance the use of data for person-centered outcomes research. Additionally in FY 2024, a newly funded OS-PCORTF project, that directly aligns with the 2019 reauthorization to include economic burdens and impacts as PCOR

outcomes, joined the Consortium. This project leverages the Medical Expenditure Panel Survey (MEPS), adding new survey domains related to economic burdens of seeking care.

Supporting Goal 2: Medicaid Data Consortium consists of 10 members representing six HHS agencies. The Consortium focused on addressing challenges researchers face when using Transformed Medicaid Statistical Information Systems (T-MSIS) data for patient-centered outcomes research, such as data quality issues, difficulty linking T-MSIS to other data, and limitations in T-MSIS for longitudinal analysis.

The OS-PCORTF engages experts via the Data Advisory TEP to improve dissemination of portfolio resources to the research community. The TEP consists of stakeholders with expertise in patient-centered outcomes research, maternal health, health equity, Medicaid data, artificial intelligence, PCOR data infrastructure, patient advocacy, and communications. In FY 2024, the TEP met five times to discuss opportunities to disseminate OS-PCORTF resources, the consortia activities, and how to engage early career researchers. During these meetings, the TEP provided input on evolving PCOR data infrastructure needs and opportunities for the OS-PCORTF to respond to HHS goals.

Accomplishments in Data Infrastructure

PCOR data infrastructure is the methodologies, tools, and services that promote accessible, high-quality data and related data resources for conducting patient-centered outcomes research. Projects' impacts on advancing data infrastructure were assessed across the four domains below.

OS-PCORTF projects collectively advanced the ability of researchers to conduct patient-centered outcomes research by:

% of Projects

Improving Data Access and Use
Through efforts that support timelier conduct of PCOR studies

93%

Providing More Relevant, Comprehensive Data
Through collection and integration of patient-generated health data, inclusion of new variables, and data linkages

67%

Improving Data Quality[17]
By addressing the completeness, accuracy, consistency, timeliness, and granularity of data that affect research conclusions for PCOR and CER
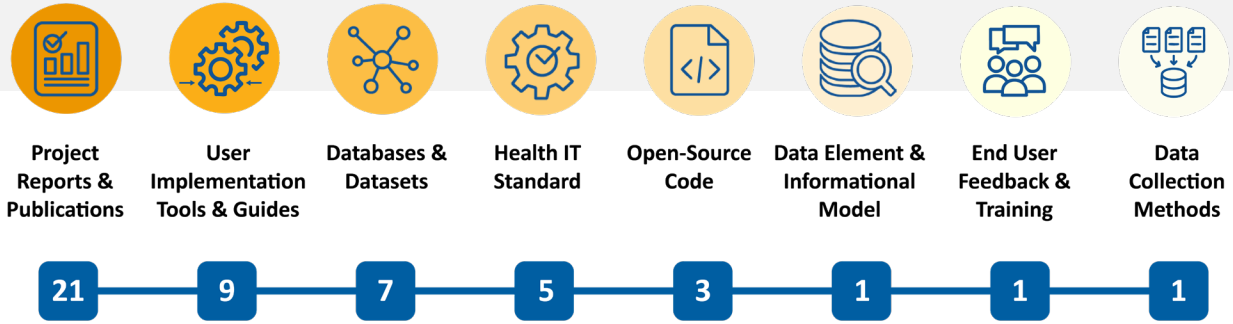
52%

Enhancing Analytic Resources
By improving or creating analytic resources for PCOR studies

48%

27 data and technical products and **21** reports and publications were produced by the **8** OS-PCORTF projects completed in FY 2024.

These products enhance researchers' **capacity to conduct robust patient-centered outcomes research** to address critical questions across areas like **substance use disorder, maternal health, and health equity.**

Project Reports & Publications	User Implementation Tools & Guides	Databases & Datasets	Health IT Standard	Open-Source Code	Data Element & Informational Model	End User Feedback & Training	Data Collection Methods
21	9	7	5	3	1	1	1

The eight completed projects produced publicly-available data and technical products available for research use.

21

New data resources are publicly accessible for research use

4

Datasets are available upon request through a Research Data Center

HL7 End User Engagement

OS-PCORTF projects have consulted several HL7 Work Groups including the Public Health Work Group, the Patient Care Work Group, the Vocabulary Work Group, and HL7 Vulcan (a community focused on integrating clinical research and clinical care using Fast Healthcare Interoperability Resources [FHIR®]). Projects also participate in HL7 Connectathons to enhance the development of FHIR implementation guides and engage in the HL7 "balloting" process (i.e., the formal process to gather input from the community) for implementation guides prior to their publication. Leveraging the HL7 standard development process increases engagement with end users, can promote uptake, and increases data interoperability.

