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# Increasing Retention in Care of HIV-Positive Women in PMTCT Services Through Continuous Quality Improvement–Breakthrough (CQI-BTS) Series in Primary and Secondary Health Care Facilities in Nigeria: A Cluster Randomized Controlled Trial. The Lafiyan Jikin Mata Study

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**Background:** Rates of retention in care of HIV-positive pregnant women in care programs in Nigeria remain generally poor with rates around 40% reported for specific programs. Poor quality of services in health facilities and long waiting times are among the critical factors militating against retention of these women in care. The aim of the interventions in this study is to assess whether a continuous quality improvement intervention using a Breakthrough Series approach in local district hospitals and primary health care clinics will lead to improved retention of HIV-positive women and mothers.

**Methods/Design:** A cluster randomized controlled trial with 32 health facilities randomized to receive a continuous quality improvement/Breakthrough Series intervention or not. The care protocol for HIV-infected pregnant women and mothers is the same in all sites. The quality improvement intervention started 4 months before enrollment of individual HIV-infected pregnant women and initially focused on reducing waiting times for women and also ensuring that antiretroviral drugs are dispensed on the same day as clinic attendance. The primary outcome measure is retention of HIV-positive mothers in care at 6 months postpartum.

**Discussion:** Results of this trial will inform whether quality improvement interventions are an effective means of improving retention in prevention of mother-to-child transmission of HIV programs and will also guide where health system interventions should focus to improve the quality of care for HIV-positive women. This will benefit policymakers and program managers as they seek to improve retention rates in HIV care programs.

**Key Words:** retention, uptake, quality improvement, HIV, PMTCT, Nigeria

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## BACKGROUND

Nigeria, with a population of more than 167 million people in 2012,<sup>1</sup> has a national HIV prevalence of 4.1% (range between states: Kebbi 1.0%—Benue 12.7%)<sup>2</sup> and an estimated 3.1 million people infected with HIV. Women account for about 58% of those infected. Despite recent advances in the implementation of prevention of mother-to-child transmission of HIV (PMTCT) interventions, PMTCT coverage in Nigeria remained as low as 25.9% in 2012.<sup>3</sup> Furthermore, a large proportion of HIV-infected women who receive PMTCT interventions get lost to follow-up either before delivery or shortly after delivery. The current rate of retention in care of HIV-infected pregnant women receiving antiretroviral drugs (ARVs), either as lifelong treatment (ART) or prophylaxis, is estimated to be 40% at 6 months postpartum (Center for Integrated Health Program. Program data 2012).<sup>4</sup>

Factors thought to be contributing to the loss of these women from care and follow-up include long waiting time in the hospitals, poor quality of services, transportation costs, and frequent hospital visits required for drug pick-ups. Following changes to the National PMTCT guidelines in 2013, with introduction of option B that is, triple ARV prophylaxis (tenofovir/lamivudine/efavirenz) as the “standard of care” for all HIV-infected pregnant and breastfeeding

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women, improving retention in care is a critical requirement of PMTCT programs if the elimination of pediatric HIV and reduction of maternal mortality are to be achieved. A national consultative forum in 2011 identified 6 critical implementation research questions that would improve the health and survival of HIV-infected women and their children. The “Lafiyan Jikin Mata” Study (LJM)—excellent health for mothers—responds to 2 of these questions:

### National PMTCT Priority 5

“How can the quality and consistency of PMTCT services be improved in facilities to ensure that all mothers and infants, irrespective of place of delivery, receive full and timely PMTCT interventions including early infant diagnosis?”

### National PMTCT Priority 3

“How can communities best be engaged to improve access and uptake of PMTCT interventions?”

## RESEARCH QUESTION

This study aims to address the research question: Will continuous quality improvement (CQI), using a Breakthrough Series (BTS) approach, increase uptake of PMTCT services and retention in care of HIV-infected pregnant women and mothers at 6 and 12 months postpartum?

