Enhancing the Data Infrastructure for Women's Health Research to Improve Women's and Maternal Health Outcomes

Improving maternal health before, during, and after pregnancy is among the nation's most pressing public health priorities. The Centers for Disease Control and Prevention (CDC) estimates 17.4 maternal deaths occurred per 100,000 live births in 2018,[2,3] and an estimated 25,000 hospital deliveries involved severe maternal morbidity, meaning women's health was significantly affected in the short- or long-term because of complications in labor and delivery.[4] Racial and ethnic disparities have left black and American Indian/Alaskan Native (AI/AN) women at disproportionately higher risk for maternal mortality than white, Hispanic, and Asian/Pacific Islander women.[5] These patterns have persisted over the last two decades despite ongoing advances in healthcare, research, and technology.[6] COVID-19 has made racial, ethnic, geographic, and age-related health disparities even more stark, shining a light on how health conditions that affect women of color correlate with negative outcomes in pregnancy and COVID-19.[7] In addition to the need for research on conditions that affect women's health over the lifespan,[8] maternal health, mortality, and morbidity are a strategic national research priority across the Department of Health and Human Services (HHS) (see Exhibit 1),[9] reflected in Healthy People 2030[10] and the 2019 Congressional reauthorization of the Patient-Centered Outcomes Research Trust Fund (PCORTF).[11] Driving change is challenging, and data is an important piece of the puzzle.

> "The dearth of comprehensive research and data is a result of both difficulties with measurement approaches and a lack of systematic understanding of the many facets of maternal morbidity… The lack of rich and comprehensive information is found not only in quantitative studies of maternal morbidity but also in qualitative ones."[1]
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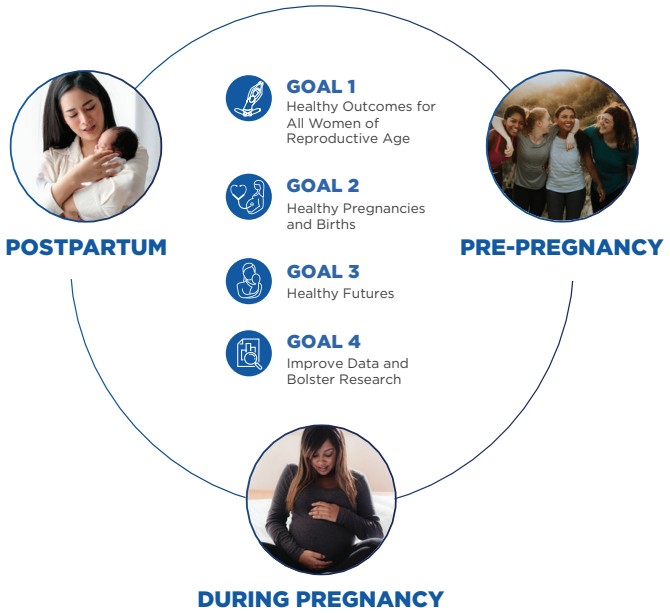
> **V FILLIPPI, ET AL. (2018)**
> **THE WHO MATERNAL MORBIDITY WORKING GROUP (MMWG)**

Having high quality data that is timely and identifies healthcare-related and social risk factors that contribute to poor outcomes is essential to improving women's and maternal health outcomes.[12] However, researchers and policymakers face challenges because

Exhibit 1. HHS Maternal Health Goals[13]



these data are often captured across multiple, disparate platforms with unique data elements, which limits researchers' ability to analyze the data in aggregate. Under the Office of the Secretary PCORTF (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 and maternal health data.

Enhancing Women's Health Data for Research.

There have been many technological advancements in recent years for treating clinical conditions that are unique to women, and there is growing demand for evidence on the performance of these technologies 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 in order to run efficiently. Two recent OS-PCORTF projects focus on forming coordinated registry networks—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.

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

The project Developing a Strategically Coordinated Registry Network (CRN) for Women's Health Technology (or WHT-CRN) is a collaboration between the Food and Drug Administration (FDA), the National Institutes of Health (NIH)/National Library of Medicine (NLM), and Office of the National Coordinator for Health IT (ONC) that began in FY 2017. It focused on developing an infrastructure to share and evaluate data on medical device effectiveness for uterine fibroid treatments, pelvic organ prolapse treatments, and elective female sterilization therapies.

KEY PRODUTS

- The Final Report on the Coordinated Registry Network for Women's Health Technology (WHT-CRN)
- Project Infographic highlights the main features of the project
- The WHT-CRN 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

The WHT-CRN was designed to fill 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. This ensures that data entering the registry network are consistent, high quality, and well suited to post-market research. Within the network, core data elements are augmented through linkages with claims, EHR data, and patient-reported outcomes (PRO) data collected via a patient-facing mobile app. The resulting dataset is broadly applicable—for example, a medical device company that developed a method to treat uterine fibroids laparoscopically leveraged the WHT-CRN's core dataset to assist their own data collection efforts. In addition, several clinical sites have pilot tested the core data elements, the project's Fast Healthcare Interoperability Resources (FHIR) implementation guide, and the project framework for data sharing and interoperability.

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 project will expand its reach into 13 clinical areas; pilot test and refine Fast Healthcare Interoperability Resources (FHIR) profiles to facilitate data sharing among 3-5 participating CRNs; pilot test instruments for capturing patient preferences; and develop and test gender- and sex-specific outcome measures for devices. These activities will strengthen the CRN's ability to gather and share uniform high-quality data on medical device safety and generate actionable evidence to improve women's health outcomes.