Improved Data Capacity for National Health Needs

The OS-PCORTF aims to improve PCOR data capacity for key national needs and HHS objectives, including maternal health, substance use disorder, intellectual and developmental disabilities (ID/DD), cancer care, as well as national emergencies and emerging health threats such as COVID-19 and environmental health. Here we describe OS-PCORTF project-specific achievements, as well as other OS-PCORTF led programmatic activities and accomplishments.

Number of FY 2024 Projects that Address National Needs

- Maternal Health — 9 Projects
- Substance Use Disorder — 4 Projects
- Intellectual & Developmental Disabilities — 2 Projects
- Cancer — 3 Projects
- Emerging Health Threats — 11 Projects

Maternal Health

The U.S. has one of the highest maternal mortality rates among developed countries.[18] To address the research priorities specified in the PCORTF reauthorization,[2] OS-PCORTF projects aim to advance data collection, standardization, harmonization, transparency, and research to help advance one aspect of the multi-prong federal government approach to reduce rates of maternal morbidity, mortality, and disparities in maternal health outcomes.[9]

OS-PCORTF Project Efforts in Maternal Health

Nearly a quarter (n=9) of FY 2024 projects target improvements in data infrastructure for maternal and child health research. Maternal health data enhancements undertaken by projects include **improving the quality of** and **expanding researchers' access to maternal and infant data** to study maternal outcomes and improve standardized representation of maternal health data elements to support data exchange for public health surveillance.

Projects also improve the **utility and comprehensiveness** of maternal and child health data by linking separate data sources—such as the Pregnancy Risk Assessment Monitoring System (PRAMS), the National Ambulatory Medical Care Survey (NAMCS), T-MSIS, and EHR data—to create new longitudinal research datasets. These datasets enable research

into the long-term impacts of different exposures (e.g., opioid use disorder [OUD] during pregnancy, genetic and chronic diseases), health care utilization, and SDOH on maternal and infant outcomes. Projects also increase accessibility and analysis of Medicaid data to enable research on the impact of value-based care programs on mothers and children.

New PCOR Resources for Maternal Health Research

Project: *Severe Maternal Morbidity and Mortality EHR Data Infrastructure*

Researchers can use the **MaternalHealthLink** web application to extract and exchange clinical EHR data needed to examine the effect of risk factors, pre-existing conditions, and interventions on morbidity and mortality for pregnant, postpartum, or lactating women and their infants. The accompanying **HL7 FHIR Implementation Guide** defines a framework for researchers to aggregate, calculate, and analyze longitudinal clinical information to examine the root causes of maternal and child morbidity and mortality.

EXPLORE PROJECT 🔍

Project: *Developing a Multi-State Network of Linked PRAMS and Clinical Outcomes Data for Patient-Centered Outcomes Research*

PRAMS collects state-specific survey data from women with a recent live birth, representing 83 percent of U.S. births each year. State agencies can use the **Framework for Linking PRAMS with Administrative Data** to plan for and implement sustainable linkages, including processes for cleaning, standardizing, and linking PRAMS data with other administrative data sources, such as vital records or T-MSIS data.

EXPLORE PROJECT 🔍

Looking Ahead

In FY 2024, OS-PCORTF funded two new projects that focus on maternal health. These projects will support maternal health research by improving the comprehensiveness of information on factors that impact outcomes and high-quality maternal care. One project will create a linked dataset on maternal health care and clinical outcomes for understudied populations. The second project will advance the United States Core Data for Interoperability Plus (USCDI+) Maternal Health initiative by developing a comprehensive USCDI+ Maternal Health Data Element list to further standardize maternal health data.

Other OS-PCORTF Maternal Health Initiatives

Preliminary Estimates of Visits to Health Centers in the United States[19]

The CDC NCHS launched an interactive dashboard that visualizes health center visits using data from the NAMCS Health Center Component. The dashboard includes a maternal health module that enables users to view and export data on the number of reproductive and maternal health visits at health centers from 2022-2023. This resource makes new maternal health data easily available to researchers for use in PCOR studies. Explore the dashboard at **https://www.cdc.gov/nchs/dhcs/prelim-hc-visits/index.htm**.
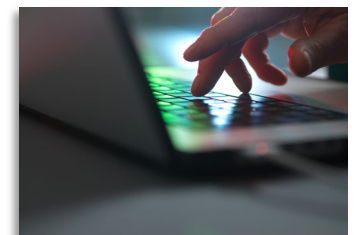
Substance Use Disorder

Substance use and misuse continue to be a national public health concern with significant impacts on individuals, their families, and communities.[20] Mitigating U.S. substance use epidemics is a national health priority as evidenced by the enactment of the 2018 SUPPORT Act, several advisory reports from the Surgeon General,[21] and numerous HHS agency initiatives, such as the Office of the Assistant Secretary for Health's *Healthy People 2030* initiative.[22] Improving data comprehensiveness and availability is necessary for federal initiatives to better understand substance use epidemics and improve outcomes among people with substance use disorder (SUD).

