

## **Draft Concept for Randomized Controlled Trial (RCT) in Akwa Ibom State**

Proposed to the  
**Ministry of Health, Akwa Ibom State, Nigeria**  
Submitted by  
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DRAFT, October 2014, Uyo, Akwa Ibom State, Nigeria

*This document outlines preliminary plans for the design, methodology, and implementation of a randomized controlled trial of the New Incentives / All Babies Are Equal project, which is carried out in selected clinics in Akwa Ibom State in collaboration with the Akwa Ibom Ministry of Health.*

*As part of a Bill & Melinda Gates Foundation Grand Challenges Explorations Round 13 grant, New Incentives was awarded \$100,000 to conduct a RCT evaluation of its conditional cash transfer program focused on increased retention in PMTCT services.*

**Title of Study:** Conditional Cash Transfers to Increase Retention in PMTCT Services in Akwa Ibom State, Nigeria

### **Purpose**

New Incentives provides conditional cash transfers to HIV-positive pregnant women at selected facilities in Akwa Ibom State, Nigeria, to increase retention of prevention of mother-to-child transmission of HIV (PMTCT) services in communities with high HIV prevalence rates. The RCT will be conducted to assess the effectiveness of CCTs at increasing retention in PMTCT services specifically in relation to regular pickup of ARV drugs for infected mothers, delivery in the hospital setting, and receipt of drugs for exposed infants. The study will also measure the HIV status of newborns.

The study will be one of the first of its kind in Nigeria, bolstering Akwa Ibom State's reputation as a leader in using rigorous research to measure the effectiveness of development interventions.

The study will measure:

1. Frequency of picking up ARV drugs
2. Delivery in the hospital
3. Receipt of Nevirapine drug for infants immediately after birth
4. Receipt of six-week dose of Nevirapine drug for infants
5. EID test for newborns
6. HIV status of newborns

### **Study Design**

To measure if the conditional cash transfer (CCT) project is successful and to determine whether reducing demand-side barriers is critical for retaining women in the PMTCT cascade, we intend to conduct a low-cost randomized control trial impact evaluation. We will randomly divide the

sample of all HIV-positive pregnant women into treatment and control group, with the control group being the comparison group used to measure the counterfactual of what would have happened to these HIV-positive women if there were no CCT program.

By conducting a small-scale RCT, we can begin to learn how effective CCTs focused on PMTCT behaviors can be at increasing retention in PMTCT services. Power calculations based on conservative estimates of potential program impact indicate that approximately 250 women are needed for each of the treatment and control group. The end line<sup>1</sup> survey will provide a deeper understanding of the expected impact of the program and the specific mechanisms driving that impact related to PMTCT objectives, as well as some information about the cash component of the CCTs, however this is not a primary focus of the study.

500 HIV-positive pregnant women in three participating hospitals<sup>2</sup> will be randomly assigned to one of the project's following groups:

1. HIV-positive pregnant women receiving CCTs: HIV-positive pregnant women will receive cash transfers conditional on satisfying the World Health Organization's recommended guidelines for PMTCT. At three different stages during and after pregnancy, mothers will be given differing amounts of Naira conditional on satisfying the following requirements: (1) registering for antenatal services during pregnancy and receiving an HIV test, (2) taking antiretroviral therapy for HIV-positive women in need of treatment for their own health and for HIV-positive women not in need of treatment for themselves, then antiretroviral prophylaxis to prevent mother-to-child transmission of the virus, (3) delivering with a skilled birth attendant at a health clinic and receiving the necessary mother and infant ART, (4) continue taking ART prophylaxis and attending a postnatal visit to receive an early infant HIV diagnosis test for their newborn.
2. Control group: No intervention received. These women will receive regular PMTCT health services provided by participating clinics but not receive the conditional cash transfer intervention. The evaluation will collect administrative data from participating hospitals, specifically prenatal and postnatal information about whether women receive prenatal checkups; are following antiretroviral treatment; where they deliver and whether ARVs were received during birth and for the newborn after birth; their own and their child's nutritional status; and data on other key health indicators that are related to the cash transfer conditions such as type of previous deliveries. The evaluation will also measure neonatal mortality rates, maternal death rates, and the HIV status of newborns. A list of individuals in the control group will be maintained that includes their name, patient number, and phone number (if listed on their patient card). No photographs of patient cards or other clinic records will be collected for individuals in the control group.

The study will not interact with women in the control group until 8-10 weeks after delivery. At this time, mothers in the control group will be invited to return to the clinic for the EID test (if they have not completed one already) and participate in a survey. At this stage, women in the

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<sup>1</sup> This survey which takes place after the program has ended is referred to as the "end line" survey even though there will be no baseline survey for individuals in the control group. Please refer to the table at the end of the document for additional details.

<sup>2</sup> Participating hospitals include [names redacted].

control group will receive a considerable incentive for participating in the EID test in the clinic and end line survey; the incentive will help them take care of their newborns and families. It is critical that hospital staff and women in the control group do not have previous knowledge about this incentive. This will prevent the incentive from changing the prenatal and delivery behaviors of women in the control group.

### **Benefits**

Randomized controlled trials are the most scientifically rigorous method for determining whether a causal relationship exists between an intervention and outcome, as well as for assessing the cost-effectiveness of an intervention. The randomized controlled trial is an essential component to measure whether the conditional cash transfer program is effective in increasing retention in PMTCT services. The results of the study will be used to raise funding to expand the New Incentives program and advocate for adoption of a PMTCT component in the national SURE-P CCT program that is administered by the Nigerian government.

Measuring whether the conditional cash transfers are effective against a control group at increasing retention in PMTCT services is the only way for New Incentives to continue raising support for the program and ensuring that limited resources from donors are effectively used.

