



**ASPE**  
ASSISTANT SECRETARY FOR  
PLANNING AND EVALUATION

OFFICE OF  
HEALTH POLICY



OFFICE OF THE SECRETARY  
**PATIENT-CENTERED OUTCOMES  
RESEARCH TRUST FUND**

# **Building the Data Capacity for Patient-Centered Outcomes Research: The 2020 Annual Report Executive Summary**

Office of Health Policy  
Assistant Secretary for Planning and Evaluation  
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## I. Introduction

The Assistant Secretary for Planning and Evaluation (ASPE) coordinates a portfolio of intradepartmental projects funded through the Patient-Centered Outcomes Research Trust Fund (PCORTF) to enhance the nation's data infrastructure for conducting patient-centered outcomes research. The PCORTF directs the United States Department of Health and Human Services (HHS) to build data capacity "... to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records."<sup>1</sup> This data capacity supports patient-centered research aimed at improving health care quality and outcomes in the United States.

In 2019, PCORTF funding was reauthorized for 10 years. The reauthorization extends the work to evolving patient-centered research needs which include research with respect to intellectual and developmental disabilities and maternal mortality.<sup>2</sup> The reauthorization also calls for a broader assessment of the types of outcomes considered in patient-centered research to include potential burdens and economic impacts.<sup>3</sup>

ASPE receives four percent of the PCORTF to fund a portfolio of projects that builds data capacity for patient-centered outcomes research that responds to HHS policy priorities and emerging research needs. In recent years, these priorities have included improving maternal health outcomes, turning the tide in the opioid crisis, generating real-world evidence, and improving the collection of social determinants of health (SDOH) data, among others. The emergence of COVID-19 has further underscored the need for a robust research data infrastructure. Several Trust Fund project teams are collaborating with other federal agencies and researchers to leverage project tools to support the nation's response to the COVID-19 pandemic. For example, several projects are supporting efforts to standardize electronic health record (EHR) data elements related to COVID-19 to facilitate more complete and timely surveillance data.

This annual report provides a synopsis of the 31 Trust Fund projects active in Fiscal Year (FY) 2020 and highlights some of the key contributions and impact of this portfolio. The projects featured in this report demonstrate a wide range of data infrastructure improvements to enable more robust patient-centered outcomes research.

## II. OS-PCORTF Portfolio Overview

The PCORTF was created to build national data capacity and infrastructure to support patient-centered outcomes research (PCOR) that provides decision-makers with objective, scientific evidence on the effectiveness of treatments, services, and other interventions used in health care.

The Office of the Secretary (OS) of HHS delegated authority to ASPE to coordinate "relevant Federal health programs to build data capacity for comparative clinical effectiveness research, including the development and use of clinical registries and health outcomes research networks."<sup>4</sup>

In keeping with this charge, ASPE's Office of Health Policy has funded and supported a portfolio of over 50 projects aimed at building data infrastructure capacity for PCOR. ASPE's portfolio is guided by a framework consisting of five research "functionalities" that enable a more robust patient-centered outcomes research data infrastructure.<sup>5</sup>

The goal of this report is to highlight the accomplishments and products of 31 active projects and describe how the portfolio contributes to expanding data capacity to enable patient centered outcomes research.

### III. Portfolio Contributions to Key HHS Priorities

Since 2010, ASPE has overseen a diverse portfolio of data infrastructure projects to enhance patient-centered outcomes research. This report highlights three key areas where OS-PCORTF projects are developing solutions to address HHS data infrastructure needs:

- Data infrastructure for PCOR on women’s health and improving maternal health outcomes
- PCOR data infrastructure in support of the COVID-19 pandemic response
- Improvements that address stakeholder priorities

The featured projects within these areas represent examples from across the portfolio of active projects, including newly funded FY 2020 projects that are just getting underway. Some projects appear more than once; when a project contributes to more than one theme, we describe that project’s unique contributions to both themes.

