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In-Home HIV Testing and Nevirapine Dosing by Traditional Birth Attendants in Rural Zambia: A Feasibility Study

Alana T. Brennan, MPH, **Donald M. Thea, MD, MSc**, **Katherine Semrau, PhD, MPH**, **Caitlin Goggin, MA**, **Nancy Scott, MPH**, **Portipher Pilingana, BSc**, **Belinda Botha**, **Arthur Mazimba, MPH**, **Leoda Hamomba, MPH**, **Phil Seidenberg, MD**

Abstract

Introduction: Access to lifesaving prevention of mother-to-child transmission (PMTCT) services is problematic in rural Zambia. The simplest intervention used in Zambia has been 2-dose nevirapine (NVP) administration in the peripartum period, a regimen of 1 NVP tablet to the mother at the onset of labor and 1 dose in the form of syrup to the newborn within 4 to 72 hours after birth. This 2-dose regimen has been shown to reduce MTCT by nearly 50%. We set out to demonstrate that in-home HIV testing and NVP dosing by traditional birth attendants (TBAs) is feasible and acceptable by women in rural Zambia.

Methods: This was a pilot program using TBAs to perform rapid saliva-based HIV testing and administer single-dose NVP in tablet form to the mother at the onset of labor and syrup to the infant after birth.

Results: A total of280 pregnant women were consented and enrolled into the program, of whom 124 (44.3%) gave birth at home with the assistance of a trained TBA. Of those, 16 (12.9%) were known to be HIV positive, and 101 of the remaining 108 (93.5%) accepted a rapid HIV test. All these women tested HIV negative. In the subset of 16 mothers who were HIV positive, 13 (81.3%) took single-dose NVP administered by a TBA between 1 and 24 hours prior to birth and 100% of exposed newborns (16 of 16) received NVP syrup within 72 hours after birth, 80% of whom were dosed in the first 24 hours of life.

Discussion: With the substantial shortage of human resources in public health care throughout sub-Saharan Africa, it is extremely valuable to utilize lay health care workers to help extended services beyond the level of the facility. Given the high uptake of PMTCT services we believe that TBAs with proper training and support can successfully provide country-approved PMTCT.

Keywords

traditional birth attendants; prevention of mother-to-child transmission; HIV/AIDS; point-of-care HIV testing; 2-dose nevirapine; resource-limited setting

Address correspondence to Alana T. Brennan, MPH, Center for Global Health and Development, Boston University, Crosstown Center, 3rd Floor, 801 Massachusetts Ave, Boston, MA 02118. abrennan@bu.edu.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to report.

INTRODUCTION

Pediatric HIV is a major cause of morbidity and mortality among young children in resource-limited settings with a high prevalence of HIV. Globally, an estimated 2.5 million children are currently infected with HIV, with 1000 children newly infected every day, 90% resulting from vertical transmission of the virus from mother to child at the time of birth.[1]

The main barrier in many low-resource areas, specifically African countries, is providing prevention of mother-to-child transmission (PMTCT) services to women in need. A study conducted in Rwanda showed that in the absence of PMTCT interventions, an estimated 30,000 infants would contract HIV from their mothers each year.[2] Unlike in adults, progression to AIDS in infants can be rapid. Without treatment, 30% of children born with HIV die before their first birthday, whereas 50% die before they turn 2 years of age.[3,4]