OS-PCORTF Project Efforts in SUD

Four FY 2024 projects are strengthening data infrastructure to support evidence-based treatment and recovery to reduce SUD impacts on the nation. Data infrastructure enhancements include efforts to improve the comparability and use of data from different administrative, clinical, and vital record data sources; develop new approaches to identify substance-involved encounters in hospital data; and create new datasets to study patient-centered outcomes. Projects are improving data capacity to study patient outcomes associated with substance use and misuse such as the impact of OUD on children in the child welfare system, the outcomes of children with prenatal opioid exposure, This year, two completed projects enhanced the **accuracy, relevance, and comprehensiveness** of available PCOR data on OUD through the creation and augmentation of two datasets to expand data collection and include new SUD-relevant variables.

New PCOR Resource for SUD Research

Project: *Linking State Medicaid and Child Welfare Data for Outcomes Research on Treatment for OUD and Other Behavioral Health Issues*

The **CCOULD Dataset and User Guide** links records from child welfare data systems in Florida and Kentucky with Medicaid enrollment and claims data of parents with SUDs. The de-identified dataset is freely available to researchers and can support patient-centered outcomes research on Medicaid services families receive and child welfare and family stability outcomes for families experiencing SUD.

EXPLORE PROJECT 🔍

Project: *MAT-LINK2: Expansion of MATernaL and Infant NetworK to Understand Outcomes Associated with Treatment for OUD during Pregnancy*

The expanded **MAT-LINK dataset** includes almost 6,000 parent-child dyads using EHR data from 11 geographically diverse clinical sites to monitor maternal, infant, and child long-term health outcomes associated with receiving medication for OUD during pregnancy. It includes eight new child follow-up variables related to health care encounters and referrals, vaccinations, and school-readiness for children up to six years old. Researchers may apply to access MAT-LINK data through the CDC NCHS Research Data Center.

EXPLORE PROJECT 🔍

Intellectual and Developmental Disabilities

Approximately 7.4 million people live with ID/DD in the U.S.[23] This population has historically experienced inadequate access to high-quality care and exclusion from public health research programs.[24] Strengthening data capacity related to the health and well-being of people with disabilities, including ID/DD, is an aim across the federal government. For example, the 2021 Executive Order on Advancing Racial Equity and Support for Underserved Communities identified people with disabilities as a key underrepresented population for federal equity initiatives,[8] and ID/DD is a specified research priority in the PCORTF reauthorization.[2] Since the reauthorization, HHS has prioritized addressing data infrastructure gaps and including people with ID/DD in patient-centered outcomes research.

OS-PCORTF Project Efforts in Intellectual and Developmental Disabilities

Two projects support the OS-PCORTF goal to improve **the quality and availability of data** to identify individuals with ID/DD within clinical and administrative datasets. One project is building data infrastructure to standardize point-of-care collection of functional disability status from patients. The project is developing a functional disability demographic checklist that will increase representation of people with ID/DD in administrative data systems. The second project is linking several state-level datasets (i.e., Support Intensity Scale scores, Medicaid claims, National Core Indicators survey data, National Core Indicators COVID-19 supplement survey data) in multiple states to provide a more holistic view of the individuals' needs and identify health disparities. The linked data will enable analysis of relationships among various sociodemographic factors, need for home and community-based services (HCBS), service utilization, Medicaid expenditures, and person-centered outcomes for the ID/DD population before and during the COVID-19 pandemic.

Other OS-PCORTF Initiatives in Intellectual and Developmental Disabilities

Improving Data Infrastructure for Person-Centered Outcomes Research on Intellectual and Developmental Disabilities[25]

Individuals with ID/DD experience disparities in health and well-being compared to people without a disability. This article published in the *American Journal of Intellectual and Developmental Disabilities,* explores opportunities and common challenges to enhance PCOR data infrastructure. The opportunities identified include developing a standardized definition of ID/DD for use in research, advancing data standards for service systems, improving data collection to identify individuals with ID/DD in clinical care settings, developing standardized outcome measures, and encouraging use of Medicaid data for ID/DD research.