#### Data Infrastructure for PCOR on Women’s Health and Improving Maternal Health Outcomes

Women’s health is one of many areas in health care that is garnering attention in the context of patient safety and SDOH,<sup>6</sup> given that women are more likely to experience disparities in health care access, care, and outcomes.<sup>7</sup> In particular, improving maternal health before, during, and after pregnancy is among the country’s most pressing public health priorities. The United States has among the highest rates of maternal mortality compared to other developed nations,<sup>8, 9, 10</sup> and persistent racial and ethnic disparities put non-white women at disproportionately higher risk for maternal mortality.<sup>11, 12</sup> Given these trends, maternal health and specifically maternal mortality has been identified as a strategic national research priority across HHS,<sup>13, 14</sup> including as part of the HHS Maternal Health Action Plan,<sup>15</sup> and is reflected in the Trust Fund’s 2019 Congressional reauthorization<sup>16</sup> and multiple maternal health initiatives.

The OS-PCORTF portfolio includes four active projects related to women’s health and improving maternal health outcomes, focused on strengthening three specific areas of the maternal health data infrastructure for PCOR:

- 1) Standardizing data collection and linking medical device registries to improve post-market surveillance and improve treatment decisions in clinical areas unique to women.
- 2) Developing a new longitudinal data set to study opioid use treatment-related outcomes in pregnant women, infants, and children.
- 3) Linking state and national data sets to create a first-of-its-kind network for analyzing patient-centered perinatal outcomes.

#### OS-PCORTF Framework for Building Data Capacity for PCOR



The project ***Developing a Strategically Coordinated Registry Network (CRN) for Women’s Health Technology*** (or WHT-CRN) began in 2017 as a collaboration between the Food and Drug Administration (FDA), National Institutes of Health (NIH) National Library of Medicine (NIH/NLM), and the Office of the National Coordinator for Health Information Technology (ONC) to develop an infrastructure to evaluate medical devices in four clinical areas unique to women’s health: stress urinary incontinence, uterine fibroid treatments, pelvic organ prolapse treatments, and elective female sterilization therapies. The WHT-CRN has filled a critical gap in infrastructure, building a network and tools to facilitate use of diverse registry data sources and standardized data elements to study women’s *health technologies*.

The utility of the WHT-CRN is being expanded through a follow-on project, ***Bridging the PCOR Infrastructure and Technology Innovation through Coordinated Registry Networks (CRN) Community of Practice (CoP)***. In this next phase, the CRNs will expand their reach into 13 clinical areas; pilot test and refine Fast Healthcare Interoperability Resources (FHIR®) profiles to promote exchange among 3-5 participating CRNs; pilot test instruments for capturing patient preferences; and develop and test gender- and sex-specific outcome measures for devices.

Another project targets two pressing issues—maternal health and opioids—by establishing the ***MAT-LINK: MATernaL and Infant Network to Understand Outcomes Associated with Treatment for Opioid Use Disorder during Pregnancy*** surveillance system. There is a dearth of national-level data on maternal, infant, and child health outcomes associated with different treatments for opioid-use disorder (OUD) during pregnancy.<sup>18</sup> MAT-LINK will collect data on maternal and infant outcomes from approximately 2,000-4,000 mother-infant pairs from six geographically diverse clinical sites for up to six years after delivery. These data will be available to researchers to analyze, share, and disseminate findings that inform patient-centered care for pregnant women with OUD, and infants and children with prenatal opioid exposure. Real-world pilots are currently under way.

**PCOR Trust Fund Impact:**  
MAT-LINK has recently published its work in the *Journal of Women’s Health*. [The article](#) describes the opioid treatments used by pregnant women, presents the data elements that will be captured in the surveillance system, and discusses how MAT-LINK can address gaps in knowledge about the management and treatment of OUD during pregnancy.<sup>17</sup>

A new Centers for Disease Control and Prevention (CDC) project will support maternal and child health research by ***Developing a Multi-State Network of Linked Pregnancy Risk Assessment Monitoring System (PRAMS) and Clinical Outcomes Data for Patient-Centered Outcomes Research***. The project will link state-level PRAMS data with birth certificates and clinical outcomes data, with the potential to expand to other maternal and child health surveillance systems. These linkages (i.e., hospital discharge, Medicaid claims, all payer claims data bases, patient-reported data with clinical and vital records data) will create a more comprehensive data set to study interventions prior to pregnancy and during the perinatal and post-partum periods. These data will include information on how social context and SDOH affect maternal health—intimate partner violence, housing insecurity, experience with incarceration—data that are not often unavailable in clinical data sets.

