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Effectiveness of a city-wide program to prevent mother-to-child HIV transmission in Lusaka, Zambia

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Abstract

Objective—To determine the population effectiveness of a city-wide perinatal HIV prevention program.

Design—An anonymous surveillance of newborn cord blood for HIV serology and nevirapine (NVP).

Methods—All 10 public-sector delivery centers in Lusaka, Zambia participated. All mother–infant pairs delivering during the 12-week surveillance period at the participating centers and who received antenatal care at a public-sector facility in Lusaka were included in the study. The main outcome measure was population NVP coverage, defined as the proportion of HIV-infected women and HIV-exposed infants in the population that ingested NVP.

Results—Of 8787 women in the surveillance population, 7204 (82%) had been offered antenatal HIV testing, of which 5149 (71%) had accepted, and of which 5129 (99%) had received a result. Overall, 2257 of 8787 (26%) were cord seropositive. Of the 1246 (55%) cord blood seropositive women who received an antenatal HIV test result, 1112 (89%) received a positive result; the other 134 comprise seroconverters and clerical errors. Only 751 of 1112 (68%) women who received a positive antenatal test result and a NVP tablet for ingestion at labor onset had NVP detected in the cord blood (i.e., maternal non-adherence rate was 32%). A total of 675 infants born to 751 adherent mothers (90%) received NVP before discharge. Thus, only 675 of 2257 (30%) seropositive mother–infant pairs in the surveillance population received both a maternal and infant dose of NVP.

Conclusions—Successful perinatal HIV prevention requires each mother–infant pair to negotiate a cascade of events that begins with offering HIV testing and continues through adherence to the prescribed regimen. This novel surveillance demonstrates that failures occur at each step, resulting in reduced coverage and diminished program effectiveness.

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Keywords

HIV; perinatal; mother-to-child; effectiveness; prevention; surveillance; Zambia

Introduction

Each year in Zambia's capital city of Lusaka, more than 10 000 babies are born to HIV-infected mothers. Without intervention, around 40% would become infected during gestation, delivery, or breastfeeding, but this risk can be reduced substantially with antiretroviral prophylaxis [1]. Since November 2001, we have been operating a large program for the prevention of mother-to-child HIV transmission (PMTCT) in Lusaka [2]. We use intrapartum and neonatal single-dose nevirapine (NVP) as the primary prophylactic intervention, because of its ease of administration, persistent efficacy in the face of breastfeeding [3], and no-cost availability from the manufacturer [4].

Monitoring the population effectiveness of the Lusaka PMTCT program is difficult. Virologic testing of infants is too costly and complex for widespread use in our setting. Serologic testing is offered after breastfeeding cessation, but uptake is low, and it is unlikely that surviving infants presenting for testing are representative of the population as a whole. Thus, we rely upon estimates of population coverage, the proportion of infected-exposed mother–infant pairs in the population that ingest a peripartum dose of NVP, as the primary metric for PMTCT program monitoring in Lusaka. Until this study, we, like others [5,6], have relied upon available process indicators to estimate population coverage; the number of prophylactic doses prescribed was divided by an estimate of the number of HIV-exposed infants in the population. However, this approach is potentially flawed [7]. HIV prevalence, typically derived from the population who accepts testing, may in fact differ in those who refuse. In addition, we have observed that as many as 26% of HIV-infected women who receive NVP for self-administration at labor onset may not actually ingest their NVP tablet [8].

The delivery center provides a unique opportunity to collect population coverage data. First, because of the inescapable need for delivery care (coupled with a strong tradition of institutional delivery in Lusaka), the great majority of women in the population will present for delivery. Second, following delivery, umbilical cord blood is discarded with the placenta and becomes available for sampling. Since anti-HIV IgG antibodies cross the placenta freely throughout pregnancy [9,10], and since NVP crosses the placenta within minutes of its rapid oral absorption [11,12], infant cord blood surveillance at delivery is an excellent source of information on both population HIV seroprevalence [13,14] and NVP coverage [8] for PMTCT program monitoring.

