The Impact of Mentor Mother Programs on PMTCT Service Uptake and Retention-in-Care at Primary Health Care Facilities in Nigeria: A Prospective Cohort Study (MoMent Nigeria)

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Background: Nigeria is a key target country in the global effort toward elimination of mother-to-child transmission of HIV. Low coverage of prevention of mother-to-child transmission (PMTCT) interventions, adherence, and retention-in-care rates in HIV-positive pregnant women are contributing factors to high mother-to-child transmission of HIV (MTCT) rates. In Nigeria, rural areas, served largely by primary health care facilities, have particularly poor indicators of PMTCT coverage. Mentor Mothers are HIV-positive women who serve as peer counselors for PMTCT clients, provide guidance, and support in keeping appointments and promoting antiretroviral adherence and retention-in-care. The Mother Mentor (MoMent) study aims to investigate the impact of structured Mentor Mother programs on PMTCT outcomes in rural Nigeria.

Design and Methods: A prospective cohort study will compare rates of retention-in-care among PMTCT clients who are supported by formally-trained supervised Mentor Mothers versus clients who receive standard-of-care, informal peer support. Study sites are 20 primary health care centers (10 intervention, 10 control) in rural North-Central Nigeria. The study population is HIV-positive mothers and exposed infant pairs (MIPs) (N = 480; 240 MIPs per study arm). Primary outcome measures are the proportion of exposed infants receiving early HIV testing by age 2 months, and the proportion of MIPs retained in care at 6 months postpartum. Secondary outcome measures examine antiretroviral adherence, 12-month postpartum MIP retention, and MTCT rates. This article presents details of the study design, the structured Mentor Mother programs, and how their impact on PMTCT outcomes will be assessed.

Key Words: Mentor Mother, PMTCT, Nigeria, adherence, retention, early infant diagnosis

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BACKGROUND

Nigeria’s 174 million people make her Africa’s most populous country.1 In 2010, HIV prevalence at antenatal care clinics (ANC) was estimated at 4.1%.2 With 60,000 new infections annually, Nigeria accounts for about one-third of new HIV infections in children among the UNAIDS 21 Global Plan priority countries.3 In 2012, only 17% of more than 200,000 HIV-positive (HIV+) pregnant women received antiretroviral drugs (ARVs) for the prevention of mother-to-child transmission of HIV (PMTCT), resulting in mother-to-child HIV transmission (MTCT) rates of nearly 30%.4 Furthermore, only 3.9% of HIV-exposed infants receive early infant diagnosis (EID) testing by 2 months of age.5

The national PMTCT program has intensified scale-up efforts, particularly at primary health care centers (PHCs) in rural areas where access and uptake is poor. The 2014 Nigerian PMTCT guidelines (pending publication) recommend the WHO “Option B”: triple ARV regimens through pregnancy and breastfeeding, to be further continued as lifelong antiretroviral treatment (ART) only if needed for maternal health. Barriers to PMTCT success include poor motivation among clients and health workers, inadequate support systems, and low adherence to medications and appointments.6,7 Current PMTCT efforts therefore need to include sustainable client and human resource interventions for maximal success.
One potential strategy to overcome PMTCT challenges and improve outcomes is through effective peer support. Mentor Mothers (MMs) are HIV-positive mothers who have successfully completed the PMTCT cascade, namely ANC clinic attendance, prenatal testing, access to ARVs, infant feeding counseling, and postpartum mother-infant pair (MIP) follow-up. MMs can provide counseling, psychosocial support, and experiential guidance to PMTCT clients who are navigating services. MMs and similar peer counselors have been successful in South Africa and other African countries. To date, no PMTCT peer counselor intervention studies have been completed in Nigeria. Furthermore, previous studies conducted in other African countries compared peer counselors to “no peer intervention.” In the MoMent (Mother Mentor) study, we evaluate the impact of a supervised, structured Mentor Mother program on PMTCT outcomes, as compared to routine informal peer support. We hypothesize that a structured Mentor Mother package will improve EID access, ARV adherence, and postdelivery MIP retention in rural communities.

RESEARCH QUESTIONS AND STUDY OBJECTIVES

1. How can mother–infant pairs be retained throughout the duration of recommended PMTCT care?
2. What is the effect of a structured Mother Mentor Intervention Program on EID uptake and ARV adherence among PMTCT clients in rural communities?

The protocol focuses on 2 primary objectives and 3 secondary objectives:

Primary Objectives

1. To measure the impact of an MM intervention package on maternal-infant pair retention in PMTCT services at 6 months after delivery.
2. To measure the impact of an MM intervention package on uptake of EID at 2 months of age.

