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

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

Enhancing Data Infrastructure to Improve Women's Health Outcomes

Improving maternal health before, during, and after pregnancy is among the nation's most pressing public health priorities. Maternal health, mortality, and morbidity are strategic national research priorities across the Department of Health and Human Services (HHS) (Exhibit 1),[1] reflected in Healthy People 2030 and the 2019 Congressional reauthorization of the Office of the Secretary's Patient-Centered Outcomes Research Trust Fund (OS-PCORTF).[2]

Patient-centered outcomes research (PCOR) requires robust data to monitor, understand, and address health outcomes that are unique to women. However, researchers face many difficulties aggregating data on outcomes for women's and maternal health to produce informative, actionable evidence on health care options. Such data are often captured across multiple, disparate platforms with unique data elements, which limits researchers' ability to analyze these data in aggregate.

Under the OS-PCORTF, the Assistant Secretary for Planning and Evaluation (ASPE) has funded multiple projects that are helping to address these challenges with better tools to collect, standardize, link, share, and analyze women's health data. The 2020-2029 OS-PCORTF Strategic Plan charts a course for the future and includes a priority area under Goal 1 around maternal health.[3]

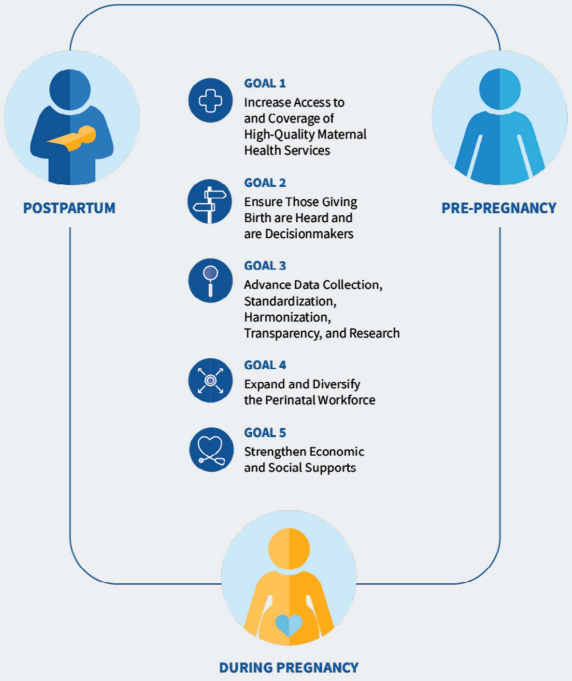
Enhancing Women's Health Data for Research

Recent technological advances in screening and testing to improve diagnostic accuracy as well as in treatment options for clinical conditions unique to women have spurred a growing demand for evidence on the performance of these interventions that better reflects women's experiences and outcomes. Patient registries can help meet this need by including real-world data on patient care and specific device exposures. However, they can also require major investments to run efficiently. Both completed and ongoing projects have focused on forming collaborations across coordinated registry networks (CRNs)—in which multiple registries align their data capture and sharing—as a mechanism for increasing the data and analytic tools available for women's health research.

"…Data collection on maternal health risks, services, outcomes in the United States continues to be fragmented, unstandardized, nontransparent, and irregular. As a result, health care systems, communities, and government entities do not have a fully informed grasp of the problem and what solutions should be deployed. Incomplete and inconsistent data collection also means maternal morbidity and mortality rates are not effectively quantified, which can slow or halt action to address known disparities in maternal outcomes."[1]

WHITE HOUSE BLUEPRINT FOR ADDRESSING THE MATERNAL HEALTH CRISIS (2022)

EXHIBIT 1. HHS MATERNAL HEALTH GOALS



Developing a Strategically Coordinated Registry Network for Women's Health Technology (WHT-CRN)

This project was a collaboration between the Food and Drug Administration (FDA), National Institutes of Health (NIH)/National Library of Medicine (NLM), and Office of the National Coordinator for Health IT (ONC) that began in 2017. The project developed an infrastructure to evaluate medical devices in four clinical areas: stress urinary incontinence, uterine fibroid treatments, pelvic organ prolapse treatments, and elective female sterilization therapies.[4] This ensured that data entering the registry network were consistent, high quality, and well suited to research in the post-market context (i.e., after receiving FDA approval or clearance). Within the network, core data elements are augmented through linkages with claims, electronic health record (EHR) data, and patient-reported outcomes (PRO) data collected via a patient-facing mobile application. **The WHT-CRN filled a critical gap in the infrastructure needed to study health technologies in women by developing standards that registries can use to capture the same core elements from diverse data sources.**

KEY PRODUCTS

- The final report on the WHT-CRN provides an overview of project activities and findings.
- The WHT-CRN common core data set, inclusive of the four core clinical data sets, is part of the larger NIH Common Data Element (CDE) Repository.
- The WHT-CRN Fast Healthcare Interoperability Resources (FHIR)® Implementation Guide (release 0.2.0), based on FHIR Version 4.0.0, focuses on capturing and exchanging data related to women's health.