Trends and Disparities in Pandemic Telehealth Use among People with Disabilities[26]

Telehealth became a critical tool for many groups to maintain continuity of care during the initial years of the COVID-19 pandemic. Using claims data from the **Medicare Telehealth Trends Dashboard** and responses to the Medicare Current Beneficiary Survey and the Census Bureau's Household Pulse Survey, this ASPE report describes audio-only telehealth use for Medicare beneficiaries with disabilities during the first two years of the COVID-19 pandemic. The study found that adult Medicare beneficiaries with disabilities were more likely than adult Medicare beneficiaries

without disabilities to use audio-only telehealth services; however, use of telehealth services by people with disabilities decreased over time, consistent with the general population.

Cancer

Cancer is a significant cause of morbidity and the second leading cause of U.S. mortality.[27] Several federal initiatives focus on maximizing data utility and improving sharing of cancer-related data, including the 2016 Cancer Moonshot initiative[6] and the 2023 National Cancer Plan.[28] Additionally, four Cancer Moonshot projects in the HHS Data Strategy[29] focus on implementing data standards, expanding data access, and linking cancer data.

OS-PCORTF Project Efforts in Cancer

Three projects are advancing the goals of the Cancer Moonshot initiative to reduce cancer mortality and improve cancer patients' and survivors' lives by enhancing the **quality, comprehensiveness, and accessibility** of data for cancer-related patient-centered outcomes research. These projects are producing data standards to enable real-time data exchange of clinical EHR data for a cancer use case, creating a longitudinal, linked dataset that captures the trajectory and impacts of cancer patient care, and developing a protype legal structure and governance framework for a federated linked cancer data system. These products will also **improve researchers' access** to clinical data to study cancer health outcomes.

Looking Ahead

In FY 2024, OS-PCORTF funded one new project focused on cancer. This project will help build technical infrastructure that supports patient-centered outcomes research for cancer by developing a prototype legal structure and governance framework for a federated linked data system (i.e., a system in which data reside across independent data systems). The framework will include guidance on governance, security and privacy controls, and sustainable operating models to support efficient design and conduct of PCOR studies while keeping patient data secure. This project is one of the four Cancer Moonshot use-case workstreams specified in the HHS Data Strategy.

Emergent Health Threats

The OS-PCORTF builds capacity for patient-centered outcomes research on national health emergencies and emerging health threats. In response to the COVID-19 pandemic, the OS-PCORTF funded several projects to improve collection, use, and accessibility of data needed for patient-centered outcomes research on COVID-19. The OS-PCORTF also seeks to improve data capacity for environmental health threats.

OS-PCORTF Project Efforts in Emergent Health Threats

Eleven projects are improving the **availability and representativeness** of data needed to facilitate research on the impact of emergent health threats, such as environmental threats and the COVID-19 pandemic, on patient-centered outcomes. These projects are linking disparate data sources (e.g., Medicaid claims, EHR, clinical registries, and various sources of SDOH and environmental data) and expanding the collection of relevant data variables, including patient-reported outcomes from electronic care plans and patient-completed forms. In some instances, these activities will develop national longitudinal data infrastructures needed to study and respond to health emergencies by augmenting existing data systems (e.g., NCATS National Clinical Cohort Collaborative [NC3], CUREID).

Researchers can leverage data products to explore relationships among SDOH, the environment, and service utilization during health emergencies on patient outcomes. For example, one project is linking data from the National Survey of Children's Health Longitudinal Cohort Study to T-MSIS to enable research on long-term impacts of COVID-19 infection and SDOH on child outcomes, including mental health.

Projects are also working to **improve the quality, completeness, interoperability, and comprehensiveness** of COVID-19 treatment and outcome data for research. Projects are developing data elements and standards, as well as common data models (CDMs), to collect and exchange treatment and outcome information across clinical settings and HIEs. Project work also focuses on **developing enhanced analytic resources,** including machine learning techniques and privacy-preserving tokenization approaches, to generate linked datasets that protect patient privacy while making information on SDOH factors, survey responses, and federal administrative data publicly available.

New PCOR Resource for COVID-19 Research

Project: *CURE ID: Aggregating and Analyzing COVID-19 Treatment from EHRs and Registries*

Researchers can access 130,000 de-identified patient-level COVID-19 treatment cases from 13 clinical sites via the **CURE ID platform**. The **CURE ID Researcher's Guide** documents how to access and use the data, summarizing data processing and pathways, data sources and characterization, data access, data security protections, data quality assurance activities, and frequently asked questions to inform researchers' use and exploration of CURE ID data.

EXPLORE PROJECT 🔍

SPOTLIGHT
Project Impacts on Real-World PCOR Infrastructure

The OS-PCORTF project *Making EHR Data More Available for Research and Public Health* provided feedback on Public Health Data Elements in USCDI versions 2, 3, 4, and USCDI+, ultimately shaping the case-based surveillance use case for USCDI+ Public Health.