## PCOR Data Infrastructure in Support of the COVID-19 Response

The COVID-19 pandemic presents unprecedented challenges and opportunities for patient-centered outcomes research. Given the urgent need for data and evidence, the pandemic motivated a select group of projects to repurpose or expand their products to support the COVID-19 response. Below, we highlight

eight projects that have leveraged their OS-PCORTF project work to bolster initiatives that address the COVID-19 pandemic.

The FDA's **SHIELD project (Systematic Harmonization and Interoperability Enhancement for Laboratory Data) Collaborative – Standardization of Lab Data to Enhance Patient-Centered Outcomes Research and Value-based Care** seeks to improve laboratory reporting processes between institutions, beginning with in-vitro diagnostic (IVD) devices. These laboratory data—while exceedingly valuable for clinical care, public health research, and surveillance programs—prove difficult to use for research due to their variability. SHIELD has standardized IVD laboratory test result data with LOINC (Logical Observation Identifiers Names and Codes) codes, making these data more interoperable, and filling crucial gaps faced by researchers and health professional working with incomplete data.

The SHIELD collaborative expanded upon its OS-PCORTF project work by developing [LOINC codes for SARS-CoV-2 diagnostic tests](#).<sup>19, 20</sup> As of June 4, 2020, HHS has mandated the implementation of SHIELD-harmonized standards across laboratories nationally so that information on every IVD test performed can be rapidly disseminated among diverse institutions.<sup>21</sup> Coupled with reporting mandates, these laboratory data will support a range of COVID-19 related activities, including epidemiologic case investigation, contact tracing efforts, monitoring volume, and use of testing resources.

The multi-agency project, **Harmonization of Various Common Data Models (CDMs) and Open Standards for Evidence Generation**, led by the FDA, the NIH National Center for Advancing Translational Sciences (NIH/NCATS), NIH National Cancer Institute (NIH/NCI), NIH/NLM, and ONC, is developing infrastructure that allows organizations to share and combine structured data from sites using different CDMs. The project will further improve on the logic undergirding CDMs by harmonizing data from four distinct models across four networks, enhancing data accessibility, functionality, and interoperability.

In response to the pandemic, NIH/NCATS has established the National COVID Cohort Collaborative (N3C), a data analytics platform leveraging work from the CDM project. By establishing a common language for COVID-19 data, the project offered researchers and clinicians swifter access to uniform laboratory data, aiding in both research and delivery of health services. The CDM project work has also been leveraged by the COVID-19 Evidence Accelerator Collaborative, an initiative that is mapping COVID-19 data elements to four CDMs (Sentinel, PCORv4.0, Observational Medical Outcomes Partnership (OMOP), and Informatics for Integrating Biology & the Bedside [i2b2]), HL7 FHIR, CDISC SDTM (Clinical Data Interchange Standards Consortium Study Data Tabulation Model), and the Veterans Administration EHR data elements to provide a venue to share findings and strategize on what additional analyses should be addressed.

FDA's project, **Source Data Capture from Electronic Health Records: Using Standardized Clinical Research Data (OneSource)**, has helped bridge the gap between data models for clinical care and those for research. OneSource is designed to forge interoperable connections between EHRs and electronic data capture (EDC) systems used by clinical trials researchers. FDA partnered with the University of California at San Francisco (UCSF) to conduct a phase 3 breast cancer clinical trial, known as the "I-SPY TRIAL." Participating sites tested a cloud-based tool that seamlessly integrates into any EHR and EDC system, allowing them to electronically transfer patient information collected at the point of care into their EDC systems. Coordination and data sharing of this kind lessens the burden of repetitive, manual data entry in both settings and optimizes the capture of individual and population-level health outcomes.