It is estimated that up to 45% of mothers with HIV in Zambia will transmit the virus to their exposed newborns if they do not receive any PMTCT intervention.[3] However, vertical transmission of HIV can be substantially reduced with the administration of antiretroviral drugs.[5] Prior to the national guideline changes in 2010, the standard of care and most widely practiced intervention used in Zambia was 2-dose nevirapine (NVP) administration in the peripartum period, a regimen of 1 NVP tablet to the mother at the onset of labor and 1 dose in the form of syrup to the infant within 4 to 72 hours after birth.[6] Phase 1 studies have shown that rapid absorption of single-dose (200 mg) NVP taken by a pregnant woman at the onset of labor, more than 1 hour prior to birth, can travel rapidly through the placental membranes and reach concentrations in the newborn necessary to decrease vertical transmission of the virus by 50%.[7–10] Because a single 200-mg dose of NVP has a reported half-life of 45 hours,[11–14] the dose to the infant 4 to 72 hours after birth is necessary to extend the concentration of the drug in the infant's system long enough for the mother-infant pair to reach a health facility for further care and treatment.13 If the mother receives the dose of NVP less than 1 hour prior to birth or not at all, the risk of vertical transmission to the infant increases, even if the infant is given the NVP syrup in a timely manner.[13] In 2010 the national PMTCT guidelines became more complex for pregnant women who test positive or seroconvert after 28 weeks' gestation.[15] This more complex regimen is highly effective in lowering transmission rates to 2% or less[13] but can be considerably more difficult to implement in rural Zambia.

Currently, Zambia is among the 25 countries with highest estimated numbers of pregnant women living with HIV who are in need of antiretrovirals to prevent vertical transmission of the virus.[1] However, access to care is problematic, especially in rural areas. One potential solution to this problem is training traditional birth attendants (TBAs) to implement at the community level one component of the PMTCT guidelines and standard of care available at the time of our study (single-dose NVP tablet and syrup[6]). This concept is logical for 2 reasons. First, up to 40% of all HIV pediatric infections occur during birth.[4] Second, most PMTCT programs in Zambia are currently based at health centers and facilities, yet an estimated 50% to 60% of infants born in rural communities are born at home with TBAs or family members.[6]

We report here on a pilot program training TBAs to perform rapid HIV testing and administer single-dose NVP in tablet form to the mother and syrup to the infant for births occurring outside health facilities in rural Zambia. Our aim was to demonstrate the feasibility and effectiveness of using TBAs to administer a rapid saliva-based HIV test at the onset of labor and provide 2-dose peripartum NVP to mothers and and their infants born at home, which, at the time of our study, was part of the national PMTCT guidelines and the standard of care in Zambia.

METHODS

Traditional Birth Attendant Prevention of Mother-to-Child Transmission Pilot Program Setting

Access to health services in the Chikankata catchment area in Mazabuka District is limited because of sparse population densities, poor road networks, and limited staffing in health facilities. In addition, some parts of the catchment area are inaccessible, particularly during the rainy season, as flooding isolates some villages for at least 2 months of the year. Currently, only the central area (composed of the mission hospital, a few shops, the main high school, the biomedical and nurse training schools, and the parliamentary constituency office) is connected to the national electricity power grid. The Chikankata catchment area has one main hospital, the Chikankata Mission, which is supported by the Salvation Army, and there are 6 rural health centers that are all Zambian government facilities. The rural health centers are on average 25 kilometers from the referral mission hospitals.

Few of the rural health centers in the Chikankata catchment area have a complete complement of health staff (clinical officer, environmental health technician, nurse, and nurse-midwife). A clinical officer is a midlevel practitioner of medicine qualified to perform general medical duties such as diagnosing and treating disease and injury, ordering and interpreting medical tests, and performing routine medical and surgical procedures. The environmental health technician is trained to provide health education, safe water, and sanitation programs to the community. The nurse and nurse-midwife are both trained to treat patients and educate the community on various medical conditions; however, the nurse-midwife has additional training in obstetrics. All services for children under 5 years of age and pregnant women at the mission hospitals and rural health centers are free of charge.

We chose to implement this pilot study in the Chikankata area because it is representative of many rural communities in Zambia and has a strong group of TBAs who are spread out geographically to adequately cater to their respective communities.

Ethical approval of the pilot program was granted by the ERES Converge Ethical Review Board in Lusaka, Zambia, and the Boston University institutional review board, with final clearance from the Ministry of Health in Zambia.