Health care service delivery in Nigeria has been fraught with myriad system challenges. Despite significant gains have been made in providing health services across the country, there remain significant challenges affecting the quality of health services from both demand and supply side. These challenges include the ability and willingness of health care providers to deliver services that are of optimum quality as outlined by national guidelines for all 3 levels of health services in Nigeria. Some of these challenges have influenced clients’ perceptions, satisfaction, and utilization of health care services. This research will focus on using CQI interventions to address health system challenges relating to retention. CQI is a health systems intervention to systematically improve the consistency and quality of service delivery using data-focused reviews and testing of local solutions.<sup>5</sup> The BTS is a specific, short-term CQI approach (6–15 months) that additionally brings together teams from several hospitals or clinics (“collaboratives”) to jointly review progress and share solutions in a focused topic area and thereby to seek improvement.<sup>6</sup>

## PRIMARY AND SECONDARY OBJECTIVES

To assess whether retention in care of HIV-infected women at 6 months postpartum is greater at health facilities implementing CQI-BTS approaches than at health facilities not implementing CQI-BTS approaches.

### Secondary Objectives

To assess whether implementation of CQI-BTS initiatives at health facilities increases:

1. Uptake of PMTCT services by HIV-infected pregnant women
2. Retention in care of HIV-infected women at 12 months postpartum
3. Retention in care of HIV-exposed babies at 6 and 12 months of age
4. Uptake of a predefined minimum set of integrated RH/PMTCT services by HIV-infected women in health facilities.

## FORMATIVE RESEARCH

Formative research was undertaken in the preparatory phase to provide insight into the knowledge, attitude, practices, and behaviors of key stakeholders in PMTCT service delivery and utilization across 2 states in Nigeria that is, Benue and Kaduna. Focus group discussions and in-depth interviews were used to understand factors that influence uptake of PMTCT services and specifically to identify aspects of health services that negatively impact retention in care, and would be amenable to a CQI intervention. Key influences included the lack of knowledge about services available within the facility and the benefits of ART usage, especially among women with less formal education. Other systemic factors within facilities found to influence service uptake and retention included long waiting time, and different appointments for getting ARVs and for other routine clinic visits. Other influential factors included cost of transportation to facility, partners’ role in supporting service utilization, and the availability of alternative healthcare services by traditional doctors and traditional birth attendants.

