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

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

Study Title: Pilot implementation of a differentiated service delivery 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 along with your infant. 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. DSD simplifies services for clients who are clinically stable (e.g., >18 years old, virally suppressed, retained in care, and healthy) by providing shorter appointment durations and less frequent appointments and antiretroviral treatment refills. This study is being done because there are limited data to guide how best to implement DSD for PMTCT clients. 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 woman living with HIV who is pregnant or within 18 months postpartum and attending the PMTCT clinic Huruma Sub-District Hospital (HSDH).

How many people will participate in the study?
Approximately 250 women and their infants (i.e., 500 people total) will participate in the study.

What happens if you agree to participate?
- At each of your PMTCT clinic visits, your healthcare provider will assess whether you meet all of the criteria to qualify as a "stable client". These criteria include:
    - Age ≥18 years
    - Being on your current antiretroviral treatment (ART) regimen for at least 6 months
    - Having no active illness in the past 6 months
    - Having not missed a scheduled visit by more than 14 days in the past 6 months
    - Viral load <50 copies/mL within the past 6 months
    - Not first pregnancy
    - Not high-risk pregnancy (as defined by your healthcare provider)

  If you meet all of these criteria, you will be eligible to have shorter and less frequent clinic visits after 6 months postpartum, such as visits every 3-6 months rather than monthly, and flexibility in your ART collection, such as in the community or by a family member rather than yourself according to your preference.

If you do not meet all of these criteria, you will continue with monthly clinic visits after 6 months postpartum according to the usual PMTCT clinic schedule.

- We will ask your permission for a research assistant to directly observe your clinic visits and encounters with healthcare providers to record the duration of your encounter with each provider and the services that were provided to you or your infant, such as adherence counselling, medication refills, or immunizations.
- We will ask you questions about your experience receiving PMTCT services today. We will ask you these questions in private. We will not write your name on the paper with your answers on it so that only the study team will know your answers and their link to your identifying information. You do not have to answer questions you do not want to answer. We will also call you after 6 and 12 months to ask you again about your experiences receiving PMTCT services. The questions we ask you in the questionnaire will take about 30 minutes.
- We will review and record the medical information that the clinic has been collecting about you, and your infant, such as your HIV infection and any treatments you or your infant have received.

How long will the study last?
Your participation in the study will last for 12 months. The direct observation will last for the next six months, and the questionnaire will be done today, and again 6 and 12 months later. You will not have to follow-up again with the research team after the 12-month questionnaire. If you are still enrolled in PMTCT clinic after the study ends, you can decide with your healthcare providers whether you can continue receiving DSD.

What are the possible discomforts or risks?
Some of the questions might feel personal or embarrassing to you. You also may experience stress or anxiety while being directly observed. We will make every effort to protect your confidentiality. A breach of confidentiality is possible but the risk for that happening is very small. If you feel participation in the study has caused you mental or emotional distress, you will be given the opportunity to attend several counselling or support sessions, including: 1) a weekly support group for women living with HIV at Moi Teaching and Referral Hospital; 2) individual counselling with a Mentor Mother at your facility; 3) referral to a psychiatrist located at the AMPATH Headquarters. It is also possible that having less frequent visits to the clinic may result in delayed detection or diagnosis of adverse events such as poor adherence or elevated HIV viral load, or a variety of health conditions. The Institutional Research and Ethics Committee in Kenya and Indiana University IRB, the members of the study team, and your healthcare providers will monitor for such events and assess the safety of DSD during the study to ensure that the risk to participants is minimized. You will be notified by immediately by phone if the study is stopped for safety reasons.

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 PMTCT services for pregnant and postpartum women 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 1000 Kenyan shillings immediately after you complete each questionnaire, amounting to 3000 Kenya shillings in total. This money is to help pay for the time it takes you to participate in the study.

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 choose to not participate or stop participating after you have started, you will not lose any benefits or rights to which you are entitled. You will be able to receive your usual medical care at the PMTCT clinic if you decide not to participate in the study at any time.

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.

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

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:_____

Consenting Staff Name:_____ Date:_____

Staff Signature:_____

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

If consented orally

Name of witness: _____

Signature of witness: _____

Date:_____

Thumbprint of participant