PROJECT AGENCIES: FDA, NIH/NLM, ONC

Bridging the PCOR Infrastructure and Technology Innovation through Coordinated Registry Networks Community of Practice (CoP)

Comparative effectiveness research (CER) often relies on data captured at the point of care (outside the context of a clinical trial), re-entered into clinical research systems, and then consolidated and transformed for analysis and research purposes. This is a complex, labor-intensive, and expensive process, which often requires duplicative data entry, extensive data quality checks, and restructuring to create research-ready datasets. In 2019, the FDA established this project, which is advancing the capacity for research supporting the linking and exchange of standardized CRN data. Building on a CRN CoP that was developed in earlier phases of the FDA Medical Device Epidemiology Network (MDEpiNet), this project established a CRN Learning Community (CLC) to create space for CRNs to share knowledge and ideas with each other in the areas of governance, informatics, methodological approaches, data linkages, interoperability, and digital solutions. The CLC has participation from CRNs across 12 clinical areas. The CRNs are pilot testing and refining FHIR® profiles to promote data exchange among three to five participating CRNs; pilot testing instruments for capturing patient preferences; and developing and testing gender- and sex-specific outcome measures for devices. **Through a collaborative approach, this project facilitated knowledge sharing and adoption of standards to support researchers conducting PCOR. This will help increase the availability of high-quality, timely, and actionable evidence, and better support research on patient use of medical devices and their health outcomes.**

KEY PRODUCTS

- The project developed more than 16 tools, including data dictionaries, implementation guides, and road maps.
- A manuscript in *BMJ Surgery, Interventions, & Health Technologies* features a tool that assesses the maturity of CRN data infrastructure [anticipated].
- A project website summarizes the scope, activities, and tools developed under each of the 12 CRNs.
- A validation study, "Validation of an indirect linkage algorithm to combine registry data with Medicare claims," was published in the *Journal of Vascular Surgery* in February 2022.
- A usability study on a mobile application, "Development and Usability Testing of a Mobile Application to Monitor Patient-Reported Outcomes after Stress Urinary Incontinence Surgery," was published in *Urology* in January 2022.

PROJECT AGENCY: FDA

Adding Electronic Health Records to the Suite of Maternal Health Data for Research

The OS-PCORTF's Maternal Health Consortium was created in 2021 to facilitate collaboration among projects focused on using EHR data for maternal health research. One of the main aims of this consortium is to assess data exchange standards, methodologies, projects, and other initiatives to inform the development of new tools for longitudinal maternal and infant health information for research.

Severe Maternal Morbidity and Mortality Electronic Health Record Data Infrastructure

KEY PRODUCTS

- The project developed a draft value set and a preliminary FHIR® implementation guide.
- The team completed an environmental scan which included an inventory of maternal and child data requirements [anticipated].

PROJECT AGENCY: NIH/NICHD

Launched in 2021, this project led by the NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) aims to strengthen both maternal and infant health data needed to examine the effect of medical conditions and/or interventions on pregnant, postpartum, or lactating women and their infants. The project is developing a set of standard data elements for EHRs and an FHIR® application programming interface (API) that improve interoperability and make data across different systems available for studies on maternal morbidity and mortality from pregnancy through 1-year postpartum. The project team also developed a preliminary HL7® FHIR® implementation guide that outlines a framework for aggregating and analyzing clinical data for research on maternal and child morbidity and mortality. The implementation guide was tested during the HL7® January 2022 Connectathon. This guide will eventually support mapping maternal health data across several use cases such as pregnancy and subsequent death within a year of a pregnancy and hypertensive disorders of pregnancy. **Through the FHIR® implementation guide, this project advances the use of EHRs to support longitudinal research on maternal morbidity including pregnancy-related conditions (e.g., pre-eclampsia), pregnancy outcomes, and maternal mortality.**

MATernaL and Infant NetworK (MAT-LINK) to Understand Outcomes Associated with Medication for Opioid Use Disorder (OUD) during Pregnancy

KEY PRODUCTS

- The MAT-LINK project webpage provides background information about the project, including partners, clinical sites, goals, and example variables. Once data collection is complete, instructions on how to access MAT-LINK data will be available on this webpage.
- The project team published an article in the *Journal of Women's Health* that describes medications and herbal supplements used by pregnant women for OUD and how MAT-LINK can address gaps in knowledge about the management and treatment of OUD during pregnancy.
- An article describing MAT-LINK surveillance methods and population characteristics from the first four clinical sites will be published in early 2023 [anticipated].

