DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
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Bethesda, Maryland 20892

Severe Maternal Morbidity and Mortality Electronic Health Record Data Infrastructure

Final Report

Submitted: April 20, 2024

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Executive Summary

This project, funded by the Office of the Secretary-Patient Centered Outcomes Research Trust Fund (OS-PCORTF), developed a standard for exchanging maternal and infant clinical health data for research purposes. Two outputs of the project included the creation of a Fast Healthcare Interoperability Resources (FHIR®) Implementation Guide (IG) Longitudinal Maternal & Infant Information for Research FHIR® IG and development of MaternalHealthLink (MHL), an open-source FHIR®-based web application for automating the extraction and exchange of clinical data, modeled after CDC's National Health Safety Network (NHSN) open-source tool called NHSNLink.

To develop the implementation guide, two use cases were used.

1. Pregnancy and subsequent death within a specific time frame: This cohort includes women who died within a year (365 days) of a pregnancy regardless of cause of death or pregnancy outcome.
2. Hypertensive Disorders of pregnancy: This use case focuses on individuals with a diagnosis of pregnancy-induced hypertension, gestational hypertension and/or postpartum hypertension diagnoses within six weeks of delivery.

The IG was piloted in two databases from NIH projects. The MHL proof of concept was done with a health information exchange (HIE) to demonstrate the feasibility of implementing the FHIR IG standard within a real-world clinical data source and making the data available for an end user such as a researcher.

Relevant entities and expert panel engagement, key components to this project, included researchers, clinicians, federal partners, scientific organizations, and vendors, to collaborate with and come to consensus on improving data exchange standards and provide greater benefit for the maternal health research community.

Scientific engagement was critical to the success of the development of the IG and MHL. A Maternal Health Consortium (the Consortium) was created in collaboration with ASPE and facilitated it throughout its lifespan from FY21 through FY23. The aim of this Consortium was to collaborate and come to consensus on improving data exchange standards and provide greater benefit for the maternal health research community. The consortium was comprised of researchers from three PCORTF projects:

- Enhancing Surveillance of Maternal Health Clinical Practices and Outcomes with Federally Qualified Health Centers' Electronic Health Records Visit Data
- MAT-LINK2: Expansion of Maternal and Infant Network to Understand Outcomes Associated with Treatment for Opioid Use Disorder during Pregnancy
- Severe Maternal Morbidity and Mortality Electronic Health Records Data Infrastructure

The Consortium developed a charter to describe the purpose, members, and roles, guiding principles, and activities envisioned for the three PCORTF project members. Lantana Consulting Group (Lantana) hosted the calls, developed agendas with input from *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and Office of the Assistant Secretary for Planning and Evaluation (ASPE), coordinated and scheduled topics and speakers, and distributed meeting minutes.

We used the NICHD Microsoft Teams site to share information including minutes, presentations, and other information. Lantana contributed to Quarterly Progress Updates as requested by NICHD. The monthly consortium calls kicked off in May 2021 and continued through September 2023. Full meeting minutes are located on the NICHD Teams site.

This Consortium became the Maternal health Consortium 1.0 that was transitioned to its 2.0 version. A call to facilitate this transition was held on September 2023 and our facilitation role was transitioned to another participating project that was very active and active for the following years. We continued to participate in the MH Consortium 2.0 representing the Severe Maternal Morbidity and Mortality (SMM&M) EHR Data Infrastructure project until his deadline and providing expertise on improving and expanding the use of EHRs for maternal health.

1. Overview and Objectives

The purpose of this project is 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. Currently, the United States lacks consistent ways to collect and share the data needed to analyze how a woman's longitudinal medical history and basic socioeconomic and demographic characteristics affect pregnancy outcomes for both the mother and the infant.

Key Objectives:

- Develop HL7/FHIR® standards and guidance for pregnancy, including pregnancy outcomes, comorbid conditions, and pregnancy-related conditions and procedures, hereafter called Standards. These Standards will support research on maternal morbidity and mortality, pregnancy, pregnancy outcomes (e.g., miscarriage, stillbirth, live birth), and pregnancy-related conditions and procedures (e.g., pre-eclampsia, gestational diabetes).
- Develop tools to facilitate adoption of the Implementation Guidance by researchers.
- Conduct testing to assess the feasibility of the Standards/ Implementation Guidance through connectathons and other HL7/FHIR® processes and modify accordingly.
- Conduct a feasibility pilot/proof of concept in a health information exchange of both the Implementation Guide and the tooling.
- Produce a report that includes the Final Standards (standards, data models and vocabularies, and implementation guidance) available on the HL7 website and MaternalHealthLink both publicly available, with references on NIH, ONC, and CDC websites, and distribute it to key research and public health partners.