Overview of Traditional Birth Attendant Prevention of Mother-to-Child Transmission Pilot Program

The TBA PMTCT pilot program, implemented from February 2009 to July 2010, sought to demonstrate the feasibility and effectiveness of using TBAs to administer a rapid saliva-

based HIV test (OraQuick, OraSure) late in pregnancy and to provide 2-dose peripartum NVP to mothers and their infants born at home.

All pregnant women in the Chikankata catchment area were approached by data collectors employed by the study and asked for their consent to participate in the pilot program at any point during their pregnancy prior to the onset of labor. Consent in this context did not refer to whether a given mother accepted or declined the HIV testing and NVP dosing because we could not control where she gave birth to her infant. Therefore, when we sought her consent to participate, she was consenting for us to collect data on her and her infant and the services they received before, during, and after birth. Our participation rates among women were high (99.6%); only 1 woman withdrew from the study after consenting (0.4%). Pregnant women were not given any incentive to be involved in the study. Because we collected demographic information on TBAs in addition to asking them about the care they provided prior to, during, and after labor, they were considered program participants. Thus, consent was obtained from them during the initial PMTCT training to allow us to collect data on them. No TBAs eligible to be involved in the pilot program declined participation.

At the time of the implementation of the program, there were 48 TBAs in the Chikankata catchment area. All were TBAs who had successfully completed a 6-week Ministry of Health TBA training course in antenatal care, family planning, birth management, counseling (on nutrition, danger signs, and prenatal care at the clinics), health education, antepartum maternal uterine growth and infant growth monitoring, home-based care, postnatal care, and referrals to local health clinics for necessary treatment. Because of budgetary constraints and the exclusion of TBAs who were illiterate, only 23 of the 48 TBAs were chosen to be involved in our program and went on to successfully complete the training for the implementation of the TBA PMTCT pilot program. The training involved 2 main components: 1) a weeklong refresher course based on the national PMTCT training for professional health care workers, which covered the essential elements of HIV and AIDS; and 2) a 4-day enhanced training course on how to use the OraQuick HIV test and how to administer NVP to a mother and child.

Traditional birth attendants who completed the study training were equipped with bicycles, clean birth kits (containing a plastic sheet for the mother to lie on, a piece of soap, a pair of gloves, gauze squares, cord ties, and a sterile scalpel blade), and kits containing rapid saliva-based HIV tests (OraQuick) and NVP tablets (200 mg) for mothers with HIV and NVP syrup (prepackaged syringes containing individual 15-mg doses) for their exposed infants. Program supervisors tracked and replaced the number of HIV saliva test kits, NVP pills, and NVP syrup syringes used by each TBA on a monthly basis. Both the OraQuick HIV rapid test and the NVP tablets and syrup can be stored unopened at a temperature no higher than 30° C. The OraQuick test has a shelf-life of 6 months. It has been evaluated in diverse settings and has shown high sensitivity (99.1%) and specificity (99.6%) for HIV antibody in both whole blood and oral fluid specimens.[14]

In the community, each TBA offered HIV volunteer counseling and testing to all mothers whose HIV status was unknown. If the mother had been previously tested at an antenatal clinic (ANC), her HIV status was noted on her ANC card, a document that all TBAs

currently use during all stages of their routine care for pregnant women or women who gave birth recently If at the onset of labor, the mother's HIV status was unknown or negative, according to the mother or her ANC card, the TBAs offered her an OraQuick test. If the mother agreed to be tested and her HIV status was positive or if she was known positive based on her ANC card, the TBA administered NVP to the mother during labor and to the HIV-exposed infant immediately after birth. The TBAs then referred all women who were HIV positive to the nearest health facility for confirmatory testing, counseling on HIV, and the standard of care for follow-up of exposed infants. All mothers and infants, regardless of HIV status, were referred for postnatal follow-up and care at the local health centers, as is the standard of care in Zambia.

RESULTS

A total of 280 pregnant women were consented and enrolled into the pilot program. Of those 280 women, 124 (44.3%) gave birth at home with the assistance of a study TBA and were the focus of the pilot program (Figure 1). Of the 124 women, 16 (12.9%) were known to be HIV positive based on their ANC card; 101 of the remaining 108 (93.5%) accepted the OraQuick test. All these women tested HIV negative.