In response to the COVID-19 pandemic, FDA has continued its collaboration with UCSF's team to support an "I-SPY COVID Trial." I-SPY COVID is utilizing the OneSource platform to collect and analyze patient data to treat acute respiratory distress syndrome (ARDS) in COVID-19 patients. These data allow



clinicians, researchers, and pharmaceutical companies to compare ARDS interventions to existing therapies and quickly assess treatment efficacy to decrease mortality and time on ventilators.

The FDA project, **Collection of Patient-Provided Information through a Mobile Device Application for Use in Comparative Effectiveness and Drug Safety Research**, developed the widely-applicable MyStudies app for capturing and linking patient-generated health data (PGHD) to claims and EHR data from Sentinel's participating partners. While initially piloted among pregnant women, this app can be reconfigured for diverse patient populations and health research topics, allowing for a novel level of flexibility in health care research.

The FDA has leveraged the MyStudies app to build the [COVID MyStudies app](#),<sup>23</sup> 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. The app is available for free in the Apple and Google stores, and the project team has released a publicly available user guide.<sup>24</sup> This shift highlights the app's flexibility and usability across diverse populations, having rapidly shifted from collecting PGHD from pregnant women to supporting consent gathering among clinical trials participants.

**PCOR Trust Fund Impact:**

The COVID MyStudies app is being offered for free during the COVID-19 public health emergency, with technical assistance from Harvard Pilgrim Health Care Institute.<sup>22</sup>

Investigators can incorporate consent documents into their trials, and incorporate trial-specific branding into the app.

As of May 2021, the app had been downloaded 2,360 times on iOS and 231 times on Android.

The Agency for Healthcare Research and Quality's (AHRQ) **Capstone for the Outcome Measures Harmonization (OMH) project** builds on previous OS-PCORTF work. The prior project identified barriers that hinder the implementation of harmonized outcome measures in PCOR, which will be addressed in the Capstone project: the burden placed on clinical sites to conduct data collection and disruption to care delivery and difficulties surrounding clinical data extraction from patient records. Using depression as a use case, AHRQ is leveraging electronic patient-reported outcomes (PRO) standards and specifications developed by the **Advancing the Collection and Use of Patient-Reported Outcomes through Health Information Technology** project to assist providers with the collection of harmonized depression outcome measures in EHRs. Symptoms of depression have increased during the pandemic, creating an urgent need to transition to remote care delivery and alternatives to in-person data collection methods.<sup>25</sup> The project team is poised to assist in the rapid transition to virtual collection of PRO measures on depression. At the conclusion of the project, the team will be more broadly disseminating the project tools, including making a SMART on FHIR app publicly available through the SMART App Gallery and through the Epic site for open-source apps.

**PCOR Trust Fund Impact:**

The tools for calculating and displaying the harmonized patient-reported outcome measures are being used at 21 practices (11 from the PRIME Registry and 10 from PsychPRO) and by five clinicians located at different practices within the Baystate Health system.

As of May 2021, 305 patients have completed the PHQ-9 remotely using the tools developed under this project, and the team is actively gathering data on use among clinicians and practices.

The CDC's project, Enhancing Data Resources for Researching Patterns of Mortality in Patient Centered Outcomes Research: Project 1 – Adding Cause-Specific Mortality to the National Center for Health



Statistics (NCHS) *National Hospital Care Survey by Linking to the National Death Index (NDI)*, aims to increase the scope and availability of mortality data for PCOR by linking the NCHS

National Hospital Care Survey data to the NDI, EHRs, and emergency department records. The NDI is a centralized database of death record data on file in state vital statistics offices. This database contains information health researchers may leverage for mortality ascertainment to assess disease etiology and risk factors and analyze the efficacy of a host of clinical interventions and therapies. Improvements to the mortality data infrastructure have allowed NCHS to release estimates of COVID-19 deaths, enhancing current surveillance efforts.<sup>26</sup> NCHS is providing provisional death counts to deliver the most currently available data on deaths due to COVID-19 ahead of official processing of state-level death certificates by NCHS. Based on death certificates, these provisional data include data on comorbid conditions, race and ethnicity, and location of death. These data increase the timeliness of data available to researchers to support COVID-19 surveillance activities.