Secondary Objectives

1. To optimize and implement a training and supervision program for MMs in Nigeria.
2. To assess acceptability of an MM program among PMTCT stakeholders in rural communities.
3. To measure the impact of the MM program on a. Pre- and post-delivery ARV uptake and adherence, measured by maternal viral load at 6 months postpartum.
   b. Early (6 weeks to 2 months) and later (6 months) postpartum MTCT rates.
   c. MIP retention in care at 12 months postdelivery.

FORMATIVE RESEARCH

Before finalizing the study protocol, formative research was conducted to examine barriers to PMTCT service uptake, access, and retention, as well as exploring the acceptability of MMs and the experiences of women providing informal peer support for PMTCT clients.

The formative research provided baseline information about the PMTCT program and guided the final MM intervention package. Values and experiences were explored among PMTCT “users” namely ANC clients, HIV+ mothers providing informal peer support, HIV+ mother supporting group members, and women of reproductive age; also, among “providers” namely health care workers, PMTCT program implementers, policy makers, and also “potential facilitators,” including male partners, community/religious leaders, and traditional birth attendants. Eleven focus group discussions (including a total of 105 participants) were conducted among PMTCT users and male partners. Key informant interviews were conducted among PMTCT “providers,” “potential facilitators,” and “users” (N = 31). Focus group discussions and key informant interviews were conducted with semi-structured interview guides and were audio-recorded and transcribed verbatim. Content and thematic analyses were manually performed and reviewed by 10 paired analysts.

The main findings on barriers to PMTCT service uptake, access, and retention included the following: financial cost of transportation to PHC, poor provider attitudes, erratic drug and test kit supply, 24/7 services not guaranteed, poor client awareness of/confidence in available PHC services, and intense community-level HIV stigma. In general, the formative research found MMs to be acceptable. Participants put high value on MM’s formal training, psychosocial support, positive living with HIV, maternal, and PMTCT experience, and accessibility within the community. A few participants expressed reservations regarding MM home visits due to perceived stigma.

The Institute of Human Virology Nigeria’s Support to PMTCT Sites

Most primary health care facilities and referral hospitals in Nigeria providing HIV-related services (including PMTCT interventions) are supported by local nongovernmental organizations through funding mechanisms such as the US Government’s President’s Emergency Plan for AIDS Relief. The Institute of Human Virology-Nigeria (IHVN) provides support to > 1,000 health facilities in 10 states, including the MoMent study states of Federal Capital Territory (FCT) and Nasarawa, in North-Central Nigeria. HIV prevalence among the adult population in FCT is 8.1% and 7.5% in Nasarawa; estimated 2014 populations for these states are 3,028,807, and 2,394,334, respectively. HIV prevalence in these 2 states is among the highest in Nigeria compared with the overall national HIV prevalence in 2012 of 3.4% among 37 states. In the 2 study states, IHVN is the single largest provider of President’s Emergency Plan for AIDS Relief-supported HIV services, including testing and treatment and supports at least 40% of PMTCT-providing facilities in each state.
METHODS

Study Design

The protocol is a prospective matched-cohort study where PMTCT outcomes in MIPs are being compared in intervention and control arms. Originally, a cluster randomized trial was planned. However, after sites had been randomized, the standard of care in the 2 states was revised including basic peer support/counseling being required for all PMTCT facilities. This changed the characteristics of sites already randomized and with it the balance of sites between arms. We therefore decided to follow 2 cohorts of HIV+ pregnant women/mothers who receive support either from the MM program or routine program support (including Informal Peer Supporters (IPS))—and to report changes in potential confounders over the study duration.

Study Sites

Study sites were selected from the 102 PHCs in the FCT and in Nasarawa State. A desktop review first identified sites that had offered PMTCT services for more than 6 months and where there was no previous formal MM program. Sites were then individually assessed to ensure that there were ≥2 PMTCT-trained staff, ≥1 HIV+ pregnant women booking per month, ≥1 HIV-exposed infant brought for EID every 3 months, and staff willing to support the study.

Study PHC Allocation and Matching

Following these assessments, 26 of the 102 available PHCs were eligible for inclusion. Intervention PHCs were matched with controls according to 4 criteria:

- Number of EID-trained staff.
- Number of PMTCT-trained staff.
- Monthly number of new ANC clinic clients.
- Proportion of HIV-tested pregnant women confirmed HIV+.