2. Background - Problems Addressed

The maternal mortality rate in the United States tracks at 32.9 per 100,000 births, based on the most recent data from 2021. Of the approximately pregnancy-related deaths occurring in the United States yearly, more than 80% are attributable to preventable causes. Research is an essential component of understanding the reasons and finding solutions to the high maternal mortality rates. Research forms the evidence base for future policies and interventions. In 2019, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) convened two workshops, including a community engagement forum, that examined the current state of the science, identified research gaps, and focused on the priorities for maternal mortality and morbidity research. The inability to link maternal and infant health records was cited as a challenge to fully understand the risks associated with severe maternal morbidity (SMM) and maternal mortality. Moreover, considerations identified to reduce maternal mortality included standardized definitions, additional data quality checks within the vital statistics data system to validate maternal deaths and understanding the hospital factors and clinical practices associated with lower rates of maternal morbidity and mortality. This proposal was to develop the infrastructure to work toward these goals.

Both maternal and infant health data are needed to examine the effects of medical conditions and/or interventions on pregnant, postpartum, or lactating mother and the infant. The United States lacks an efficient means to analyze how a woman's longitudinal medical history and basic socioeconomic and demographic characteristics affect pregnancy outcomes for both the mother and the infant. A pregnant woman who has pre-existing conditions, such as cardiac disease, may see various providers, including obstetricians and specialists. However, because of fractionated care, the woman's data may not be available to all her providers or to the infant/child providers.

Lack of the ability to gather and analyze these data limits our ability to prioritize which health conditions and treatments should be addressed. A lack of adequate samples has limited research on smaller highly at-risk groups (e.g. American Indian/Alaska Native). Additionally, a lack of population representative data at the national level limits researchers' ability to identify the full range of causes of severe maternal morbidity and maternal mortality. Some linked data are already available, but geographic coverage is poor and missing for lower resourced and rural areas.

HL7 FHIR® Implementation Guide and MHL are now both publicly available. Researchers now have access to the needed tooling that can be used to extract data from electronic health records for research questions that can leverage real-world data.

3.Methodology

Environmental Scan

As part of requirements gathering, we conducted an environmental scan and documented those findings in a report, Maternal & Infant Health Information Exchange Standards Review of Resources for Data Capture for Research. We distributed the report to interested stakeholders in July 2021. This environmental scan and review described the landscape of existing and emerging maternal and infant health data exchange standards for the purposes of research. The review drew from a wide range of work by standards development organizations (SDOs) as well as information from research organizations and industry subject matter experts. It describes and assesses data exchange standards, methodologies, projects, and other initiatives to inform development of new artifacts for a FHIR IG specifying longitudinal maternal and infant health information for research.

Technical Expert Panel (TEP)

Early in the project, we reached out to researchers, informaticists, clinicians, electronic health record vendors, and other stakeholders from state and federal organizations as well as industry agencies with interest or expertise in maternal health to join the Technical Expert Panel (TEP). We convened three TEPs from July 2021 to March 2023. At the first TEP, we introduced the project and facilitated a discussion about maternal health data including information the TEP deemed as a priority. The second TEP in December 2021 primarily focused on terminology and building value sets. The third TEP in March 2023 recapped the project including a demonstration visualization of the pilot data.

Develop Data Definitions and Clinical Terminologies

The TEP focused on terminology and included an overview of value sets and interoperability considerations which highlighted that indicating pregnancy isn’t as easy as checking a box for most electronic health record vendors. To pull data from electronic health records, we needed to confirm the clinical focus and data element scope as well as define the inclusion and exclusion criteria for the value set concept of pregnancy. We shared a draft value set concept of Pregnancy for the two use cases during the TEP and collaborated with stakeholders in the following months to refine the value set that was ultimately incorporated into the Implementation Guide.

Standards Development

In addition to socializing the project with the HL7 community, the Project Proposal and Project Scope Statement (PSS) were developed to kick off the HL7 IG development and balloting approval process. We received sponsorship from the HL7 Public Health Work Group. We kept other interested HL7 Work Groups such as Patient Care and Vocabulary informed of progress throughout the project by attending five HL7 Working Group Meetings and testing the IG at two HL7 FHIR Connectathons.

Feasibility report of a pilot of the Standards

Testing the IG at the January 2022 HL7 FHIR Connectathon track focused on the two uses cases—also known as clinical measures. Notable achievements included demonstrating the measure evaluation functionality of NHSNLink to query maternal health data staged on a FHIR server and show the resulting cohort viewed using the basic user interface of this tool. The contractor led the connectathon with participation from several implementers including Kids First with Children’s Hospital of Philadelphia (CHOP) acting as a data source actor.

The second connectathon in 2022 HL7 FHIR track’s primary purpose was to evaluate data sources that have FHIR data related to the two use cases. The connectathon led with participation from the Immunology Database and Analysis Portal (ImmPort) team as a data source actor.

Notable achievements included testing the measure against the ImmPort FHIR server a confirming the measure logic of the two use cases worked as intended by capturing the correct patients into each cohort.