**PCOR Trust Fund Impact:**

The NCHS [surveillance data](#) on COVID-19 deaths is a publicly available data resource, with daily and weekly updates of multiple data files, visualizations, and COVID-19 summary statistics.

Each of the 19 surveillance datasets has received thousands to hundreds of thousands of views and downloads. The dataset on Provisional COVID-19 Death Counts by Sex, Age, and State has been viewed 2.46M times, with 198K downloads, as of May 2021.

NIH/National Institute on Drug Abuse's (NIDA) *Emergency Medicine Opioid Data Infrastructure - Key Venue to Address Opioid Morbidity and Mortality (Project CODE PRO – Capturing Opioid Use Disorder Electronically and Patient Reported*

*Outcomes)* seeks to standardize measurement of OUD-specific common data elements (CDEs) in order to track and improve OUD care quality in emergency department settings. This project will assess the use and integration of OUD CDEs in the American College of Emergency Physicians Clinical Emergency Data Registry and study the collection of PRO data in emergency department EHRs. This would allow researchers to aggregate uniform data from disparate sources, improving interoperability and linkages between EHRs, research networks and registries for opioid-relevant research. The project team has

leveraged its OUD data dictionary to conduct an ad hoc analysis of emergency department utilization trends and outcomes for substance use disorders (SUDs) and mental health conditions during the pandemic. In a recent publication, the team conducted an analysis that uncovered trends in emergency department visitations and increases in deaths from SUDs or OUD from January 2019 through November 2020.<sup>27, 28</sup>

**PCOR Trust Fund Impact:**

The project team has published articles to raise awareness of PRO data collection in relation to OUD.

- Venkatesh A, Malicki C, Hawk K, D OG, Kinsman J, Taylor A. [Assessing the readiness of digital data infrastructure for opioid use disorder research](#). *Addiction Science & Clinical Practice*. 2020;15(1).

The joint Office of the Assistant Secretary for Preparedness and Response (ASPR) and AHRQ *Assessing and Predicting Medical Needs in a Disaster* project created a data platform to conduct PCOR that supports medically-related disaster response and recovery efforts. The platform provides the researcher community with expanded data to study health care utilization. Building on existing federal data resources, including the Healthcare Cost and Utilization Project (HCUP) data, the data platform provides federal researchers and emergency management personnel with evidence-based data to inform decision-making on the type and volume of medical expertise and supplies that should be deployed locally during a disaster. The ASPR team was able to leverage this data infrastructure to assess the impact of COVID-19 on shelter-seeking behavior. Their research demonstrated dramatic decreases in shelter utilization during the pandemic, likely due to concerns about sustained in-person contact. This information is critical for real-time planning to ensure that vulnerable population who would normally access medical and human services through shelters are reached through other mechanisms.

#### PCOR Trust Fund Impact:

Researchers at ASPR have used the platform and tools to conduct analysis that contributes to real-world decision making:

- In response to the COVID-19 pandemic, ASPR worked with the American Red Cross and academic researchers to assess the effects of COVID-19 on disaster shelter utilization.
- In response to Hurricane Dorian, ASPR conducted a quick-turnaround analysis of historical hurricanes that traveled up the Easter Seaboard and caused substantial flooding.
- In response to the Kincadee fires, ASPR presented a smoke inhalation analysis to California public health partners, emergency management, researchers, and health professionals, which resulted in modified resource allocation.