To minimize bias, site allocation and matching was performed by researchers external to the study. Following this process, 10 control and 10 intervention sites were selected: 3 control and 6 intervention sites in FCT; 7 control and 4 intervention sites in Nasarawa.

Study Population

Pregnant women, 15 years of age or more, who were HIV positive, either newly or previously diagnosed, and attended at least 1 ANC clinic appointment before delivery. They should not have previously received the services of a peer counselor, or have ever functioned as a peer counselor themselves. They should plan to continue receiving services at the PHC recruitment site.

Control and Intervention Arms

MIPs in both arms have access to the same HIV-related care and treatment provided by nurses at the clinics. This includes provider-initiated HIV testing, efavirenz-based Option B PMTCT regimens, infant feeding counseling, EID, and referral for pediatric ART if infant is HIV+.

In the control arm, HIV+ pregnant women and mothers have access to any IPS that is available at the PHC. The support provided by IPS was not specifically defined and was variable across sites in terms of counselor selection criteria, training, expectations, and supervision.

In the intervention arm, HIV+ pregnant women are linked with an MM as soon as their HIV status is confirmed. In general, 1 MM is responsible for 10–15 mothers. There was no equivalent expected ratio for IPS in the control arm. Table 1 compares the main characteristics of the MM intervention with the standard-of-care IPS arm.

MM Selection and Training Curriculum

MMs were HIV+ mothers selected from the community who had completed PMTCT at least once, ideally with an HIV-negative child. They are 18–45 years old, speak at least 1 local language, and ideally read and write in English at fifth-grade level. They should have disclosed their HIV status to a partner or family member and be willing to disclose their status to peers. They accept the need for flexible working hours.

The curriculum was based on peer counselor training materials previously developed by IHVN and the Clinton Health Access Initiative (CHAI)-Nigeria, with the addition of materials from the published literature. MM training was cofacilitated by the IHVN PMTCT implementation and MoMent study teams. The curriculum covered the following:

1. The Impact of HIV in sub-Saharan Africa and Nigeria.
2. The Role of MMs in Comprehensive HIV Programs.
3. Basics of HIV.
4. Basic Communication and Counseling Skills.
5. HIV Testing and Counseling.
6. General HIV Care and Treatment.
7. PMTCT and Pediatric HIV Care and Treatment.
8. Adherence to HIV Care and Treatment.
10. Confidentiality.
11. Record-keeping.
12. Linkage Referrals.
14. Family Planning and Reproductive Health.
15. Infant Feeding and Child Nutrition.
16. Childhood Immunizations.
17. Identification and Referral of the Sick Child.

MM Responsibilities and Home Visits

MMs link with new PMTCT clients at ANC clinics. They provide counseling and psychosocial support (including disclosure, drug adherence, and infant feeding) and promote and support early infant HIV testing. As needed, they link referred clients to higher-level care, visit, and track clients in the community to improve retention and inform facility clinical staff of ill clients needing additional care.
MMs make a first home visit within 5 days of linking with the client and visit every 2 weeks thereafter. After delivery of the infant, MMs visit their mothers within 7 days of facility delivery, or within 3 days of nonfacility delivery and every 2 weeks thereafter until the infant is 12 months old. They additionally call or visit clients in the event of missed clinic appointments.

MM Supervision
The MM intervention package includes structured supervision by Mentor Mother Supervisors (MMS) who are positioned at each intervention site. MMS all have post-secondary diploma or bachelor’s degree-level education; HIV+ status is however not a requirement. MMS receive the same basic HIV, PMTCT, and Maternal and Child Health training as MMs and additionally received training on routine PHC register and study data collection tool documentation. All MMS were fluent in written and spoken English and spoke at least 1 dominant local language from the local community. MMS responsibilities were to coordinate MM activities including PMTCT reorientations and updates, complete case management registers that track all MIP care and testing appointments, flag MIPs who have missed appointments, and assign community tracking and follow-up to MMs. Finally, MMS review and audit the MM logbook through random PMTCT client interviews.

Viral Load Assessment in Mothers and DNA PCR Testing of Infants
Viral load (VL) testing, not routinely available, is an objective measure of ARV adherence compared with recall or pharmacy refill and allows for identification of participants with high values, requiring immediate medical review. Maternal VL as well as infant HIV status will be additionally assessed at 6 months postpartum to evaluate maternal adherence and MTCT rate, respectively.

Sample Size Estimation
The primary outcome measures are as follows:

1. Proportion of exposed infants receiving EID by 2 months of age.
2. Proportion of MIPs retained in care at 6 months postpartum.