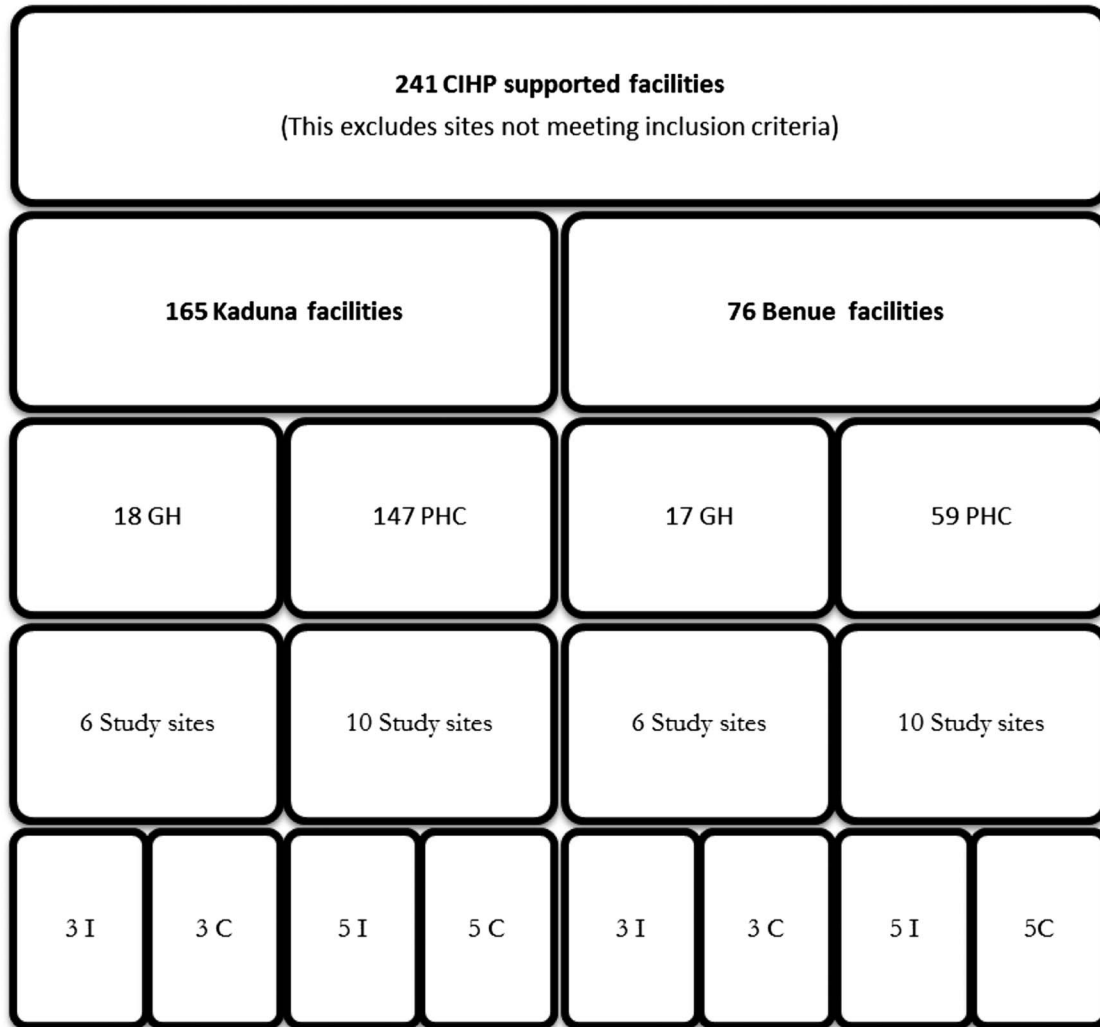
## THE CENTER FOR INTEGRATED HEALTHCARE PROGRAMS SUPPORT FOR PMTCT

The Center for Integrated Healthcare Programs (CIHP) is a nongovernment organization based in Abuja, Nigeria. CIHP provides family-focused, comprehensive quality HIV/AIDS care and treatment services including PMTCT. Transitioning from Columbia University/ICAP programs in late 2011, CIHP is funded by various donors including the Centers for Disease Control and Prevention/PEPFAR. CIHP supports over 1100 government and nongovernment health facilities to provide family-focused comprehensive HIV care and treatment services including PMTCT. Working across 4 Nigerian states, namely Benue, Kaduna, Kogi, and Gombe, CIHP provides support through capacity building, supportive supervision, mentorship, and health system strengthening. These health facilities generally perform at a higher level of care compared with other Government of Nigeria sites where there is less standardization of care.

## METHODS

### Study Design

A cluster randomized controlled trial in which 32 public primary and secondary health care facilities were randomized into 16 intervention and 16 control sites. The control sites



**FIGURE 1.** Randomization flow chart. C, control sites; I, intervention sites; GH, general hospital; PHCs, primary health centers.

receive routine CIHP support, whereas the intervention sites receive routine CIHP support plus structured CQI-BTS interventions.

### Study Sites

Based on predefined site selection criteria, 32 sites were selected from a total of 241 CIHP-supported eligible sites providing PMTCT services in Benue and Kaduna states in December 2013. The following criteria were used to select health facilities for the study:

- Facility supports antenatal care (ANC)/PMTCT services and has capacity to provide ART until 12–18 months postpartum
- Onsite delivery of HIV+ women by the facility
- Provision of postpartum care follow-up for HIV+ women
- At least 2 HIV+ women attend ANC per month for general hospitals and at least 1 HIV+ women per month for primary health centers (PHCs)
- Availability of, at least, 2 trained community health extension workers

- Facilities providing PMTCT services for more than 6 months before onset of study

CIHP baseline program information shows that 25% of ANC attendees use secondary health facilities and 75% of ANC attendees use primary health facilities. Consequently, about a third (6) of sites selected in each state are secondary health facilities and two thirds (10) are PHCs.