### **Randomization**

After registering for ANC services and obtaining their HIV test results, HIV-positive pregnant women will be randomly assigned to either the treatment or control group. Women assigned to the control group will not interact with the New Incentives program and will continue receiving hospital services as usual without the intervention. Women assigned to the treatment group will be directed to a room where the New Incentives Field Officer will then enroll the woman in the program.

Randomization will be carried out using a computer-based random assignment generator.

Logistics of Randomization:

1. Pregnant women register for ANC
2. Pregnant women receive HIV test
3. ARV Counselor or HIV Lab Testers (depending on the clinic) write down the names of all women who test positive on the ABAE Sign-Up sheet. This sheet will not be publicly displayed and will be kept confidentially at the counselor or lab testers' station.
4. For every 3-5 women written down on the ABAE Sign-Up sheet, the ABAE Field Officer will note who is eligible for the cash transfers and who is not according to a randomization algorithm run by a computer and not the Field Officers.\* Ineligible women will not go to the ABAE room and will continue with regular ANC services or leave the clinic if they are finished. It is essential that these ineligible women are not informed about the program because such information might lead to a biased result or negative feelings.
5. Eligible women will be referred to the ABAE room to enroll in the program.

\*This protocol prevents nurses, counselors, and/or field officers from selecting who should be in the treatment group because some have long-term relationships with patients. For example, if the randomization were to occur for every other positive case, a hospital or ABAE staff member might be

able to list their favored client as the person eligible for the treatment group. It is important to ensure that new PMTCT patients have an equal chance of enrolling in the treatment group as long-term PMTCT patients.

Both women in the treatment and control groups will participate in a survey 6-10 weeks after delivery. This 6-10 week timeframe was intentionally chosen to monitor whether women in the control group attend the EID visit six weeks after delivery. For women who do not attend this visit by week 8 post delivery, New Incentives will invite them back to the clinic by first calling to ask them to complete the EID test for their newborns and reminding them about the incentive they will receive if they return to the clinic. For those women in the control group who still do not come to the clinic, New Incentives will offer to send a bike to transport them to the clinic and then as a final solution, send a trained surveyor to conduct a survey at the women's household or preferred meeting location if the woman agrees. The trained surveyor will be a person who is certified to collect a Dried Blood Sample (DBS) from the infant at the household to send it for EID testing. If it is not possible to recruit surveyors with this experience, a nurse or trained community health worker will accompany the surveyor.

A similar procedure will be followed for women in the treatment group who do not attend the EID visit. The implication of this process is that some women will complete an EID test at 6 weeks while others might complete the EID test 8-10 weeks after birth. Infants who complete the EID test 8-10 weeks after birth will be more exposed than infants who complete the test 6 weeks after birth. This is a risk of bias in the study but because the increased risk of transmission during four weeks of breastfeeding is limited, we consider this an acceptable bias. The alternative would be to invite all women in the control group to test their infant at six weeks but in such a scenario, we would not be able to compare retention in the EID component of PMTCT.

### **Roles**

The Ministry of Health is in charge of supervising and running the clinics where the RCT study will be conducted. New Incentives, in partnership with the Ministry of Health, implements the conditional cash transfer program. The operations of the program will remain consistent with how the program has been implemented since June 2014.

*Training:* The Ministry of Health will supervise trainings at all clinics participating in the study and train hospital staff on the value of RCTs. This will be a 1-2 hour training. New Incentives will prepare all training materials and provide health workers with food and refreshments during the training

*Implementation:* The Ministry of Health will be listed as a lead implementing partner in all press releases and documentation of the study, including on the first page of the final study report.

*Dissemination:* The Ministry of Health will be invited to accompany New Incentives to meetings in Abuja in 2016 to disseminate study findings to key federal stakeholders working on SURE-P and related programs. The goal of these meetings is to advocate for SURE-P to adopt a PMTCT component into its national maternal health CCT program.

The Ministry of Health in Akwa Ibom will have authorization to distribute and share the final research report for free.

New Incentives will continue implementing the CCT program in coordination with the Ministry of Health. New Incentives will be the primary liaison with the independent researcher who is the author of the study and lead designer. New Incentives will provide regular reports to the Ministry of Health regarding progress with the study.

An independent researcher based in the United States will lead the study design, develop survey protocols, and conduct analysis of study data. The researcher will author a technical study report upon completion of the study and will submit the report to the Bill & Melinda Gates Foundation.

### **Confidentiality**

New Incentives will obtain written consent from all women in the treatment group participating in the study. Written consent is always obtained for women participating in the cash transfer program but the consent form will be modified to inform women that their participation will be used in a research study.

Women in the control group will sign a consent form when they complete a questionnaire 8-10 weeks after delivery. At the beginning of the study, consent cannot be obtained from women in the control group because it would result in most women saying no because they are not receiving anything<sup>3</sup> and do not know what the study is for since we cannot share details of the CCT program without creating negative feelings and potential controversy in the clinic. Such negative attitudes would bias the study by influencing the attitudes women in the control group have towards the clinic. The study design was specifically developed to limit interaction with women in the control group and rely on administrative data.

### **Funding**

The Bill & Melinda Gates Foundation is the owner of the study research and results. It is required for the independent researcher to publish the results of the study in a publically available journal. Implementing partners of the study will not author the study but will receive recognition for implementing the study and pioneering the program.

### **Study Risks and Assessment**

[Table redacted]

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<sup>3</sup> Similar studies generally provide incentives for individuals in a control group to participate in the study. Because this program is evaluating incentives, a control group that is not receiving any incentives is needed.