Enhancing Data Standards and Linkages for Longitudinal Research

In FY 2024, 15 projects focused on providing more relevant and comprehensive data to support longitudinal patient-centered outcomes research. These projects extend the analytic utility of existing data through linked datasets that create a more holistic picture of individual patients' health. Projects aimed at enhancing longitudinal data resources also improve data linkage infrastructure and processes by streamlining federal data request processes, developing linkage governance frameworks, and documenting data linkage policies to improve researcher access to linked data. These projects extend the availability of longitudinal health outcomes data that span patients' lives, care settings, and clinical trajectories, as well as enable deeper analysis of risk factors, disease trends, and treatment effectiveness.

Number of FY 2024 Projects that Enhance Data Standards and Linkages

Extending Data Linkages
8 Projects

Improving Data Standards
3 Projects

Improving Data Linkage Infrastructure & Governance
7 Projects

Extending Data Linkages

Data fragmentation is a persistent challenge for patient-centered outcomes research and requires linkages of disparate datasets to provide investigators with the data needed to answer PCOR questions. Sources of rich, linked data that are accessible to researchers are needed to advance the data capacity for patient-centered outcomes research.[30]

OS-PCORTF Project Efforts in Extending Data Linkages

Eight projects are linking a variety of datasets representing administrative, EHR, and survey data to improve the insights that can be drawn from existing data. Several projects bring together disparate data sources, including EHR data, federal administrative data, survey data, emergency services records, and demographic information. The resulting linked datasets capture myriad variables to enable researchers to examine a **more comprehensive set of longitudinal information** on health care provided to individuals across settings, as well as the diverse factors that affect health

outcomes over time, including care received, SDOH, and family and community context. For example, one project is creating publicly-available state-specific databases that capture an unprecedented panoramic view of medical care received by patients, **increasing the amount of data available** to study the relationship among insurance, services used, community and SDOH factors, and health outcomes.

New PCOR Resource for Data Linkage

Project: *Data Linkage: Evaluating Privacy Preserving Record Linkage Methodology and Augmenting the National Hospital Care Survey with Medicaid Administrative Records*

The project linked 2014-2017 Centers for Medicare & Medicaid Services (CMS) claims data to EHR data from the 2014 and 2016 National Hospital Care Survey (NHCS) at the patient-level using privacy protecting record linkage (PPRL) techniques. The linkages produced three datasets: 1) **2014 NHCS/Medicare Linked Dataset**, 2) **2016 NHCS/Medicare Linked Dataset**, and 3) **2016 NHCS/Medicaid Linked Dataset.** De-identified data are publicly available, and researchers must apply to access restricted data through the NCHS Research Data Center.

EXPLORE PROJECT 🔍

Improving Data Linkage Infrastructure and Governance

The ability to link data relies on identifiable information that is consistently represented and available across disparate data sources. Often, different systems collect different identifiers or use unique formatting for data elements, which can lead to linked datasets containing a high degree of missing information or that provide an inaccurate picture. At the same time, there is a need for new linkage techniques that preserve individuals' privacy while still enabling linkage of sensitive information.

OS-PCORTF Project Efforts in Improving Data Linkage Infrastructure and Governance

Seven projects are enhancing data linkage infrastructure, creating centralized linkage resources, improving privacy-preserving linkage techniques, and creating data governance resources to aid in performing data linkages. Various projects aim to **reduce burden on researchers** as they link data by developing **standard governance approaches** and guidance for data linkage efforts. Outputs include machine-readable standards for metadata that describe data linkage and data use requirements for high-priority HHS clinical and administrative datasets, a database of requirements for linking mortality data within the 57 reporting jurisdictions, and a streamlined data sharing process that improves **accessibility of CMS data** for federal agencies. These resources can support policymakers and researchers in efficiently determining the appropriateness of linking individual-level datasets and using the linked data for research purposes.

New PCOR Resource for Data Linkage Infrastructure and Governance

Project: *Human-Centered Design Study on Federal Data Access and Acquisition Processes of CMS Data*

The project conducted a human-centered design study to understand and identify current gaps in the federal agency data request process for CMS data. The project developed four prototype resources to facilitate a more streamlined, transparent, and user-friendly data request process that meets federal agency partners' needs while ensuring compliance with relevant laws and policies. These resources will make CMS data more accessible to federal agencies to support their own research and/or create new linked datasets that may ultimately be made available to external researchers.

EXPLORE PROJECT 🔍

Two projects are also advancing data linkage techniques that preserve individuals' privacy by evaluating the **accuracy and completeness of PPRL methodologies**. By improving PPRL tools, the OS-PCORTF is helping to improve the overall security and accuracy of processes to exchange protected health information when linking datasets.