Methods

The Lusaka PMTCT program has been described in detail elsewhere [2]. However, there are a few aspects of its procedures that are particularly germane to this surveillance exercise, which we will briefly reiterate here. Women seeking public sector obstetrical services in Lusaka receive their primary antenatal care in the 24 clinics of the Lusaka District. HIV testing and NVP services are available at no cost in each facility. There is a city-wide policy to offer HIV testing to all antenatal women, and, in those who refuse, to offer testing again at a subsequent antenatal visit. Women who accept testing receive individual post-test counseling. Prophylactic NVP is given to seropositive women at the time of diagnosis, along with instructions to ingest the tablet at the time of labor onset. Whether HIV testing has been offered or accepted, the test result, and receipt of NVP are documented in the obstetrical record through the use of a code. Delivery services are offered at 10 of the Lusaka District clinics and at the University Teaching

Hospital. Upon presentation in labor, HIV-infected women are identified by the code in their antenatal record, and asked whether they need a replacement NVP dose prior to delivery. The same code serves to remind clinicians to dose infants with NVP prior to discharge from the facility.

Between 7 June and 31 August 2003, we collected anonymous cord blood specimens from the discarded placentas of live-born public sector deliveries in the city of Lusaka. Participating facilities included all 10 clinics that provide delivery services in the Lusaka District, and the labor ward of the University Hospital. Facilities were staffed continually and an attempt made to obtain specimens from every delivery. In the event of a failed attempt, the reason was noted. At delivery, approximately 5 cm^3 of cord blood were obtained in an anticoagulated collection tube affixed with a unique number. From each woman's antenatal record, we extracted the following non-identifying information onto an anonymous surveillance form: her age and gravidity, whether she had been offered HIV testing in antenatal care, whether she had accepted it, whether she had received the result, and, if seropositive, taken possession of a NVP tablet. We also recorded the dates of these events when available. A carbon copy of the form, marked with the unique specimen number, was placed in the patient record. At the time of discharge, clinical personnel recorded whether the infant was given NVP prophylaxis on the surveillance form and then removed it from the patient record. (All infant NVP in the Lusaka PMTCT program is administered by nursing staff prior to discharge from the delivery facility.) We obtained a single cord blood specimen in the instance of twin or triplet birth. Babies who were born before arrival at the delivery center and those who were stillborn were excluded from the surveillance exercise; these are relatively rare events and if coupled with other patient-level information (e.g., clinic of delivery) the anonymity of an individual could have been jeopardized.

Cord blood specimens were analyzed for HIV antibodies via a serial rapid antibody algorithm, consisting of a highly sensitive screening test (Determine HIV-1/2, Abbott Laboratories, Abbott Park, Illinois, USA) with positive results confirmed by a second rapid test (Capillus HIV-1/HIV-2, Trinity Biotech, Wicklow Co, Ireland). Discrepant results were resolved with a third 'tie breaker' rapid assay (Genie II HIV I/II BioRad Laboratories, Redmond, Washington, USA). This algorithm is expected to be > 99.9% sensitive and > 99.8% specific in field settings [15]. In a few cases, the results of the antenatal test (abstracted from the medical record) did not agree with the result of the cord blood test. Although we report the results of both, we believe that the cord blood test results are definitive and were used to categorize women as to their HIV serostatus in this study. Those specimens found to be seropositive were analyzed for NVP with a validated quantitative high-performance liquid chromatography (HPLC) assay developed at the University of Alabama at Birmingham Antiviral Pharmacology Laboratory. We have previously reported that of 179 women in whom NVP ingestion was directly observed by study personnel, in 178 (99.4%) the drug was detectable in the cord blood; this validates cord blood HPLC as an objective and sensitive measure of adherence [16].

Primary outcome measures

Population NVP coverage was defined as the proportion of HIV-exposed infants in the population in whom both the maternal and infant NVP doses were received. (Infant HIV-exposure was ascertained by cord blood antibody testing, [13] maternal NVP dosing was determined by cord blood chromatography, and infant NVP dosing was determined by direct observation.) Only receipt of both the maternal and infant doses of NVP has been proven to be effective in preventing perinatal transmission [17]. Maternal dosing alone will often fail to achieve a prolonged infant prophylactic level, especially if the ingestion to delivery interval is short [18]. Infant dosing alone has been shown to have modest, if any, prophylactic efficacy

[19]. Thus, we selected population NVP coverage as the primary indicator of PMTCT program performance in this surveillance.

Maternal adherence was defined as the proportion of women who were given a NVP tablet in antenatal care that actually ingested it (as measured in the cord blood). It differs from coverage in that the denominator is restricted to those women who knew their HIV status and took possession of a NVP tablet for ingestion at labor onset. To assess the comparability of age, gravidity, and other continuous variables between groups we used unpaired, two-tailed Student *t*-tests. Categorical variables were analyzed by chi-squared or Fisher's exact tests. All analyses were performed using SAS System release 9.0 for Windows (SAS Institute, Cary, North Carolina, USA) The study was approved by the University of Zambia Research Ethics Committee and the University of Alabama at Birmingham Institutional Review Board.