Figure 1 shows the number of sites that were eligible in each state and randomized.

### Study Participants

Participants are HIV-infected pregnant women presenting at antenatal clinics for first booking with gestational age of 34 weeks or less, and who are ART naive and accept ARVs and agree to remain in care for at least 6 months postpartum.

### Control and Intervention Arms

Individual pregnant women and mothers attending facilities in the control and intervention arms receive the

**TABLE 1.** Interventions and Support at Control and Intervention facilities

Interventions Provided to Women or Support Provided to Clinic	Control	Intervention
1 Same day HIV testing	Yes	Yes
2 HIV-infected pregnant women receive option B “test and treat”	Yes	Yes
3 Option B ARV prophylaxis according to the national guidelines, that is, the same day	Yes	Yes
4 Lifelong ART based on CD4 count, and/or WHO staging	Yes	Yes
5 Postpartum visits and follow	Yes	Yes
6 Receive routine CIHP support (SoC*, DQA†)	Yes	No
7 Receive structured CQI activities (SoC, DQA, MoC)	No	Yes
8 Application of collaborative BTS for 18 months	No	Yes
9 Establishment of facility QI team	No	Yes

\*SoC assessments evaluate service quality using predefined quality indicators. These assessments do not follow a specific schedule, and different versions of tools are used across sites.

†DQA assessments occur monthly and review the quality of health data collection in terms of accuracy, completeness, and reliability.

DQA, data quality assurance; SoC, standard of care.

same routine health care and interventions; this includes a “test and treat” protocol that is, same day HIV testing and initiation of triple ARVs [tenofovir + efavirenz + lamivudine (TDF + EFV + 3TC) (option B)] of HIV+ pregnant women. Clients eligible for lifelong ART based on CD4 count, and/or WHO staging, continue ARVs (AZT/3TC/NVP; AZT/3TC/LPVr; and AZT/3TC/abacavir) indefinitely for their own health while those not eligible continue ARV prophylaxis according to the national guidelines. For the purpose of this study, antenatal clients are seen for ARV drug refills until delivery according to the national schedule of ANC appointments. Postpartum visits follow the immunization schedule that is, 6, 10, and 14 weeks and thereafter 2 months until 12 months. Facilities in the control arm continue to receive general health system support from CIHP. Table 1 summarizes the differences between control and intervention arms.

### Intervention Package

Intervention sites are assisted to perform CQI reviews of the specific areas of care that are agreed by the teams and also to participate in the collaborative learning sessions that are central to the BTS. CQI interventions use rapid cycles of data collection, testing of solutions, and review of changes that are then implemented using the Plan-Do-Study-Act model (Fig. 2). Driver diagrams are developed to understand the primary and secondary drivers for low retention of HIV+ mothers and to formulate action plans and indicator sets to address these. At each site, a quality improvement team (QI team) will be established from among the local staff. Local government and state level QI teams will also be set up to provide oversight of the health facilities’ QI initiatives. The BTS is a collaborative learning approach conducted quarterly whereby participants from the intervention sites meet together at a central location in each state. At these sessions,

teams share experiences and progress and so learn from each other and how they might adapt and implement changes. Between the collaborative sessions, improvement coaches who are part of the study team follow up site teams at regular intervals through physical site visits and also telephone calls to guide implementation of change ideas. Site teams are also encouraged to communicate with each other through telephone calls and cross-site visits to strengthen learning and exchange of ideas.