In the subset of 16 mothers who were known to be HIV positive and gave birth at home, 13 (81.3%) took single-dose NVP administered by a TBA between 1 and 24 hours prior to birth and 100% of the exposed newborns (16 of 16) received NVP syrup within 72 hours after birth, 80% of whom were dosed in the first 24 hours of life. All mothers and infants who took NVP received the drugs from a TBA except for 1 mother-infant pair who obtained both the single-dose NVP and the syrup from the local health center. Three women who were HIV positive did not receive single-dose NVP because 1) the TBA arrived late, resulting in the OraQuick test being done after birth and NVP syrup given only to the newborn; 2) the woman went into premature labor (25 weeks' gestation); and 3) the woman declined to tell the TBA her HIV status until after the child was born.

DISCUSSION

Traditional birth attendants have been successfully assisting mothers to give birth to children in sub-Saharan Africa for millennia. Some argue that TBAs are often closer and more influential within their communities than formally trained health care staff because they usually speak the local language, are more affordable, provide essential social support during childbirth, and have the trust and respect of local community members.[16–19] In resource-limited settings, TBAs already attend to a large portion of births and could be used to further expand the availability of certain PMTCT services to mothers and children in need.[20]

Our pilot study demonstrates that point-of-care testing and NVP dosing in the home by TBAs are feasible and adequately capture the large number of women who give birth outside health facilities. Ideally, skilled birth attendants should attend births, but this is an unforeseeable goal in most African countries because of challenges in training adequate numbers of skilled birth attendants and providing adequate facilities within these small

isolated villages where women will continue to live and give birth. This study demonstrates that in these situations, point-of-care service such as HIV testing and NVP dosing can be provided to the mother and newborn. In this study, more than 90% of women with unknown or HIV-negative status accepted a rapid saliva-based HIV test at the onset of labor, and more than 80% of mothers with HIV and 100% of their infants received NVP in a manner timely enough to lower the risk of vertical transmission of the virus to the infant. These results help to confirm the value of extending PMTCT services beyond health facilities and training a cadre of women who are well respected and accepted in the community.

Since the completion of our study, the government of Zambia, through its Ministry of Health, has adopted more efficacious PMTCT regimens based on World Health Organization recommendations15 in further attempts to reduce the burden of HIV from mother-to-child transmission. The current antiretroviral therapy (ART) regimens are highly complex for pregnant women who test positive or seroconvert after 28 weeks' gestation, consisting of 300 mg of zidovudine (AZT) to be taken twice daily during the antenatal period, 200-mg single-dose NVP at the onset of labor along with 150 mg of lamivudine and 300 mg of AZT to be repeated every 12 hours until birth, and lamivudine (150 mg) coupled with AZT (300 mg) twice daily for 7 days postnatally. In addition, all HIV-exposed breastfeeding infants must be started on daily NVP prophylaxis (dose ranges from 10 to 15 mg depending on infant weight) from birth and continued throughout the duration of breastfeeding, whereas HIV-exposed non-breastfeeding infants must also be started on daily NVP from birth but only up until 6 weeks of age. All exposed infants must also be started on co-trimoxazole (40 mg) from 6 weeks until HIV status is confirmed negative.[15] We recognize the change in the guidelines as a limitation to the generalizability of our results; however, at the time of our study, 2-dose NVP was one of the recommended and most widely used PMTCT strategies. More importantly, we were able to demonstrate that TBAs can feasibly implement of the national guidelines for PMTCT prevention strategies, and we do not see any reason why TBAs would not be equally effective in implementing more efficacious regimens in future PMTCT programs in settings similar to Zambia.