Results

Over the 12 week surveillance period, 10 384 women gave birth to live infants at public sector institutions in Lusaka. From these, we obtained 10 194 specimens (98%, Fig. 1). Mothers from whom we were unable to obtain cord blood specimens did not differ from those from whom we did obtain specimens with respect to age, gravidity, or whether they had been offered and/or accepted HIV testing in antenatal care (data not shown). Of the 10 194 women from whom we obtained specimens, 8787 (86%) had received their antenatal care at a public sector facility within Lusaka (and thus at a facility that was providing PMTCT services at the time of the surveillance.) We refer to these women and their infants as the surveillance population below.

The 8787 maternal members of the surveillance population were a median of 23 years old (range, 12–50). Their median number of pregnancies (including the present one) was 2 (range, 1–13). On cord blood testing, 2257 mothers (26%) were HIV seropositive (Fig. 2, step A); 7204 women (82%) had been offered HIV testing in antenatal care, of whom 5149 (71%) had accepted testing (Fig. 2, Steps B–C). HIV prevalence was similar among those who had been offered antenatal HIV testing (1854 of 7204, 26%) as compared with those who had not (403 of 1583, 25%; $P = 0.9$). However, HIV prevalence was significantly lower among women who accepted antenatal HIV testing (1250 of 5149, 24%) as compared with those who refused it (604 of 2055, 29%; $P < 0.0001$).

Of 5149 women who accepted HIV testing in antenatal care, 5129 (99%) received a test result (Fig. 2, Steps C–D). Of these, 1246 (24%) were seropositive on cord blood testing at delivery. Of the 1246 women who were cord blood seropositive and who received an HIV test result in antenatal care, 1112 (89%) received a positive test result. The remaining 134 comprise false-negative antenatal tests, false-positive cord blood tests, clerical errors at the level of the antenatal clinic or delivery site, and seroconversions between the first test and delivery, and are discussed in more detail below.

Of 1112 cord blood seropositive women given a positive HIV test result in antenatal care, 751 (68%) had NVP detected in the cord blood (i.e., maternal non-adherence was 32%; Fig. 2, Step F). Women who adhered to the maternal NVP dose had a shorter mean interval between HIV testing and delivery than women who did not adhere (96 ± 46 versus 104 ± 46 days; $P = 0.006$), but they did not differ by age or gravidity. Among the 751 infants born to mothers who adhered to intrapartum NVP, 675 received directly observed NVP by a health care worker (90%; Fig. 2, Step G).

Population NVP coverage

Of 2257 infants born to HIV-seropositive mothers in the surveillance population, 675 (30%) had evidence of both maternal and infant NVP dosing. Reasons for failed coverage (70%)

included (Fig. 3): mother was not offered HIV testing in antenatal care (n = 403; 18%), mother refused HIV testing (n = 604; 27%), mother did not receive her test result and/or NVP tablet at post-test counseling (n = 4; < 1%), mother's test result in antenatal care was recorded as negative (n = 134; 6%), mother did not ingest NVP at labor onset (n = 361; 16%), and infant was not dosed with NVP prior to discharge (n = 76; 3%).

Discussion

This novel, surveillance-based evaluation demonstrates that despite a seemingly robust PMTCT program in the city of Lusaka, only a minority of HIV-exposed infants are receiving appropriate prophylaxis. In order for a given infant to receive perinatal HIV prophylaxis, a specific sequence of events must transpire, one that begins with the offering of PMTCT services and HIV testing and continues through good medical record keeping and encouragement of adherence to the prescribed regimen. Our study demonstrates that failures can and do occur at each step along this cascade, resulting in reduced coverage and diminished program effectiveness.

Among the most striking findings of this surveillance exercise is the large proportion (32%) of HIV-infected women in the population who do not actually ingest the NVP tablet given to them in antenatal care. We have previously described a rate of 26% non-adherence to NVP in the more controlled circumstances of a clinical trial [8], but these new data suggest that the problem may be worse among an unselected clinic population and perhaps potentiated by longer intervals between receipt of the tablet in antenatal care and delivery. The finding of low NVP adherence, combined with our observation that women who refuse testing are more likely to be HIV infected than those who accept testing, seems to indicate that reliance upon simple process indicators (such as numbers of women tested or numbers of NVP doses given out) may substantially overestimate PMTCT program performance.