At both individual clinics and hospitals, and also at the learning sites, all changes proposed and tested are documented. Simple “run charts” are developed that show changes in performance over time as each new solution or change is implemented and tested.

### DATA MANAGEMENT AND PROCESS INDICATORS

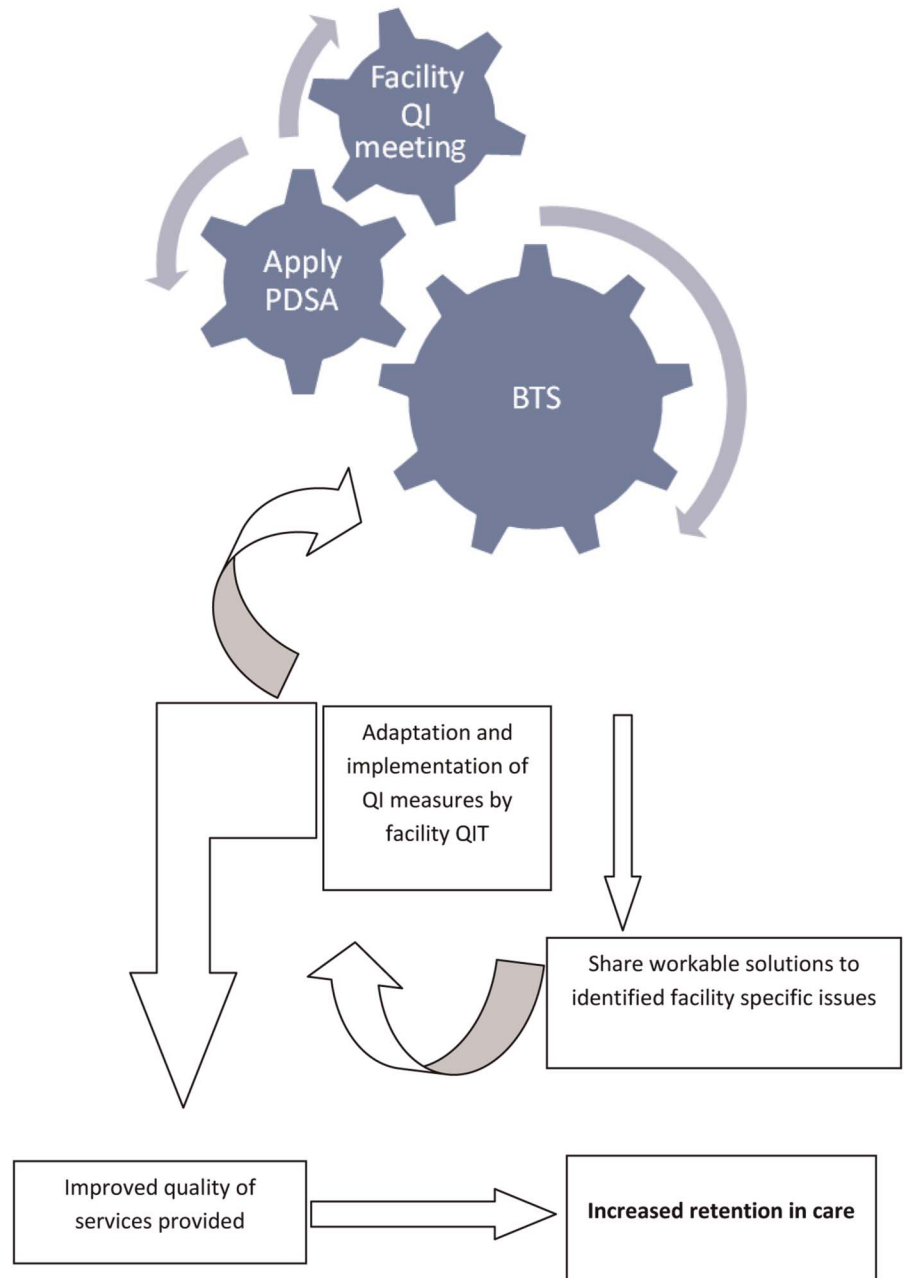
Primary outcome data are sourced from the local health facility registers. Data collection and entry occur weekly in both study arms by research assistants. A monthly review of these data is conducted by the LJM study team. Table 2 provides information on data sources for each primary outcome measure. In addition, process measures are routinely collected to assess the integrity of implementation of the CQI-BTS intervention.