Although the government of Zambia is no longer focused on empowering TBAs to administer drugs, the proven commitment of these women could be crucial in the government's efforts to increase adherence to antiretrovirals among women and their infants late in pregnancy and after birth while the mother is breastfeeding, a period when the risk is known to be the highest.5 Zambia's 2010 guidelines for PMTCT state that lay health care workers, such as TBAs, are to fill more of an educator's role about basic knowledge and skills related to HIV/AIDS and PMTCT, such as encouraging pregnant women to go for early antenatal booking by 14 weeks' gestation and to give birth in health care facilities.[15] One aspect of the government guidelines is focused on TBAs providing support for women and their infants to adhere to ART and to co-trimoxazole for pneumocystis pneumonia prophylaxis. As more efficacious PMTCT regimens are adopted nationally in countries such as Zambia, adherence to more complex drug regimens and medication dosing schedules becomes increasingly more important for such programs to be effective.

Resistance to NVP after a single dose in women and children with HIV is a major concern and not something we evaluated in this pilot study Results of a meta-analysis estimated that

approximately 30% of women and more than half of children who became HIV infected despite PMTCT intervention measures developed NVP resistance mutations after single-dose NVP intake.[22] Providing women and children in our study with the recommended standard of care for PMTCT likely led to NVP resistance but at the same time prevented transmission of HIV from mother to child, which was the primary focus of the program.

Our findings should be considered alongside their limitations. First, our lack of a comparison group, dropped early on because of funding restrictions, and the cross-sectional design prevent us from assessing the impact of the TBA pilot program on specific outcome indicators (ie, increase in the uptake of NVP among mother-infant pairs). However, we believe that the high acceptance of the OraQuick test among mothers who had negative or unknown HIV status around the time of birth and the high uptake of NVP among mothers with HIV and their exposed infants during the peripartum period are adequate process indicators. Second, Chikankata, although representative of many rural communities in Zambia, does have slightly better infrastructure and a potentially stronger community of literate TBAs than many rural areas, making a program like this potentially more difficult to implement in areas that are not comparable. Third, one characteristic that may be necessary for TBAs to adopt these practices would be literacy. Because TBAs were chosen on the basis of their level of literacy and had to be limited to 23 because of a restricted budget, the results of this pilot program may not be generalizable to TBAs who are illiterate. Because they need to be able to attend multiple training sessions (national PMTCT training for professional health care workers and 4-day enhanced training on how to use the OraQuick HIV test and how to administer NVP to a mother and child), women who were chosen needed to be literate in their local language. Fourth, we recognize that a woman actually receiving postpartum follow-up care is reflective of the mother's situation and understanding, as well as the influence of the TBA and facility staff. Sixteen women with HIV and their infants in our pilot program were referred to their local health clinic for necessary care; however, because our study ended at the point of referral to the clinic, we cannot report on whether they received follow-up services. Fifth, we recognize that one of the main barriers to accessing proper care during labor and birth is the lack of affordable transportation (cars, bicycles, ambulances, etc) either for the pregnant woman to access the health facility or for the TBA to attend a home birth in a timely manner. Communication between the women and the TBAs was highlighted as a limiting factor in our study. There were 166 women (59.5%) of 279 who gave birth at home. In 31 of those births (18.7%), the mothers either gave birth alone or with a family member's assistance. When the woman gave birth without assistance from a TBA, close to 90% of the time, it was because the mother or family did not inform the TBA that she was in labor, making it impossible for the TBA to attend the birth.

Two recent reviews stated that community-based solutions are essential to ensure that both women and their children have access to the full cascade of PMTCT interventions.[23,24] The PMTCT programs that do not extend beyond facilities and fail to engage lay staff will not be able to achieve the level of PMTCT coverage required to decrease vertical transmission from mother to child.[25,26] Although there is no research supporting TBAs administering the current more complex PMTCT treatments, research has shown that TBAs have been successful in providing lifesaving interventions along with administering and monitoring adherence to treatment regimens that are far more complex than a single oral dose of NVP to

a mother and her infant. The results from a randomized controlled trial conducted in the Lufwanyama District in Zambia's Copperbelt Province showed that TBAs were able to effectively administer simple interventions (neonatal triage, prevention of hypothermia, and resuscitation) that helped to reduce neonatal mortality.[27] Some TBAs have also been trained in various resource-limited settings to deliver tuberculosis treatment and monitor adherence, a complex regimen that takes up to 6 to 8 months to complete,[28,29] and prophylaxis for malaria prevention to pregnant women.[30]