The feedback and insight gained at these HL7 testing events were incorporated into the refinement of the iteratively developed IG. Throughout the project, feedback for development of the IG was solicitated as part of the regular standing calls with stakeholders such as National Institutes of Health, Centers for Disease Control and Prevention, Office of the National Coordinator, and from the TEP members. As part of the HL7 IG development process, we engaged with the HL7 Public Health Work Group for additional feedback and guidance. After a final technical edit, we packaged the IG and submitted the Notice of Intent to Ballot it through the HL7 process which entailed seeking approval from the FHIR Management Work Group and the Technical Steering Committee. After obtaining approvals from this thorough and rigorous HL7 review process, we successfully balloted the IG in May 2022. For the remaining part of 2022, we reconciled the comments by creating dispositions amenable to each commenter and then incorporated updates into the final specification. In January 2023, we began the HL7 publication request process seeking approvals from HL7's Public Health Work Group, the FHIR Management Group, and the Technical Steering Committee. HL7 published the IG in March 2023. To pull data from electronic health records, we needed to confirm the clinical focus and data element scope as well as define the inclusion and exclusion criteria for the value set concept of pregnancy. We shared a draft value set concept of Pregnancy for the two use cases during the expert panel and collaborated with stakeholders in the following months to refine the value set that was ultimately incorporated into the IG. Then we mapped the information to United States Core Data for Interoperability (USCDI) and to FHIR Resources.

Proof of Concept pilot in a health information exchange organization

The pilot site criteria were developed and used to research HIE organizations that had the potential to be a good site for the pilot. The team contacted nine HIE organizations and proceeded with good site for the pilot. The team proceeded with HealtheConnections (HeC). HeC fit the business and technical requirements and were available within the project timeline. As part of the onboarding process and planning sessions, agreement was reached and HeC executed a Non-Disclosure Agreement (NDA) and a Business Associate Agreement (BAA) to establish the parameters and expectations for the pilot.

Prior to the pilot kickoff, HeC convened a series of MHL configuration planning discussions. The pilot team reviewed the two measure cohort definitions and assessed HeC initial data for quality and completeness. We emphasized that HeC was responsible for identifying clinical records to be used in the pilot. We confirmed no protected health information (PHI)/personal identifiable information (PII) would be shared. We both acknowledged that for this proof-of-concept, the patient cohorts would be small, and that scalability could be a future post-pilot consideration.

Microsoft® Power BIMHL source code was used to visualize the data from the proof-of-concept pilot. We generated a dashboard for each measure demonstrating the Related Person resource between mother/child in the clinical data and visualizing the underlying clinical data available for mother and child in the two respective cohorts.

4. Accomplishments by Final Deliverables

Through this project funded by the OS-PCORTF, National Institutes of Health (NIH) engaged stakeholders and experts to build a standard for exchanging maternal and infant clinical health data for research purposes. Two key deliverables of the project included the creation of a Fast Healthcare Interoperability Resources (FHIR®) Implementation Guide (IG) Longitudinal Maternal & Infant Information for Research FHIR® IG and development of MaternalHealthLink (MHL), an open-source FHIR®-based web application for automating the extraction and exchange of clinical data. The project culminated in piloting/proof of concept MHL with a health information exchange (HIE) to demonstrate the feasibility of implementing the FHIR® IG standard within a real-world clinical data source and making the data available for an end user such as a researcher.

5. Lessons Learned and considerations for future work

There are some lessons learned and suggestions for future work that we see as ways to assist others doing similar projects as well as increase the impact of this project.

Timing

Timing is critical. There are a lot of components to developing the IG and MHL tooling. In the methodology section of this report, we outline many necessary steps of the IG development for which the timing of events is out of the control of this project's team (e.g. balloting and sponsorship). It is important to understand this prior to the development of a timeline and use this information to create internal deadlines. Moreover, it is imperative to have back up strategies in place to address potential challenges with timing and piloting.

Collaboration

With the development of the Consortium and the facilitation of multiple TEPs, we cannot over emphasize the importance of interdisciplinary teams, multi-agency input, open dialogue across business sectors, and understanding the perspective of all users and beneficiaries of the tools being developed.

Increase Engagement

Increase direct engagement by researchers and other potential end users of the IG and MHL. We facilitated multiple opportunities for engagement but recognize there is a need for even more. This would also allow for an increased understanding of data quality and analytics needs of researchers and end users.

Additional Pilot

Future directions for this project include conducting a second expanded pilot using an actual research study. We would like to test the incorporation of additional data sources and the scalability of solution with greater volume of data from multiple sources.

Enhancements

Enhancing MHL security and authentication options, scaling MHL capabilities for identity management, accounting for appropriate resources to support expected data persistence, and developing a maternal health research tool kit are all things we would like to see in the future to enrich the MHL and the IG developed with this project.