PROJECT AGENCY: CDC

The CDC, in partnership with NIH, the Substance Abuse and Mental Health Services Administration (SAMHSA), and Centers for Medicare and Medicaid Services (CMS), are addressing the lack of national-level data on maternal health outcomes through the MAT-LINK surveillance network. Initiated in 2019, the project established a topic-specific health outcomes surveillance network to monitor maternal and infant health outcomes. The network consisted of four clinical sites across the U.S. (Phase I)—Boston Medical Center, the Ohio State University, University of Utah, and Kaiser Foundation Research Institute Northwest in Oregon and Washington. The project developed core measures for OUD during pregnancy to inform what standardized data can be collected, analyzed, and rapidly shared to support patient-centered care for pregnant women with OUD and infants and children with prenatal opioid exposure.

In 2021, MAT-LINK expanded by adding three clinical sites (Phase II)— University of New Mexico, University of Rochester, and University of South Florida—and extended child follow-up from two years to six years of age for all clinical sites. The expansion adds geographically diverse clinical sites with varied racial, ethnic, and socioeconomic characteristics, and enables the capture of data on over 5,000 linked dyads that includes more comprehensive developmental data of children who were

prenatally exposed to opioids. The project team plans to disseminate the results of its work to improve policies, clinical practice recommendations, and clinical decision-making. **Results from MAT-LINK can be used to improve understanding of maternal and infant health outcomes following medication for OUD during pregnancy and the role of mediating and moderating factors on maternal and infant outcomes.**

Enhancing Surveillance of Maternal Health Clinical Practices and Outcomes with Federally Qualified Health Centers' Electronic Health Records Visit Data

KEY PRODUCTS

- A manuscript focusing on the FQHC sampling procedures is under development [anticipated].
- NAMCS dataset linked to the NDI and HUD administrative data [anticipated].

PROJECT AGENCY: CDC

The National Ambulatory Medical Care Survey (NAMCS) is the only source of nationally representative clinical visit-level data on ambulatory health services, including maternal health care services provided at federally qualified health centers (FQHCs). Initiated by the CDC in 2021, this project is enhancing and expanding NAMCS data collection procedures for maternal health visits to FQHCs. NAMCS will transition from manual patient record abstraction to electronic data transmission of EHR data and expanding the collection of data elements to enable data linkages between NAMCS data, the National Death Index (NDI), and the Department of Housing and Urban Development (HUD) administrative data. **The NAMCS dataset produced by this project will be a nationally representative set of data on maternal health treatment and outcomes at FQHCs that will be linked to additional data sources and support more robust PCOR.**

Linking Maternal Survey Data with Other Health Data

Self-reported data collected through surveys like the Pregnancy Risk Assessment Monitoring System (PRAMS) add unique personal perspectives about an individual's health care journey. Linking these data with other health-related data enriches the information available for PCOR.

Developing a Multi-State Network of Linked Pregnancy Risk Assessment Monitoring System (PRAMS) and Clinical Outcomes Data for Patient-Centered Outcomes Research

KEY PRODUCTS

- The project will make the linked PRAMS datasets, codebooks, data dictionaries, and guidance for developing data access proposals available to external researchers [anticipated].
- The project has a webpage on the CDC website that disseminates information about PRAMS special projects.

PROJECT AGENCY: CDC

PRAMS is a surveillance project of the CDC Division of Reproductive Health and state departments of health. PRAMS covers approximately 81 percent of all live births in the US.[5] Critically, PRAMS captures patient voices, including social context (e.g., intimate partner violence, housing insecurity, incarceration), behavioral health, and social determinants of health (SDOH) data that are self-reported by patients.

The aim of this project is to link state-level PRAMS data with state birth certificates and clinical outcomes data (e.g., hospital discharge data, Medicaid claims, all-payer claims databases). The project is also establishing a state-based learning community supported by a coordinating center to provide technical support for using a standardized methodology for linking data sets. As part of the learning community, several states are participating in virtual learning sessions and pursuing linkages of PRAMS to a wide range of data including Medicaid claims; home visitation and pre-kindergarten data; and hospital discharge data. **Linking PRAMS with other health data will enrich data for PCOR by adding self-reported information that will provide a more comprehensive understanding of multiple determinants of maternal and infant health outcomes.**

Looking to the Future

These OS-PCORTF projects are paving the way for enhanced PCOR studies on maternal health that can help the nation make progress on high rates of maternal morbidity and mortality. Through better data infrastructure, including data standardization to improve data exchange and linking key data sources, researchers will be able to conduct complex and longitudinal studies to improve women's health.

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Publication Date: October 2022

aspe.hhs.gov/collaborations-committees-advisory-groups/os-pcortf