Critical aspects of the study implementation are routinely tracked for compliance with study processes as outlined in the protocol. The number and frequency of data quality assessments, standard of care assessments, change ideas tested, and collaborative learning sessions held will be monitored. In addition, facility QI team meetings and site visits by research associates are routinely tracked.

### SAMPLE SIZE ESTIMATION AND DATA ANALYSIS PLAN

The sample size was calculated using the Windows Programme for Epidemiologists.<sup>7</sup> It is assumed that the expected rate of retention in care in the control arm at 6 months postpartum will be 40%. The CQI-BTS approach will be deemed effective if there is a 20% absolute increase in retention of mothers at 6 months postpartum, namely the rate of retention in care in the intervention arm will be  $\geq 60\%$ .

The minimum sample size was first calculated to detect the expected difference of proportions assuming individual randomization with a level of significance set at 95% (2-sided) and at 80% power. We found that 94 mother–infant pairs would be needed in each arm under individual randomization. Second, bearing in mind that this trial will randomize the intervention package under several clusters, the sample size was inflated by an inflation factor (IF). The IF was calculated as follows:  $IF = 1 + (m - 1) r_0$ , where  $m$  is the size of each cluster, and  $r_0$  the internal variability that represents how strongly individuals within clusters are related to each other. In our case, it is difficult to estimate this internal variability a priori because of the lack of primary data. It is possible that the standardized structure of the intervention tested within the trial will lead to a relatively low cluster internal variability;



**FIGURE 2.** Conceptual framework for CQI-BTS. QIT, quality improvement team; PDSA, Plan-Do-Study-Act model.

alternatively, because the intervention package depends on the individual capacity/will of health care personnel, this may increase across clusters. Hence, we believe it is reasonable to assume a  $\rho$  value of 0.10, as recommended by most authors. We set the number of cluster at 16, which gave an IF of 2.9. Additionally, because this research is being carried out in an operational context, we allowed for up to 20% of routine data to be incomplete or maternal mortality in pregnancy and therefore data on retention in care not available for analysis. Based on these assumptions, a total of 327 mother–infant pairs are needed in each arm. In summary, a total of 640 pregnant HIV-infected pregnant women will be recruited that is, there will be 16 clusters in

each arm with a minimum number of 20 HIV-infected pregnant women per site.

### Data Analysis Plan

Descriptive analyses will be conducted to outline baseline characteristics of both participants and clusters. Summary statistics of primary and secondary outcomes will be presented using frequency tabulations and simple means. Bivariate analysis will be done to identify potential prognostic factors confounding the distribution of baseline characteristics among the arms that require adjustment. This will be carried using the adjusted Pearson  $\chi^2$  test to compare categorical

**TABLE 2.** Outcome Measure/Data Source Log

Outcomes	Data Source	Study Instrument
Primary		
Proportion of HIV+ pregnant women in care 6 months postpartum	PMTCT ARV register, mother and child care form	Mother child care form
Secondary		
Proportion of HIV+ pregnant women initiating ARV prophylaxis or treatment within 2 weeks of enrollment	PMTCT HCT register, PMTCT ARV register	Mother child care form
Proportion of HIV+ pregnant women care 12 months postpartum	PMTCT ARV register, mother and child care form	Mother child care form
Proportion of HIV-exposed infants with DBS samples taken at 6–8 months of life	Child follow-up register	Mother child care form
Proportion of HIV-exposed infants receiving cotrimoxazole prophylaxis	Child follow-up register	Mother child care form
Proportion of HIV-exposed infants receiving ART prophylaxis at birth to 6 weeks of life	Child follow-up register	Mother child care form