Looking Ahead

In FY 2024, OS-PCORTF funded three new projects that enhance data standards and linkages. These projects seek to upgrade federal data infrastructure for performing secure data linkage, storing linked data, guiding appropriate use of linked data, and developing legal and governance linkage structures to both improve PCOR investigators' access to linked data and serve as models for future HHS data sharing initiatives.

Improving Data Standards

Data harmonization, achieved through the use of standard data elements, as well as standardized approaches to linking datasets are key to producing comparable and interoperable data that can be seamlessly shared across systems as well as producing accurate, consistent, and comprehensive linked PCOR datasets.

### OS-PCORTF Project Efforts in Improving Data Standards

Three projects address the need for greater data standardization for patient-centered outcomes research. These projects are improving the **consistency, quality, and interoperability** of PCOR data using common data models (CDMs). Some projects are enabling **standardization of T-MSIS data elements** to two CDMs. This standardization will **increase the accessibility of T-MSIS data** for research and **improve efficiency** for researchers in linking and analyzing Medicaid data. One project is creating an automated service to map multiple CDMs to each other to support cross-network and cross-CDM interoperability and data sharing for patient-centered outcomes research. By enabling translation between CDMs and facilitating CDM network interoperability, the project will expand research access to clinical data across a range of populations and settings.

Leveraging Technology Solutions to Advance Research

OS-PCORTF projects leverage leading technology solutions to enhance analytic resources and improve data accessibility for patient-centered outcomes research. Four projects use data standardization and machine learning techniques to identify and collate relevant EHR data for research, as well as statistical techniques to create synthetic datasets that reflect trends in real-world data. Projects leveraging technology to advance research also improve data interoperability and use of real-world data in research and decision-making by developing standards for real-time data exchange.

Number of FY 2024 Projects that Leverage Leading Technology Solutions

Enhancing Standards for Real-Time Data Exchange
1 Project

Artificial Intelligence
2 Projects

Synthetic Data
1 Project
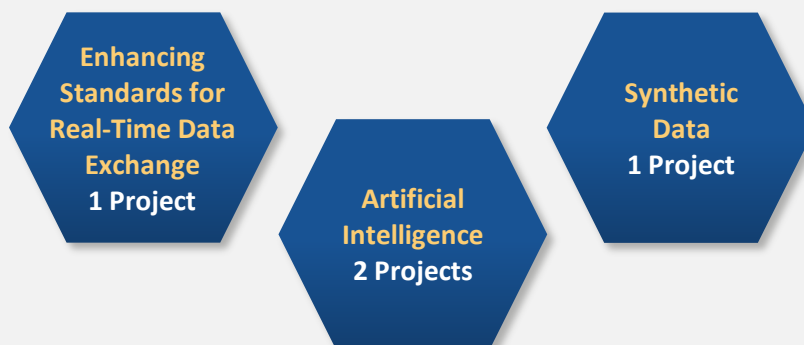
Enhancing Standards for Real-Time Data Exchange

Advancements in standards-based application programming interfaces (APIs) enable exchange and use of data from traditionally siloed systems. These standards further enhance the capacity for PCOR studies to generate stronger real-world evidence and support clinical decision-making.

OS-PCORTF Project Impacts in Enhancing Standards for Real-Time Data Exchange

One project developed standards to enable real-time data exchange between otherwise unconnected systems. This project increased the **availability of clinical data** for research, public health, and evaluation of health outcomes by developing a scalable FHIR-enabled application that improves the **interoperability of EHR data and efficiency** with which EHR data can be exchanged with public health surveillance systems. The implementation guides can also improve and streamline researchers' access to EHR data when implemented in their health system setting.

New PCOR Resource for Real-Time Data Exchange

Project: *Making EHR Data More Available for Research and Public Health*

This project developed a [Reference Architecture (RA) HL7 FHIR Implementation Guide](#) and Substitutable Medical Apps, Reusable Technologies on Fast Healthcare Interoperability Resources application (SMART-on-FHIR® app), the [Health Data Exchange App (HDEA)](#), for a real-time data exchange system (MedMorph) to improve the availability of clinical EHR data for research and public health in four use cases that represent infectious disease, chronic disease, healthcare services, and research: hepatitis C, cancer, healthcare surveys, and research data exchange. The RA implementation guide provides a common method and workflows for automating exchange of EHR data for research and public health purposes. A harmonized and reusable infrastructure such as MedMorph helps reduce implementation burden, enhanced functionality to support more types of use cases, and automation to support reduce reporting burden.

