Plan Overview

A Data Management Plan created using DMPTool

Title: “Implementation of an Opt-Out Testing and Rapid Diagnostic strategy for Syphilis and HIV in Pregnant Patients presenting to the Emergency Department.”

Creator: Irene Stafford

Affiliation: The University of Texas Health Science Center at Houston (uth.edu)

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Template: NIH-Default DMSP

Project abstract:

According to preliminary 2022 Centers for Disease Control and Prevention (CDC) surveillance data, over 80% of pregnant patients with a newborn affected by congenital syphilis (CS) did not receive timely testing or treatment for syphilis, underlining the pitfalls of the current health care strategy for patients who face barriers to healthcare. In July 2023, Houston Health officials declared a syphilis outbreak as record-high incident cases were reported, including 9-fold increase in CS. In published pilot data from Houston, 70% of mothers who had a newborn with CS had no prenatal care, but 35% had visited the emergency department (ED) before delivery and were not tested for syphilis. These ED visits represent a critical missed opportunity to identify and treat pregnant patients with syphilis and reduce the incidence of CS. To stop the escalating rates of CS in high prevalence regions, implementation of an opt-out and rapid point-of-care (POC) syphilis screening strategy with immediate presumptive treatment should be implemented for pregnant patients presenting to care in non-traditional settings, including the ED. The FDA-cleared CLIA-waived DDP Chembio rapid point-of-care (POC) HIV-Syphilis diagnostic test has demonstrated 94% sensitivity for the detection of T. pallidum in whole blood with a turn-around time of 15 minutes and is ideal for this purpose. Identification and immediate treatment through the ED may improve access to care for underserved pregnant populations with syphilis without access to primary healthcare and may improve treatment completion for all stages of syphilis, ultimately reducing CS. We hypothesize that through implementation of an opt-out and rapid testing strategy in the ED for pregnant patients without prenatal care, we will increase timely and full treatment of syphilis compared to a pre-implementation cohort of pregnant patients with syphilis in Houston. We plan to leverage the clinical cohort to more accurately define the test performance of the Chembio DPP® Syphilis TnT and the Diagnostics Direct Syphilis Health Check (SHC) IgM research-use only POC tests for the detection of treponemal or both treponemal and non-treponemal IgM antibodies in whole blood or serum of neonates at risk for CS compared to the routine newborn nontreponemal test (RPR) for CS diagnosis. We hypothesize that use of the POC Syphilis TnT test in neonates at

risk for CS may elucidate the temporal relationship between maternal infection and fetal immunologic response and add to the current diagnostic standards described in the 2021 CDC Treatment Guidelines.

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Copyright information:

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We intend to prospectively follow approximately 625 women with out prenatal care and those who test positive for syphilis and/or Human Immundeficiency Virus (HIV) during the pregnancy through delivery and up to one year postpartum to determine infection status for the paired dyad. This will include all obstetric and demographic varaibles. It will also include all infection related varaibles and social and economic factors. All data wil be stored in an electronic secured institutional databse using de-identified ID numbers for data analysis. Data collection will occur in the emergency room and obstetrical clinic and delivery centers.

The final dataset will include self-reported demographic and behavioral data from interviews with participants conducted as routine care along with laboratory, obstetrical and infection related data that is collected according to standard obstetrical care and for patients with syphilis and HIV. The data will also include infection related data from the neonate of infected mothers including routine and standard laboratory data collected in linked newborns. In addition, research data regarding serologic tests from otherwsie discarded hematologic specimens will also be recorded. We will share de-identified individual-participant level (IPD) data. Appropriate measures such as assigning the patients and their newborns with unique study ID numbers will be used for data de-identification and sharing. THe data collected is standarad of care and only otherwsie discarded blood at birth will be used for serologic tesing and will not be used in the care of the patient and therefore does not require informed consent, outside of routine care, which will be collected in the emergency room setting and the prenatal clinics.

To facilitate interpretation of the data, a data dictionary will be created, shared, and associated with the relevant datasets.

All de-identified individual patient and neonatal data will be made available in csv, txt format and will not require the use of specialized tools to be accessed or manipulated.

In accordance with FAIR Principles for data, we will use open file formats (e.g. JPEG, MP4, CSV, TXT, PDF, HTML, etc.). Whenever possible, we will use common data elements to structure and organize our data.

Aggregate clinical data from the study will be available in clinicaltrials.gov.

We will use Persistent Unique Identifiers (PIDs) to improve data findability across all dissemination outputs. PIDs used will include DOIs for outputs (e.g., datasets), Research Resource IDentifiers (RRIDs) for resources, and Research Organization Registry (ROR) IDs and funder IDs for places, as much as possible to make data identifiable and findable. We will also use indexed metadata, such as MeSH terms with a unique URL to make scientific data easily findable. We will keep our ORCID Records up to date with DOIs for our datasets and publications, ROR, and funder IDs to increase findability.

All scientific data generated from this project will be made available as soon as possible, and no later than the time of publication or one year after the end of the funding period, whichever comes first. The duration of preservation and sharing of the data will be a minimum of 10 years after the funding period.

There are no anticipated factors or limitations that will affect the access, distribution or reuse of the scientific data generated by the proposal.

Controlled access will not be used. The data that is shared will be shared by unrestricted download.

To protect participant privacy and confidentiality, shared data will be de-identified by linking each patient to a unique

study number that is only controlled by the research team and is under an institutional password protected database.

Lead PI, Dr Irene Stafford, ORCID ID0000000228037329, will be responsible for the day-to-day oversight of lab/team data management activities and data sharing. Broader issues of DMS Plan compliance oversight and reporting will be handled by the PI and Co-I team as part of general campus stewardship, reporting, and compliance processes.The Office of the Executive Vice President & Chief Academic Officer (EVP/CAO) and The Office of Data Science (ODS) at UTHealth Houston will provide joint institutional oversight for the DMS plan. Datasets resulting from this research will be cataloged with in the institutional DEPUT. DEPUT is the institutional oversight management portal supported by UTHealth Houston for DMS validation and tracking. Project Contact PI will update data status in DEPUT, and the institutional office of Sponsored Projects Administration (SPA) will perform annual validation according to the DMS plan. Validation results will be reported to EVP/CAO and ODS for review. Gaps, if any, will be identified with appropriate correcting measures implemented. The PI will have overall responsibility for compliance with data collection, storage, and safety protocols.

Planned Research Outputs

Dataset - "“Implementation of an Opt-Out Testing and Rapid Diagnostic strategy for Syphilis and HIV in Pregnant Patients presenting to the Emergency Department."

All data will be de-identified and stored in a password protected instittutional database with restricted access. The dataset with IPD of the pregnant and postpartum patient along with the neonate will be stored in this database. All research laboratory tests including the results of the research-use only tests for the neonate will also be recorded.

This dataset will be made avaaible for future studies and investigators according to NIH policies and with written request to the Principal and all co-investigators.

Planned research output details

Title	Type	Anticipated release date	Initial access level	Intended repository(ies)	Anticipated file size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
“Implementation of an Opt-Out Testing and Rapid Di ...	Dataset	2029-08-31	Restricted	None specified		Creative Commons Attribution 4.0 International	None specified	Yes	No