HCT, HIV Counselling and Testing; DBS, dried blood spot.

variables and adjusted 2-sample *t* test to compare quantitative variables. Generalized estimating equations (GEE) will be used as an extension of standard binary logistic regression to control for identified prognostic factors. Robust standard error estimations will be carried out along with the GEE to improve standard error estimates. The pattern of missing data will be explored by comparing the women lost to follow-up and those who finished the study to see if observed characteristics were associated with dropout. Missing data—lost to follow-up—will be managed by multiple imputation method based on the assumption that reasons for loss to follow-up were not study-related, and data were considered missing at random. The multiple imputation generates data based on predictions from observed characteristics, which are imputed for the missing data in the regression analysis (GEE). The following definitions will be used when generating outcome variables that will be compared between control and intervention arms.

### First ANC Visit

Date of the first contact between client and health provider at the booking clinic or otherwise when ANC counseling/education is done before initiation into PMTCT.

### Uptake

When an HIV-infected pregnant woman has enrolled and initiated PMTCT services through the collection of ARV prophylaxis at the ANC/PMTCT clinic.

### Retention in Care

Enrolled HIV-infected pregnant woman attends scheduled visits at stated time ( $\pm 2$  weeks) and at least 70% of previous scheduled visits.

### Partial Retention in Care

Enrolled HIV-infected pregnant woman attends scheduled visits at stated time ( $\pm 2$  weeks) but only 30%–69% of previous scheduled visits.

### Not Retained in Care

Attends less than 30% of scheduled visits ( $\pm 2$  weeks).

### Lost to follow-up

Final outcome of an enrolled client who is missing or whose status is “unknown.”

All statistical analyses will be carried out using Stata Version 12 (Stata Corp).

## ETHICAL CONSIDERATIONS

LJM targets healthcare workers and their work practices to improve the quality of services delivered to HIV+ pregnant women and thereby to improve their retention in care; changes in work practices may also influence the quality of care to non-HIV-infected women, yet consent is not requested from these women. Consent from individual women is also limited to the use of routine data and additional data as required for the study but not with respect to the intervention, which is being implemented with the health workers. Consent will not be sought from healthcare workers because health workers cannot meaningfully refuse interventions, because the interventions will be delivered to the health care team as a unit. Ethics approval including amendments has been provided by the Nigerian National Health Research Ethics Committee.

## TIMELINES

Sites were randomized and selected between November 2013 and January 2014, and baseline data were collected in March–April 2014. The CQI-BTS intervention started in May 2014 with enrollment and data collection on individual participants starting in June 2014. Enrollment is expected to be completed in June 2015. Allowing for a minimum of 9 months of follow-up from enrollment to 6 months postpartum, the follow-up of patients for primary outcome measurement is expected to be completed in February 2016.

## CHALLENGES AND LIMITATIONS

The LJM study design was revised because of change in the national PMTCT guidelines that now recommend “Option B” in all facilities rather than Option A for PHCs and Option B for secondary health care facilities only. The national ART regimen for pregnant women also changed to recommend lifelong ART for adults with a CD4 <500 cells per millimeter. These changes resulted in several delays in study implementation because health workers required re-training, and there was uncertainty about what would be the

standard of care. Because of time constraints, one of the original study objectives that related to increasing demand in the community while improving the quality of care in facilities was dropped. The original design was a step-wedge study. However, with the various changes to the national protocol and therefore standard of care, there was not enough time to collect the necessary baseline data before starting a CQI intervention, we therefore changed to a cluster randomized control design.

### CONCLUSIONS

Results of this trial will inform whether quality improvement interventions are an effective means of improving retention in PMTCT programs and will also guide where health system interventions should focus to improve the quality of care for HIV-infected women. This will benefit policymakers and program managers because they seek to improve retention rates and scale up services in HIV care programs.

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