EXPLORE PROJECT 🔍

Artificial Intelligence

Artificial intelligence is a fast-growing technology with direct applicability for improving PCOR data capacity. These solutions can address challenges associated with analyzing large quantities of data, including limitations in data (e.g., unstructured data, self-reported data) used in PCOR studies, timeliness of data, and preserving individuals' privacy.[31]

OS-PCORTF Project Impacts in Artificial Intelligence

Two projects are leveraging artificial intelligence, including machine learning techniques, such as split learning predictive modeling and natural language processing. These projects aim to improve **consistency, comparability, and interoperability** of EHR data from HIEs and provide **more comprehensive data** on SUD outcomes by linking hospital survey and National Death Index (NDI) data using an algorithm that can extract data from structured and unstructured text fields.

Synthetic Data

Synthetic data that simulate trends and relationships in real-world data are a promising solution to the challenges of producing timely, accessible, and high-quality data that protects individuals' privacy. The creation of synthetic data can enable developers to more easily share data with researchers, compared to real-world data. As a nascent innovation, the limitations of using synthetic data still need to be explored.[32]

OS-PCORTF Project Impacts in Synthetic Data

One project is using privacy-preserving statistical techniques to develop synthetic data for research. It will increase researcher **access** to linked datasets from the NCHS Linkage Program by developing public-use synthetic datasets modeled after existing restricted-use NCHS datasets, including National Health Interview Survey and linked NHCS-federal administrative data. The creation methodologies will support ongoing efforts to develop a synthetic data infrastructure that can be applied to other linked datasets as more data become available to address key PCOR concerns.

Advancing Person-Centeredness

The OS-PCORTF focuses on expanding the collection and analysis of comprehensive and relevant data to advance the person-centeredness of outcomes research. Over half (n=23) of FY 2024 projects enhance availability of data specified in the 2019 reauthorization: SDOH, disability status, environmental factors, and economic outcomes.[2] Project efforts address health disparities through improved data collection efforts, data linkages, and development of PCOR databases.

Number of FY 2024 Projects that Advance Person-Centeredness

Expanding SDOH & Environmental Data
20 Projects

Gathering Patient-Reported Data
4 Projects

Facilitating Research for Underserved & Understudied Populations
11 Projects

Expanding Social Determinants of Health and Environmental Data

As the scope of patient-centered outcomes research broadens, there is a need for more comprehensive data to build the evidence base on drivers of disparities in health outcomes. Existing PCOR data insufficiently capture the interactions between people's characteristics and experiences that may impact health outcomes, such as socioeconomic, environmental, and other non-medical factors.[33] Collecting these data can enhance PCOR person-centeredness by broadening the focus to whole individuals, rather than focusing on clinical encounters.

OS-PCORTF Project Efforts in Expanding SDOH and Environmental Data

Twenty projects engage in various efforts to improve inclusion and use of SDOH and environmental data for PCOR inquiries. Many projects are **improving the availability and utility** of environmental and SDOH data for patient-centered outcomes research by linking state and federal administrative databases (e.g., all-payer claims databases, AHRQ Healthcare Cost and Utilization Project, U.S. Department of Housing and Urban Development administrative data), datasets (e.g., T-MSIS, NHCS, NDI, Personalized Environment and Genes Study), and EHR data to study health disparities. These data and technical resources will enable researchers to study the influence of non-medical

factors on disparities in childhood obesity, chronic health conditions, COVID-19 treatments, health care coverage and utilization, maternal health care provided at Federally Qualified Health Centers, morbidity, and mortality, among others.

Projects are also producing **more comprehensive** data on SDOH and environmental factors by augmenting existing datasets with new variables that capture more granular and additional years of data. In FY 2024, five OS-PCORTF projects worked to enhance the comprehensiveness of AHRQ's SDOH Database, which AHRQ previously developed with OS-PCORTF funding, through new variables and data linkages that expand its utility for new populations and outcomes.

Other OS-PCORTF Initiatives in Expanding SDOH and Environmental Data

Data Capacity to Achieve Health Equity: New OS-PCORTF-Funded Data Products

ASPE increased awareness of portfolio activities and impacts at AcademyHealth's 2024 Annual Research Meeting. The panel presentation showcased datasets and resources produced by four health equity-focused OS-PCORTF projects:

- New National Ambulatory Medical Care Survey (NAMCS) datasets and tools.
- Improved processes for mapping T-MSIS data to research CDMs.
- The AHRQ SDOH Database.
- MEPS supplement on direct care expenditures and data on indirect costs.