Sample size estimation was calculated using STATA 11 sampclus (StataCorp LP, College Station, TX). Although the study design is a prospective cohort design, we approached the sample size estimate as although it were a cluster randomized trial. The sample size accounted for an intracluster correlation since the MM intervention is implemented at the facility rather than individual level. Using the following assumptions:

- In the control arm, 20% of exposed infants receive EID testing by 2 months of age (IHVN program data), and an estimated 30% of MIPs are retained in care at 6 months postpartum.
- Ten PHCs in each study arm.
- Intracluster correlation = 0.05, type II error (1-β) = 0.8 and type I error α = 0.05.

A minimum of 21 MIPs per PHC are needed to detect an absolute difference of 20% for EID uptake (20% vs. 40%) and 6-month retention-in-care (30% vs. 50%).

Adjusting for maternal mortality ratio in Nigeria (560 per 100,000) and infant mortality rate for Northern Nigeria (77.8 per 1000 live births), plus an estimated 5% PMTCT client transfer-out rate, a final sample size of 24 MIPs per PHC (480 MIPs total at 20 PHCs) was determined.

Data Sources and Management
Routine patient data are manually recorded in national registers and logbooks provided to the PHCs (Table 2). Primary study analyses will be based on these data, which are abstracted onto separate study case report forms (CRFs) and entered into the study database.

TABLE 1. Comparison of Study MMs to Standard-of-Care Informal Peer Support

<table>
<thead>
<tr>
<th>Informal Peer Support</th>
<th>MMs</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-positive woman</td>
<td>Yes</td>
</tr>
<tr>
<td>Experiential PMTCT knowledge</td>
<td>Yes</td>
</tr>
<tr>
<td>Formal preselection criteria</td>
<td>No</td>
</tr>
<tr>
<td>Formal training/curriculum</td>
<td>No</td>
</tr>
<tr>
<td>Certification</td>
<td>No</td>
</tr>
<tr>
<td>Payment for services</td>
<td>Yes (same amount)</td>
</tr>
<tr>
<td>Linked to HIV+ clients at ANC registration</td>
<td>Yes</td>
</tr>
<tr>
<td>Perform HIV tests for ANC clients</td>
<td>No</td>
</tr>
<tr>
<td>Supervision</td>
<td>Weak</td>
</tr>
<tr>
<td>Maintains client logbook</td>
<td>Yes (unstructured, nonstandard; data recorded not strongly tied to client outcomes)</td>
</tr>
<tr>
<td>Clear scope of work and deliverables</td>
<td>No</td>
</tr>
<tr>
<td>Structured intensity and frequency of client contact/home visits</td>
<td>No</td>
</tr>
<tr>
<td>PMTCT Reorientation</td>
<td>No</td>
</tr>
<tr>
<td>Audit of activities and visits through client interviews</td>
<td>No</td>
</tr>
</tbody>
</table>

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At the intervention sites, the MMS collect study data on a daily basis. At control sites, the Site Research Officers collect data without interfering with routine operations. Study data are extracted from routine PHC registers onto hard-copy CRFs. Research Associates visit PHCs twice monthly and validate and collect the hard-copy CRFs. The CRFs are submitted to the Data Manager, who ensures data accuracy and enters the CRF data into the study database. The study uses the REDCap (www.project-redcap.org/) database platform.

### Analysis Plan

Given the matched-cohort design, the comparison will be outcomes among the MIP cohorts exposed or not exposed to MMs. We will adjust for clustering by using logistic regression with random effects using generalized equation estimation because PHCs are the units for MM implementation. Unlike cluster randomized control trials, this prospective cohort design is susceptible to confounding factors at the individual and PHC level. Potential confounding factors identified a priori include MIP characteristics such as gestational age at presentation or distance to PHC, MM/IPS workload and frequency of client interaction, and PHC/community characteristics (staffing levels and turnover rate, and frequency of support group meetings). Potential covariates will be first examined in unadjusted models. Characteristics associated with the outcome at the $P < 0.05$ level, and known risk factors for outcomes regardless of level of significance will be included in multivariate models. Any characteristic that alters significant odds ratios by $>20\%$ will be retained. Table 3 displays the study definitions that will be used in the analysis.