## Improvements in PCOR Data Infrastructure to Address Stakeholder Priorities

In December 2019, Congress reauthorized the Trust Fund, creating opportunity to further ASPE's efforts to enable five functionalities for PCOR data infrastructure over the next decade. In light of the reauthorization, ASPE gathered input on remaining challenges and areas where patient-centered outcomes research data infrastructure could continue to be improved from a diverse group of stakeholders (e.g., government, academic, health systems) who had experience in a range of areas including policy, research, and informatics. Five themes consistently appeared across the functionalities, many of which are being addressed by active projects: 1) consistent adoption and use of data standards; 2) better access to SDOH data that are not routinely collected during care delivery; 3) ability to access, integrate, and use patient-provided information; 4) increased access to data sets; and 5) expanded collaboration across the local, state, and federal levels.<sup>29</sup>

**Theme 1: Consistent adoption and use of data standards.** Stakeholders suggested multiple improvements to data standards, including consistency in collecting, cleaning, and presenting data and the importance of promoting adoption of and adherence to standards across the health system. A cross-agency project from FDA, NIH, and ONC focused on the *Harmonization of Various Common Data Models and Open Standards for Evidence Generation*, targeting cancer-related data sharing across four networks: 1) FDA Sentinel; 2) the Accrual to Clinical Trials (ACT) Network; 3) the National Patient-Centered Outcomes Research Network (PCORnet); and 4) the Observational Health Data Sciences and Informatics (OHDSI)

**Theme 2: Better access to SDOH data that are not routinely collected during care delivery.**

Stakeholders focused on the need for expanded access to federal data sets to support SDOH-focused PCOR. An ongoing project from AHRQ will specifically address this need. The ***Enhancing Patient-Centered Outcomes Research (PCOR): Creating a National Small-Area Social Determinants of Health Data Platform*** will leverage existing data sources to develop a national standardized database of readily linkable SDOH variables. The database will include key information at multiple geographic levels such as income, employment, food, housing, education, health status, and health care access and utilization.<sup>30</sup> The data can be used by external researchers to link to other data sets or look across counties and zip codes assessing SDOH-related characteristics.

A project from AHRQ and NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) addresses the need for standardized SDOH data by improving ***Data Capacity for Patient-Centered Outcomes Research through Creation of an Electronic Care Plan for People with Multiple Chronic Conditions***. The project is developing an interoperable clinician-facing and patient-facing electronic care (eCare) plan—a tool that provides information on patient health concerns, preferences, interventions, and health status over time—that allows for the aggregation of EHR and patient-centered data across multiple settings and sectors. The eCare plan app will capture SDOH data on food insecurity, poverty, and homelessness using the FHIR Resource Questionnaire, which will increase the interoperability of this information and improve its availability in EHRs.

**Theme 3: The ability to access, integrate, and use patient-provided information.** Specific areas for improvement included mechanisms to promote the collection of PROs among patients and the integration of patient-provided information into the EHR. AHRQ and ONC's project, ***Advancing the Collection and Use of Patient-Reported Outcomes through Health Information Technology***, addressed both of these needs by first refining and harmonizing health IT standards and implementation specifications to enhance the sharing of PRO data. The project then developed apps for collecting and integrating PRO data into EHRs and other health IT systems, and pilot tested two apps in a health care system.

**PCOR Trust Fund Impact:**

The [AHRQ SDOH database](#) (beta version) includes county-level data (2009-2018) and zip code-level data (2011-2018) related to: social context, economic context, education, physical infrastructure, and health care context.

Users downloaded files 5,423 times (Jan – Apr 2021):

- 1,200 total downloads for each of the 2018 county data file and the SDOH codebook file
- 1,100 total downloads of the SDOH documentation file
- 800 downloads of the 2018 zip code tabulation area level data file

**PCOR Trust Fund Impact:**

In collaboration with patients, AHRQ and NIH/NIDDK developed a [LOINC code](#) that indicates if patients are having trouble adhering to their care plan. The panel includes two codes, one documenting challenges and one recording the specific areas of treatment affected by the challenges. The answer list for challenges includes social risk factors such as financial concerns, lack of insurance, transportation limitations, and lack of neighborhood resources.