With the rapid growth in access to antiretrovirals for mothers and infants, we cannot ignore the critical shortage of health care workers in many resource-limited settings heavily burdened by the HIV epidemic. Despite the 2010 PMTCT guideline changes, 50% of women in rural Zambia are still giving birth at home. In many rural areas, TBAs are often the only caregivers willing and available to assist mothers before, during, and after birth. Traditional birth attendants provided with enhanced training along with ongoing supervision and support[31] could successfully deliver certain PMTCT services to women and infants in need,[32] ultimately providing an efficient, cost-effective[33] intervention to reduce infant and child deaths from HIV and AIDS infection and extended PMTCT services beyond government facilities.

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AUTHORS

Alana T. Brennan, MPH, holds an MPH in epidemiology from Boston University and has more than 5 years of experience working in the field of public health as a project leader and data analyst. She works as a data analyst for Boston University's Center for Global Health and Development and is currently enrolled in the epidemiology doctoral program at Boston University.

Donald Thea, MD, MSc, has pursued a full-time career in both domestic and international clinical and epidemiological infectious disease research, primarily in HIV/AIDS and childhood pneumonia. Dr. Thea received an MD from Columbia University College of Physicians and Surgeons and was trained in tropical medicine at the London School of Hygiene & Tropical Medicine and in infectious diseases at New England Medical Center.

Katherine Semrau, PhD, MPH, has more than 10 years of experience in the fields of HIV prevention, child mortality, and epidemiology. She is currently Assistant Professor of International Health and Director of the International Research Coordinating Center. Dr. Semrau has a PhD in epidemiology from Boston University and an MPH in international health and epidemiology from the University of Alabama–Birmingham.

Caitlin Goggin, MA, is the Deputy Country Director of the Zambia Country Program, Center for Global Health & Development, and holds an MA in international development

studies from Saint Mary's University, Halifax, Canada, a BA with honors in political science and international relations from Carleton University, Ottawa, Canada, and a Certificate in Adult Education from Saint Francis Xavier University, Antigonish, Canada.

Nancy Scott, MPH, has 10 years' experience in international public health. Ms. Scott is Instructor of International Health at Boston University School of Public Health, where she teaches a course in critical analysis and public health writing. She is currently a DrPH candidate at Boston University and holds an MPH in International Health from Boston University and a bachelor of science in biology from Santa Clara University.

Portipher Pilingana currently holds the position of Research Coordinator at Zambia Center for Applied Health Research and Development, Lusaka, Zambia.

Belinda Botha currently holds the position of Technical Logistics Coordinator at Zambia Center for Applied Health Research and Development, Lusaka, Zambia.

Arthur Mazimba, MPH, is the Field Director for the Zambia Chlorhexidine Application Trial, under the Center for Global Health & Development and based in Choma, Zambia. He holds an MPH in international health from Boston University School of Public Health and a BSc and a National Graduate Diploma in agriculture sciences from the University of Zambia and the Natural Resources Development College.

Leoda Hamomba is the Project Director for the Boston University Prevention of Mother to Child Transmission of HIV Integration Project (BUPIP), under the Zambia Center for Applied Health Research and Development, Lusaka Zambia. She holds an MPH from the University of Zambia, Department of Community Medicine with a BSc in nursing with a major in Community Health. She has more than 10 years' experience in managing health service delivery programs in the field of Maternal and Child Health.

Philip Seidenberg, MD, is a board-certified emergency physician trained at Stanford University School of Medicine and the University of New Mexico for residency. He is currently an Assistant Professor in the Department of Emergency Medicine at the University of New Mexico and is an Honorary Lecturer in the Department of Medicine at the University of Zambia School of Medicine.