Gathering Patient-Reported Data

Collecting patient-reported data, particularly patient-reported outcomes, can improve the person-centeredness of PCOR studies by obtaining patient perspectives and focusing on outcomes most important to patients.[34]

OS-PCORTF Project Efforts in Gathering Patient-Reported Data

Four projects are improving the data collection infrastructure and direct collection of patient-reported data to support patient-centered outcomes research. Projects advancing whole-person care among medically underserved populations are developing interoperable apps and data collection tools to gather data directly from patients. Projects are **improving the quality and availability of important patient-reported data** accessible to PCOR investigators by developing 1) a patient-facing, FHIR-based application that collects patient-generated health data for an electronic care plan, and 2) a point-of-care checklist to better identify people with ID/DD and increase their representation in administrative data.

Looking Ahead

In FY 2024, OS-PCORTF funded one new project that advances patient-centered outcomes research on economic outcomes. The project will expand MEPS collection of patient- and caregiver-reported data on the economic burden and impact of seeking and receiving health care. The project will make the MEPS linkable to the AHRQ SDOH Database, enabling geographic analysis of the impact of SDOH factors (e.g., race/ethnicity, age, employment) on health care access and use as well as economic outcomes.

Facilitating Research for Underserved and Understudied Populations

The ability to identify outcomes for people who are medically underserved and underrepresented in research is a key component of conducting comprehensive patient-centered outcomes research.[35,36] However, data for these populations and communities are sometimes unavailable or are not representative.[37] To better address health disparities through patient-centered outcomes research and increase the representativeness of PCOR data, improvements to the data capacity and infrastructure to collect data on underserved and historically understudied populations are needed.

OS-PCORTF Project Efforts in Research for Underserved and Understudied Populations

Multiple projects are providing **more comprehensive data** on medically underserved and understudied populations, including Medicaid beneficiaries, people with disabilities, and refugees, by linking relevant data sources (e.g., Office of Refugee Arrivals Data System, EHRs, NAMCS, National Survey of Children's Health Longitudinal Cohort) to T-MSIS data. The resulting datasets will enable researchers to study the outcomes and effects of policies and programs designed to increase access to and improve quality of health care services for these groups. In addition to linking datasets, projects are developing and evaluating **standardized data linkage methodologies** and technical resources that federal, state, and external researchers can adopt to link PCOR data to Medicaid claims. Projects also aim to improve **data quality and harmonization** through refined data collection techniques and data standardization activities, including expanding data collection to improve representativeness of underserved populations and utilizing CDMs to harmonize data elements.

Looking Ahead

In FY 2024, OS-PCORTF funded one new project that advances patient-centered outcomes research for underserved populations. The project will advance data standardization for sickle cell disease data by developing a minimum core set of USCDI+ data elements and a FHIR IG to facilitate the interoperability of these sickle cell disease data elements across health care delivery systems. This will support researcher access to high-quality data to study the full range of factors that affect patients with sickle cell disease.

Other OS-PCORTF Initiatives in Research for Underserved and Understudied Populations

Feasibility of Obtaining Identifiers for Self-Directing Home and Community-Based Services Users in Medicaid Claims[38]

Federal initiatives, including the 2023 Executive Order *Increasing Access to High-Quality Care and Supporting Caregivers*[39] and the HHS and U.S. Department of Labor Home and Community-Based Services Federal Opportunities Regarding Workforce and Research Data (HCBS FORWARD) workgroup[40] call for expanded data collection efforts to address gaps in HCBS workforce knowledge. This OS-PCORTF-funded report explored the feasibility of creating a linkable database to identify and distinguish self-directing HCBS program participants from other Medicaid HCBS participants. This research can inform future efforts aimed at facilitating data linkages with T-MSIS and other federal administrative data to conduct PCOR studies on self-directing HCBS participants and direct care workers.

Conclusion

This year marks the halfway point of the implementation of the OS-PCORTF Strategic Plan. Throughout this past year, ASPE has coordinated across federal agencies and programs to build and strengthen data capacity for patient-centered outcomes research. This report highlights OS-PCORTF progress in FY 2024 toward achieving the four Strategic Plan goals:

- Enhance data capacity for national health needs.
- Improve standards for longitudinal research.
- Promote innovative technologies.
- Enhance patient-centeredness and engagement to strengthen infrastructure for impactful patient-centered outcomes research.

The OS-PCORTF portfolio reflects HHS' commitment to addressing key national goals, HHS agency missions, and researcher needs. Informed by subject matter experts and PCOR stakeholders, resources developed under the OS-PCORTF improve data quality, provide more relevant and comprehensive data for research, enhance or create analytic resources for PCOR studies, and improve the access and use of data. ASPE will continue to leverage HHS agency partnerships to expand data capacity and promote the adoption and use of available resources in the coming years.

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