**PCOR Trust Fund Impact:**

ONC developed the [Patient Reported Outcomes \(PRO\) FHIR Implementation Guide](#), which focuses on capturing and exchanging PRO data electronically using the FHIR (4.0) standard. The Implementation Guide (version 2.0) has gone through several rounds of ballot comments through HL7.

**Theme 4: Increased access to data sets, especially de-identified and linked data sets.** Stakeholders emphasized the need for access to de-identified data that would support PCOR. A project from ONC gives researchers another data source option to test early solutions and hypotheses by creating **A Synthetic Health Data Generation Engine to Accelerate Patient-Centered Outcomes Research**. Use of synthetic data eliminates the risk of re-identifying anonymized data and bypasses challenges from combining disparate data sources. The project will enhance the capabilities of Synthea™, an open source software that creates large amounts of clinically realistic, synthetic patient health records. The project will result in data generation modules for opioid, pediatric, and complex care use cases that increase the ability by users to generate synthetic patient.

In another project, ONC and NIH/NLM are **Training Data for Machine Learning to Enhance Patient-Centered Outcomes Research (PCOR) Data Infrastructure**. The project will yield valuable insights into the aspects that are key to building training data sets and foundational aspects that will improve the use of machine learning in research. Machine learning can quickly synthesize large volumes of data in complex formats and curating high-quality training data sets are critical to robust machine learning models. The project will then develop two use cases, kidney disease and drug resistance in tuberculosis patients, leveraging federal data assets from NIH/NIDDK and NIH/National Institute of Allergy and Infectious Diseases (NIAID).

Stakeholders highlighted the need for secure, linked patient-level data sets to support patient-centered outcomes research. A project from CDC's NCHS **Data Linkage: Evaluating Preserving Privacy Methodology and Augmenting the National Hospital Care Survey with Medicaid Administrative Records** will improve access to linked federal data assets. The project will use privacy preserving record linkages to link Medicaid claims data from the Center for Medicare & Medicaid's Transformed Medicaid Statistical Information System (T-MSIS) with the 2014 and 2016 National Hospital Care Survey. Linking these data will allow researchers to examine person-level outcomes for a range of topics including opioid use interventions, medication protocol evaluations, social programs as a health determinant, and health disparities.

**Theme 5: Expanded collaboration across the local, state and federal levels.** Stakeholders emphasized the need for collaboration at all levels to leverage and enhance existing data sources and infrastructure. The CDC's **Childhood Obesity Data Initiative (CODI): Integrated Data for Patient-Centered Outcomes Research Project** is building linkage capabilities, coding upgrades, and other enhancements to facilitate access to longitudinal clinical and community child-specific data. The project is fostering collaboration across sectors and levels through a pilot of enhanced linkage and de-duplication tools in the Colorado Health Observation Regional Data Service (CHORDS)—a PCORnet Clinical Data Research Network—which involves three major health care systems in the Denver, Colorado metro area.

These nine projects are examples of how the OS-PCORTF is addressing the needs and priorities of stakeholders. While the Trust Fund will continue to address priorities for patient-centered outcomes research data infrastructure in these areas moving forward, broader adoption of these products is needed to increase their reach.

In addition to the input gathered above, ASPE is gathering input from partners at HHS agencies and from external stakeholders through workshops sponsored by the National Academies of Medicine and Engineering throughout 2021. Collectively, this input will inform ASPE's effort to develop a new strategic plan through 2029.

