"FIMR-HIV Prevention Methodology"
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Supporting Statement
Part B

Contact Information

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List of Attachments

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The respondents providing the information for the proposed project are HIV-infected pregnant or recently post-partum women. Currently the FIMR-HIV Prevention Methodology (FHPM) is operating in ten sites across the country, and is considering further expansion in 2012. CityMatCH will implement this project, and partner sites will collect the information and enter the data. CDC will have access to de-identified data via a web-based data system that is currently being developed.

FHPM defines cases as an "HIV-exposed infant/fetus ≥ 24 weeks gestation and < 24 months age at the time of the review". Cases selected for review are not chosen randomly, but rather prioritized by individual sites based on the woman/infant's particular experiences. Priority cases include perinatally infected infants, late maternal HIV diagnosis, no or inadequate prenatal care, lack of maternal HIV treatment and/or poor viral load suppression during pregnancy, or the lack of antiretroviral prophylaxis during labor and delivery.

Partner sites are responsible for identifying and interviewing approximately 30 women in their communities each year. Cases are identified through a variety of means, and include both passive and active case detection strategies. Sites form partnerships with HIV case managers and prenatal care providers who can alert FHPM staff to potential cases. Sites will also conduct regular reviews of existing HIV and disease surveillance systems to identify missed cases.

Women known as HIV-infected and pregnant or recently delivered, will first be contacted by their health care provider or public health staff and asked for permission to be contacted by FHPM staff. Women identified as potential participant cases and who have agreed to be contacted, are approached by a trained staff member as soon as possible identification as a possible case regarding their willingness to participate in the project. Interested women will sign an informed consent form, and will be asked to identify a convenient time and location for a face-to-face interview to occur. A trained staff member will conduct the scripted interview, which typically takes approximately 90 minutes. If a woman is interviewed before all perinatal HIV prevention interventions have been completed (i.e. six weeks of infant antiretroviral prophylaxis, or determination of infant HIV-infection status), sites will attempt to re-interview the woman at a time and location convenient for the woman after all

interventions have been completed and the HIV status of the infant is known.

Project sites will also conduct a chart abstraction to gather healthcare data on the women agreeing to participate in the project. Potential data sources include the infant's birth certificate and medical records regarding maternal HIV care, prenatal care, labor and delivery care, newborn care, post-partum/reproductive health care, and pediatric care. Data collection forms have been created for each of these data sources. The project puts particular emphasis on the completion of abstractions of the prenatal care records, labor and delivery records, pediatric care records, and the maternal interview in order to compile adequate information for a high-quality case review.

At least 30 cases will be reviewed at each of the ten sites each year (for an overall total of approximately 300 cases). This was chosen as a feasible number of cases given the level of time and work needed to collected the in-depth qualitative and quantitative data.

2. Procedures for the Collection of Information

The project will attempt to conduct maternal interviews for each case selected, in addition to the medical chart abstractions. These data collection efforts will typically only need to be carried out once for each of the cases included in the project.

Chart abstractions will be based on the relevant data collection instrument developed for that purpose by FHPM. Data is collected by trained chart abstractors, and will not place a burden on clinics, hospitals, or their staff. Once collected, data will be de-identified (including the removal of patient identifiers and the names of healthcare providers and clinics/hospitals) and entered into the FIMR-HIV Data System (FHDS). Hard copies of the data will be stored in a secure, locked location at each site, and will be destroyed after review.

The Maternal interview is conducted in face-to-face format using a scripted survey administered by a trained staff member. This survey will differ from the chart abstraction in its efforts to capture a woman's overall experiences before, during, and after her pregnancy. The survey will include both qualitative and quantitative measures of a woman's experiences and insights into the healthcare and social service systems for HIV-infected pregnant women in her community. As with data from the chart

abstraction, maternal interviews will be de-identified before entry into the electronic data collection system, and hard copies will be destroyed after the case review.

From these data we will learn the challenges, obstacles, and gaps in community-level health systems for the prevention of perinatal HIV transmission. FHPM is designed to both identify and address these missed prevention opportunities. Collecting the information less frequently would result in a less robust assessment of these issues.

For HIV-infected women participating in the project, this is a one-time data collection, unless they have a second pregnancy, are selected for case review under the priority assessment and consent to participate.

3. Methods to Maximize Response Rates and Deal with Nonresponse

FHPM has been granted a Non-Research Determination by the National Center for HIV, Hepatitis, STD, and TB Prevention (NCHHSTP) at the Centers for Disease Control and Prevention (Summary Statement Attachment 7). Because FHPM is a non-research project whose participants are chosen non-randomly, efforts to maximize response rates and deal with nonresponsive differ from those of other studies classified as research.

FHPM's goal is to provide an in-depth, comprehensive view of gaps in perinatal HIV prevention efforts within community-level health and social service systems. Women approached for inclusion in the project may decline to participate. To ensure a detailed overview of community-level factors, however, participating women are offered a token of appreciation for their time. In most sites this consists of a $50 gift card.

FHPM is not a research project and the data are not collected as a representative sample. Data is used to identify local missed perinatal HIV prevention opportunities and to guide local public health to address systems issues. If a site does not meet the suggested number of 30 cases to review, technical assistance will be provided to them to assess their case-finding approach and strategies across participating sites will be shared.

4. Test of Procedures or Methods to be Undertaken

This is a novel approach to perinatal HIV prevention and for which previous data do not exist. FHPM is the first instance in which the National Fetal and Infant Mortality Review (National FIMR) methodology has been applied to perinatal HIV prevention

efforts. The data collection instruments have not been used in previous studies.

By design, both National FIMR and CityMatCH have provided services and done other projects in sites currently participating in FHPM. These communities were selected in part because of their success in implementing the National FIMR methodology to address community-level healthcare factors contributing to infant mortality, in addition to their substantial burden of HIV infections.

Due to the non-random selection of both project sites and their participants, FHPM does not plan to use the data collected for extensive statistical analyses. FHPM data will be used to provide a clearer picture of community-level health system gaps within each project site. FHPM plans to compile descriptive statistics for each project site and for the FHMP sites as a whole. It should be noted, however, that this data is not generalizable to other communities, states, or to the country as a whole.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Individuals conducting the analysis and consulted on statistical aspects are the project officers from Centers for Disease Control and Prevention, 1600 Clifton Rd., MS E-45, Atlanta, GA 30333.

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Individuals collecting and analyzing the data are from CityMatCH, University of Nebraska Medical Center, 982170 Nebraska Medical Center, Omaha, Nebraska 68190-2170

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