### TABLE 2. Study Data Sources

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Routine Site Register Sources</th>
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<tbody>
<tr>
<td>Proportion of infants receiving EID (DNA PCR test by 2 mo postdelivery)</td>
<td>Child follow-up, mother–infant pair case management registers</td>
</tr>
<tr>
<td>Proportion of mothers and exposed infants retained in PMTCT program at 6 mo postdelivery</td>
<td>Child follow-up, mother–infant pair case management registers</td>
</tr>
<tr>
<td>Proportion of mothers ART-adherent pre- and postdelivery</td>
<td>PMTCT-ARV register</td>
</tr>
<tr>
<td>Proportion of exposed infants receiving NVP within 72 h of life (uptake)</td>
<td>Delivery, PMTCT-ARV, and mother–infant pair case management registers</td>
</tr>
<tr>
<td>Proportion of mothers who delivered at a health facility</td>
<td>Delivery register, peer counselor (MM or IPS) logbook</td>
</tr>
<tr>
<td>Proportion of exposed infants completing 6 wks of NVP (adherence)</td>
<td>PMTCT-ARV register</td>
</tr>
<tr>
<td>Proportion of infants HIV positive at initial and 6 mo postdelivery</td>
<td>Child follow-up and mother–infant pair case management registers</td>
</tr>
<tr>
<td>Proportion of mothers and exposed infants retained in PMTCT program at 12 mo postdelivery</td>
<td>Child follow-up, mother–infant pair case management registers</td>
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</table>

### Status and Timelines

The 2010 National PMTCT guidelines were revised after the release of the 2013 WHO Consolidated Guidelines; a draft integrated guideline was completed in mid-2014. The major difference in PMTCT guidelines was the removal of Option A (Azidothymidine (AZT) monotherapy) as an option for HIV+ pregnant women who did not need ART for their own health at PHCs where ART training or supervision was not available for staff. All facilities at all levels of health care were to implement Option B. The MM intervention and supervision package was launched in January 2014; enrollment of HIV+ pregnant women started in April 2014 and will be completed by June 2015. It is expected that the last live birth will be in September 2015 and 12-month follow-up of MIPs will be completed by September 2016.

### Ethical Considerations

#### Consent

Written informed consent is requested from HIV+ pregnant women aged $\geq 15$ years. In Nigeria, young women are considered to have “attained the age of majority” and therefore able to provide consent when they are aged $\geq 16$ years; young women aged 15 years and who become pregnant are also deemed to have “attained the age of majority” and can consent to participation in research. Consent for study enrollment of exposed infants is sought from the mother, father, or appropriate guardian.

#### Confidentiality

All study staff and MMs received client confidentiality training. Hard copies of study procedures and CRFs are stored in secure locked cabinets at PHCs and at HIV’N’s central data storage room. Electronic data are stored in a password-protected database. Access to study records is limited to study staff.

### Potential Risks

There is a small additional risk associated with the single blood draw from mothers for VL at 12 months postpartum, and from exposed infants for DNA PCR at 6 months postpartum that are not standard practices.

### Benefits

Potential benefits for mothers include knowing her viral load at 12 months postpartum and identifying those needing immediate medical review. The 6-month DNA PCR provides...
addition of an opportunity for HIV diagnosis in still-exposed breastfeeding infants.

CHALLENGES AND LIMITATIONS

Geographical Location and Health Care System Level

The MoMent study is being implemented at the primary health care level, where there are many quality-of-care issues, which may potentially confound the impact of intervention. Rural PHCs commonly experience ARV and HIV test kit stock-outs, which may influence EID testing uptake. Other barriers experienced by staff will be documented.

Security Issues

Some study PHCs are located in areas of intermittent ethnic and political unrest. Insecurity and riots have previously disrupted health care services for both patients and providers including peer counselors, and this may affect study enrollment and implementation.

Study Limitations

The nonrandomized design potentially amplifies the effect of confounders and makes interpretations regarding the impact of the intervention more complicated. Strategies were implemented to identify and collect relevant data to be included in analysis.

PMTCT Program Managers’ Involvement

National- and state-level PMTCT program managers were actively involved in protocol development and implementation. Nasarawa and FCT State HIV program staff participated in Mentor Mother trainings and monitoring visits to study PHCs.

WHAT THE STUDY WILL ANSWER AND RELEVANCE FOR THE NATIONAL PROGRAM

Retention along the PMTCT cascade is a critical indicator of success for the national PMTCT program, and one of the most challenging aspects for delivery of care. The study has already identified factors that impact on PMTCT uptake and retention-in-care, such as reminders of available services and benefits, psychosocial support, easier access to drugs and services, and friendly care. For the past several years, Nigerian peer counselors have provided key support to PMTCT clients, but often in an unstructured, informal manner. No rigorous evaluation of the impact of this potentially important intervention has been conducted in Nigeria to inform policy makers and program managers. The MoMent study aims to assess the impact of a structured peer support program on PMTCT retention and adherence in 2 high-burden states.

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