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Quick Point

- Our pilot study demonstrates that point-of-care testing and nevirapine dosing in the home by traditional birth attendants is feasible and adequately captures the large number of women who give birth outside health facilities.
- Traditional birth attendants provided with enhanced training along with ongoing supervision and support could successfully deliver certain prevention of mother-to-child HIV transmission services to women and infants in need.

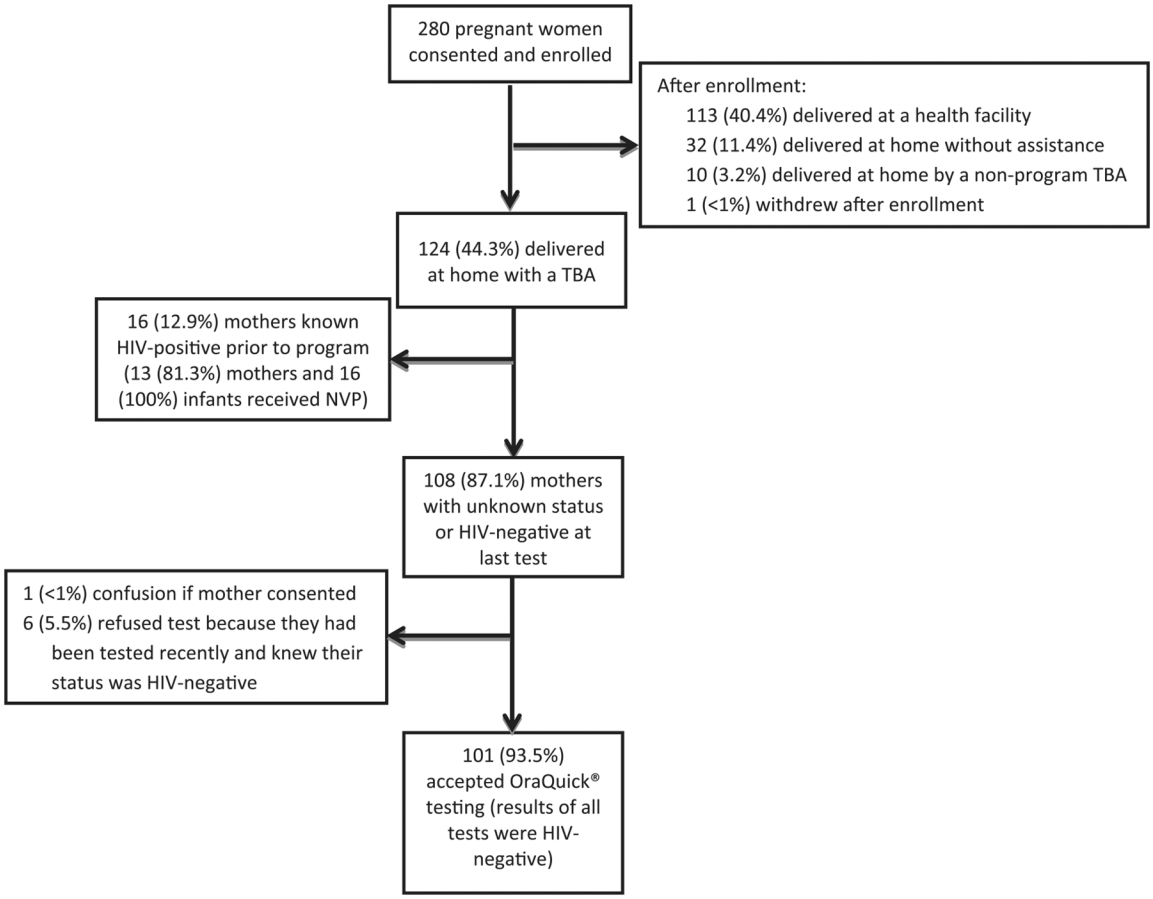

Figure 1.
Selection of Pilot Program Participants