Differentiated Service Delivery for Pregnant and Postpartum Women Living With HIV and Their Infants

NCT06629753

April 1, 2024

Moi University College of Health Sciences / Moi Teaching and Referral Hospital
Institutional Research and Ethics Committee (IREC)
Informed Consent Form - Providers

Study Title: Pilot implementation of a differentiated service delivery model for pregnant and postpartum women living with HIV and their infants

Name of Principal Investigator: Bett Kipchumba[1], John Humphrey[2]

Name of Organization: Moi Teaching and Referral Hospital[1], Indiana University[2]

Name of Sponsor: National Institutes of Health, USA

PART I: INFORMATION SHEET
Introduction:
We are asking you to participate in a research study. This form provides you with information about the study. The information below will be read aloud to you. Please ask questions about anything you do not understand before deciding whether you want to participate in the study. If you decide to participate the study, you will be given a copy of this consent form.

Why is this study being done?
This study plans to learn more about the implementation of differentiated service delivery (DSD) for prevention of mother-to-child HIV transmission (PMTCT) clients (i.e., pregnant and postpartum women living with HIV and their HIV-exposed infants. DSD is recommended in the 2022 Kenya HIV treatment guidelines for PMTCT clients. However, there are limited data to guide how best to implement DSD for this population. The goal of this study is to implement and study the implementation of DSD for PMTCT clients at Huruma Sub-District Hospital. This research is being done by investigators at Moi University, Moi Teaching and Referral Hospital (MTRH), and Indiana University. You are being asked to be in this study because you are a healthcare provider or administrator who provides PMTCT service delivery at Huruma Sub-District Hospital (HSDH).

How many people will participate in the study?
Approximately 15 providers/administrators will participate in the study.

What happens if you agree to participate?
First, we will ask you to participate in a series of 12 workshops at HSDH to plan and implement DSD for PMTCT clients. Three workshops will occur during a two-week period prior to DSD implementation. The purpose of these workshops will be to identify anticipated barriers/facilitators to DSD implementation and determine the roles of each provider/administrator in operationalizing DSD at HSDH. Then, 9 audit/feedback workshops will occur during DSD implementation, every two weeks during the first 3 months of DSD implementation then monthly during the next 3 months. The goal of these workshops will be to discuss barriers and facilitators to DSD implementation, including its acceptability to providers and adoption in the clinic. You will also be asked to complete a brief questionnaire during each workshop assessing your perceptions about the feasibility and acceptability of DSD for PMTCT clients. Each workshop will be audio-recorded, last for up to one hour and occur during a weekday when you do not have work-related responsibilities.

Second, we will ask your permission for a research assistant to directly observe your encounters with PMTCT clients and record how the clinic operates on a day-to-day basis. A research assistant will be stationed within the PMTCT clinic for 10 consecutive working days within 6 weeks before DSD implementation, and for 6 months during the implementation of DSD. The research assistant will record the number of PMTCT clients seen each day, the duration of each

encounter, and what services were provided clients each day (e.g., adherence counselling, phone call, community outreach). The data collected through direct observation will be used to assess the impact of DSD on routine clinic processes. A final workshop and 10-day direct observation period will occur at 12 months after start of DSD implementation at HSDH to assess how DSD has been maintained at the site over time.

How long will the study last?
The study will last for 13 months.

What are the possible discomforts or risks?
Some of the topics discussed at the workshops might feel personal to you. You also may experience stress or anxiety while being directly observed. We will make every effort to protect your confidentiality outside of the workshops. Additionally, the research assistant will be as unobtrusive as possible during direct observation, and all findings will be reported in aggregated and de-identified manners, as the goal is to assess the clinics processes rather than evaluating individual performance.

What are the possible benefits of the study?
There are no direct benefits to you for participating in the study. However, the researchers hope that the knowledge gained from this study will help improve services for pregnant and postpartum women living with HIV and their infants in the future.

Who is paying for this study?
The United States National Institutes of Health (NIH).

Will I be paid for being in the study?
You will be given 1,000 Kenya shillings for your participation in each workshop, up to 12,000 shillings in total. Refreshments will also be provided during each workshop.

Will I have to pay for anything?
No, taking part in the study will not cost you anything.

Is my participation voluntary?
Yes, taking part in this study is voluntary. You have the right to choose not to participate. If you choose to participate, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?
The study team may decide to remove you from the study without your permission if the study team thinks that being in the study may cause you harm or for any other reason. A study team member will inform you in such a case.

Who will see my research information?
We will do everything we can to keep your records confidential, but we may share them with others if required by law, or to individuals or organizations that oversee the conduct of research studies, including Indiana University. The results from the research may be shared at a meeting or published in articles. Your information will be kept private when any information is presented.

Certificate of Confidentiality
We have a Certificate of Confidentiality from the United States NIH. These protections only apply to data held in the United States.

This Certificate helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law in the United States. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- A member of the United States government who needs it to audit or evaluate the research;
- Individuals at the universities, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly; and
- To relevant authorities as required by other Federal, State, or local laws.

Will my information be used for research in the future?
Information collected from you during this study may be used for future research or shared with other researchers for future research if you provide consent. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

Who do I contact if I have questions?
You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call the local study principal investigator Bett Kipchumba at 0721894658.

If you have questions about your rights as a research participant or if you wish to voice your concerns about the study, please contact the IREC office in Eldoret, Kenya at 0787723677 or write to P.O Box 3-30100, Eldoret, Kenya.

PART II: CERTIFICATE OF CONSENT

Agreement to be in the study
I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that my participation in this study is voluntary. I choose to take part in this study. The study staff will give me a copy of this consent form if I want a copy.

Participant Name:_____ Date:_____

Participant Signature:_____

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
27 JUN 2024
APPROVED
P. O. Box 4606 - 30100 ELDORET

Consenting Staff Name:_____ Date:_____

Staff Signature:_____