Expanding Maternal Health Data for Research.

Pregnant women represent a traditionally understudied population in relation to vaccines and therapeutics, with significant gaps in outcomes data. Rates of opioid use dependency (OUD) at delivery have increased fourfold in the last 20 years;[14] however, there is a lack of surveillance systems for collecting outcomes data on pregnant women with OUD or receiving medication-assisted therapy. Two OS-PCORTF projects target the need for surveillance of maternal opioid use and monitoring of health outcomes among women, infants, and children.

MATernal and Infant NetworK (MAT-LINK) to Understand Outcomes Associated with Treatment for Opioid Use Disorder during Pregnancy

The CDC in partnership with NIH, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Centers for Medicare and Medicaid Services (CMS), are addressing the challenge of a lack of national-level data on maternal health outcomes with the 2019 project *MATernal and Infant NetworK (MAT-LINK) to Understand Outcomes Associated with Treatment for Opioid Use Disorder during Pregnancy*. MAT-LINK will serve as a health outcomes surveillance network to monitor maternal, infant, and child health outcomes across the nation.

KEY PRODUCTS

- The project website provides MATernal and Infant NetworK (MAT-LINK) Updates
- A publication by Tran et al. Journal of Women's Health 2020 that describes MAT-LINK's data and research capabilities.
- An upcoming report will detail core OUD surveillance variables and procedures for accessing project data collected by external researchers. [anticipated]

PROJECT AGENCIES: CDC, CMS, NIH, SAMHSA

The network will establish core measures for OUD during pregnancy so that standardized data can be collected, analyzed, and rapidly shared to inform patient-centered care for pregnant women with OUD, and infants and children with prenatal opioid exposure. It will also provide a data platform to aggregate linked maternal and infant health data for research. The project team plans to disseminate the results of its work to improve policies, clinical practice recommendations, and clinical decision-making. Real-world pilots are underway at four clinical sites across the nation, with more than 2000 dyads and counting. MAT-LINK's collaboration with real clinical settings is designed to incorporate the kinds of data generated at healthcare visits, resulting in findings that are both evidence-based and practical.

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

A 2020 project, *Developing a Multi-State Network of Linked Pregnancy Risk Assessment Monitoring System (PRAMS) and Clinical Outcomes Data for Patient-Centered Outcomes Research*, is a partnership between the CDC Division of Reproductive Health, other federal and academic institutions, and state departments of health. The project has begun work to support maternal and child health research by linking state-level monitoring data (PRAMS) with birth certificates and clinical outcomes data (e.g., hospital discharge data, Medicaid claims, all payer claims databases). The project is establishing a state-based learning community supported by a coordinating center to provide technical support for using a standardized methodology for linking data sets and will create a process to facilitate researchers' use of the project's data.

KEY PRODUCTS

- A final report will offer lessons learned and future recommendations on data access, data linkage, data sharing, data hosting, and sustainability. [anticipated]
- A publicly available data linkage protocol will document the methodology behind the linked data sets and detail the process of accessing the linked data. [anticipated]
- A linked data set will be made available to external researchers. [anticipated]

PROJECT AGENCIES: CDC

PRAMS was designed to reduce maternal and infant morbidity and mortality by influencing maternal behaviors before, during, and after pregnancy. It aims to identify women and infants at high risk for adverse

health outcomes, monitor their changes in health status, and measure progress towards the health goals of mothers and infants. Critically, PRAMS captures patient voices, including social context (e.g., intimate partner violence, housing insecurity, incarceration), behavioral health, and SDOH data that are self-reported by patients. Linkages between clinical outcomes data and PRAMS will provide more comprehensive data to study the effects of interventions and social context during the perinatal period and post-partum period, particularly in relation to opioid use and mental health. As the project progresses, it may expand its linkages to other maternal and child health (MCH) surveillance systems whose data will be valuable for patient-centered outcomes research.

Looking to the Future. Two other newly funded FY 21 projects are also working on making maternal health data research ready. For the project *Enhancing Surveillance Of Maternal Health Clinical Practices And Outcomes With Federally Qualified Health Centers' (FQHCs) Electronic Health Records Visit Data*, teams at CDC and the Health Resources and Services Administration (HRSA) are collecting electronic health record data from FQHCs to link to outside data sources such as the National Death Index and U.S. Department of Housing and Urban Development administrative data. This data linkage would provide critical information on SDOH and mortality post-FQHC visits. Meanwhile, NIH/National Institute of Child Health and Human Development, ONC, and CDC are working to harmonize both maternal and infant health data on medical conditions and interventions so that the data can be accessed through a FHIR® application programming interface (API). This project, *Severe Maternal Morbidity and Mortality-Electronic Health Record (EHR) Data Infrastructure*, will enable researchers to identify the full range of risk factors, including longitudinal medical history and basic socioeconomic and demographic characteristics that affect pregnancy outcomes for both the mother and the infant.

Through their work to expand the collection of standardized data and to link key data sources, these OS-PCORTF projects are enhancing the infrastructure for women's health research. They endeavor to improve the quality of data available in registries and surveillance systems; expand the networks of patients, clinicians, and health departments contributing standardized data; and expand the networks and tools available for conducting maternal health research. Their shared goal is to develop a robust evidence base of tailored and targeted research that can be used to inform and improve policies, clinical practice recommendations, and clinical decision-making related to women's health, maternal health, and health outcomes.

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