## IV. 2020 Major Accomplishments

Each year, the portfolio of projects produce tools and resources that improve the data infrastructure for patient-centered outcomes research by enhancing the capacity “to collect, link, and analyze data on outcomes and effectiveness.”<sup>31</sup> To illustrate the impact and scope of the OS-PCORTF, this report highlights three projects that concluded in Fiscal Year 2020 whose activities offer usable solutions for researchers in the following areas:

- **NDI linkages to other data sources**
- **Standardized common data elements and capture of patient-reported outcome measures capture to enrich registry data**
- **Data and analytic solutions that enhance publicly-funded databases**

**NDI linkages to other data sources.** To improve data infrastructure to study mortality, the CDC launched a project to link three important data sources on patient health—*Adding Cause-Specific Mortality to National Center for Health Statistics’ National Hospital Care Survey by Linking to the National Death Index and CMS Master Beneficiary Summary File*. The NDI is the only central data source containing information on both fact and cause of death for all deaths occurring within the US, and is therefore essential to the study of health outcomes, diseases and risk factors, and the effectiveness of a wide range of interventions. The National Hospital Care Survey (NHCS) describes national patterns of health care delivery in the hospital setting and contains key patient identifiers for linkage; while the Master Beneficiary Summary File (MBSF) contains demographic and enrollment information, and cost and utilization data for Medicare beneficiaries. Together, linkages between these data sources are intended to advance studies on mortality and post-acute care utilization following hospital care.

Thus far, the CDC has demonstrated the utility of the linked data in studies on:

- Alzheimer’s disease emergency room encounters and among hospitalized patients<sup>32</sup>
- Respiratory illness emergency department visits<sup>33</sup>
- Inpatient hospitalizations for stroke<sup>34</sup>
- Opioid-involved emergency department visits, hospitalizations, and deaths<sup>35, 36</sup>

**Standardized common data elements and collection of patient-reported outcome measures to enrich registry data.** The NIH is enhancing opioid-related research with the capture of PROs through the project **Emergency Medicine Opioid Data Infrastructure: Key Venue to Address Opioid Morbidity and Mortality (Project CODE-PRO – Capturing Opioid Use Disorder Electronically and Patient Reported Outcomes)**. Emergency departments are critical points of entry for opioid use disorder (OUD) patients, and therefore they present an opportunity to collect OUD data and conduct OUD-related research. CODE-PRO has enhanced researchers’ ability to conduct opioid-related research by developing OUD-specific common data elements (CDEs) that standardize OUD data, increase their quality, and allow their exchange. For example, the team demonstrated the utility of CDE mapping between EHRs and the American College of Emergency Physicians (ACEP) Clinical Emergency Data Registry (CEDR). The team also assessed the feasibility and acceptability of collecting electronic PROs measures from patients, piloting a mobile app to collect OUD-related PROs from emergency department patients. The goal of the patient-facing app is to expand the PROs available for opioid-related research and to ensure they are standardized and high quality data.

**Data and analytic solutions that enhance publicly-funded databases.** Well-coordinated responses to natural disasters and emergencies require local level data that allows teams to identify needs and tailor



medical response to the specific populations in specific locations. The joint AHRQ and ASPR **Assessing and Predicting Medical Needs in a Disaster** project developed a data platform for analyzing key data that can support emergency preparedness and disaster response and recovery operations. Specifically, it combines HCUP data—the largest collection of longitudinal hospital care data in the United States—and state- and county-level information related to disaster response.<sup>37</sup> The public-facing platform and tools allow researchers to access and analyze these data to learn from past crises; for example, to study the [effects of hurricanes on hospital use](#). This project will initially support comparative effectiveness research questions, such as which emergency management interventions at the county level were successful. As more data and tools become available, researchers will be able to use these data to assess different interventions based on disaster type and population, identify patient needs and trends for long-term recovery, and potentially track the long-term health consequences of a disaster.

## V. Conclusion

The OS-PCORTF Annual Report provides a synopsis of the 31 Trust Fund projects active in Fiscal Year 2020. It highlights their individual contributions and their collective contributions to federal priorities like maternal health and the COVID-19 response, and stakeholder priorities like capturing and integrating PPI and SDOH into research. The featured projects provide a window into the wide range of data infrastructure improvements being made under the OS-PCORTF to enhance the health system's capacity for patient-centered outcomes research that improves patient care and outcomes.

## References

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