Our results also indicate that seroconversions in late pregnancy and provision of incorrect HIV test results in antenatal care may represent previously unrecognized and important failure points in the Lusaka PMTCT program. A negative antenatal test result that is positive upon cord blood testing at delivery can have a number of explanations. Some cases can be attributed to the PMTCT program and its patients. These include: (1) seroconversion between the first test and delivery; (2) clerical errors at the level of the antenatal clinic; and (3) false-positive antenatal tests. The remaining cases can be attributed to the surveillance exercise itself. These include: (4) false negative cord blood tests; and (5) specimen mix-ups at delivery. Errors attributable to the surveillance exercise can be quantified [20]. We have recently reviewed the performance of rapid HIV tests used in combination algorithms [15]. Even under suboptimal field conditions, the negative predictive value of the Determine screening test typically exceeds 0.998 (i.e. the false-positive rate is less than two per 1000). Likewise, if specimen mix-ups were a major contributor (meaning the HIV testing history of a woman who tested negative in antenatal care was erroneously attached to the cord blood of a woman who tested positive in antenatal care), we would expect a large proportion of the specimens to be NVP positive as well. In fact only 13 of the 134 'seroconverters' (9.7%) were also NVP positive. Thus, we can reasonably conclude that around 10% of the apparent seroconversions can be attributed to errors in the surveillance exercise, and that the remaining majority fall into a category of *de facto* seroconversions. Whether false-negatives in ANC derive from laboratory errors, clerical errors at the level of the antenatal clinic, or from actual recent infection, the result is the same – failed coverage.

Much attention has been paid recently to developing and advocating for more efficacious PMTCT regimens [21]. Yet drug efficacy, the ability of a drug regimen to reduce the risk of transmission in a given mother–infant pair, applies only to the last step in the PMTCT attrition

cascade, namely those mother–infant pairs who are 'covered'. The population coverage model we present here demonstrates the critical importance of early steps in the cascade to the overall effectiveness of the PMTCT program. For example, Figure 2 demonstrates an 18% failure rate at the first step of offering HIV testing and a 32% failure rate (nearly double) at the later step of maternal non-adherence. Yet, in absolute terms, attrition at the first step is more important: 403 HIV-infected mothers are lost due to failure to offer testing, compared to only 361 due to non-adherence. Thus, policy makers who wish to maximally reduce the incidence of pediatric HIV in the population should focus first on ensuring that services are offered widely and on increasing antenatal HIV testing rates. Increasing the efficacy of the PMTCT regimen offered will only be expected to have a large population effect in the instance where other aspects of the program are functioning well (i.e., where coverage is high). Otherwise, resources may be better spent in maximizing coverage of simple and moderately effective interventions such as NVP, graduating later to more efficacious drug regimens.

There are limitations to this study. First, the processes we have measured in this exercise, and the ultimate outcome of population coverage, are likely to be most relevant to other urban and periurban settings in sub-Saharan Africa, where PMTCT services are delivered in a similar way. Rural and sparsely populated areas that have predominately home and/or unattended deliveries face their own unique set of challenges to PMTCT program implementation. Second, although the evidence is compelling that peripartum NVP reduces MTCT [17], and that this efficacy is evident months later even in breastfeeding populations [3], population coverage is in fact a surrogate marker for what ultimately matters: HIV-free child survival. Although we did not measure this, our previous work suggests that NVP in cord blood correlates well with lower HIV infection rates in the exposed newborn [8,16].

In response to the findings of this research, we have begun to make program reforms at each step in the 'attrition cascade', including clinic-level incentives to ensure all women are offered services, community efforts to encourage HIV testing and NVP adherence, and quality assurance programs for the small clinical labs that are performing the HIV rapid testing. It is our belief that problems in our program made clear in this analysis should not be interpreted as limitations in our research effort; rather, they are its focus.

These data indicate that population coverage is an important indicator of PMTCT program performance, and that all efforts should be made to maximize it. A key unanswered question in resource limited settings is whether the introduction of more complicated and potent PMTCT regimens may adversely affect population coverage and paradoxically negate their superior efficacy with reduced coverage. Alternatively, antiretroviral regimens that are perceived as highly efficacious by patients and staff may be better received than simpler ones, resulting in both higher coverage and increased efficacy. We are currently in the process of piloting more efficacious antiretroviral combinations in Lusaka and assessing the extent to which their increased complexity affects coverage rates and viral resistance patterns. Understanding the relationship between regimen complexity and population coverage in high prevalence, resource-poor settings is a particularly urgent operations research question.

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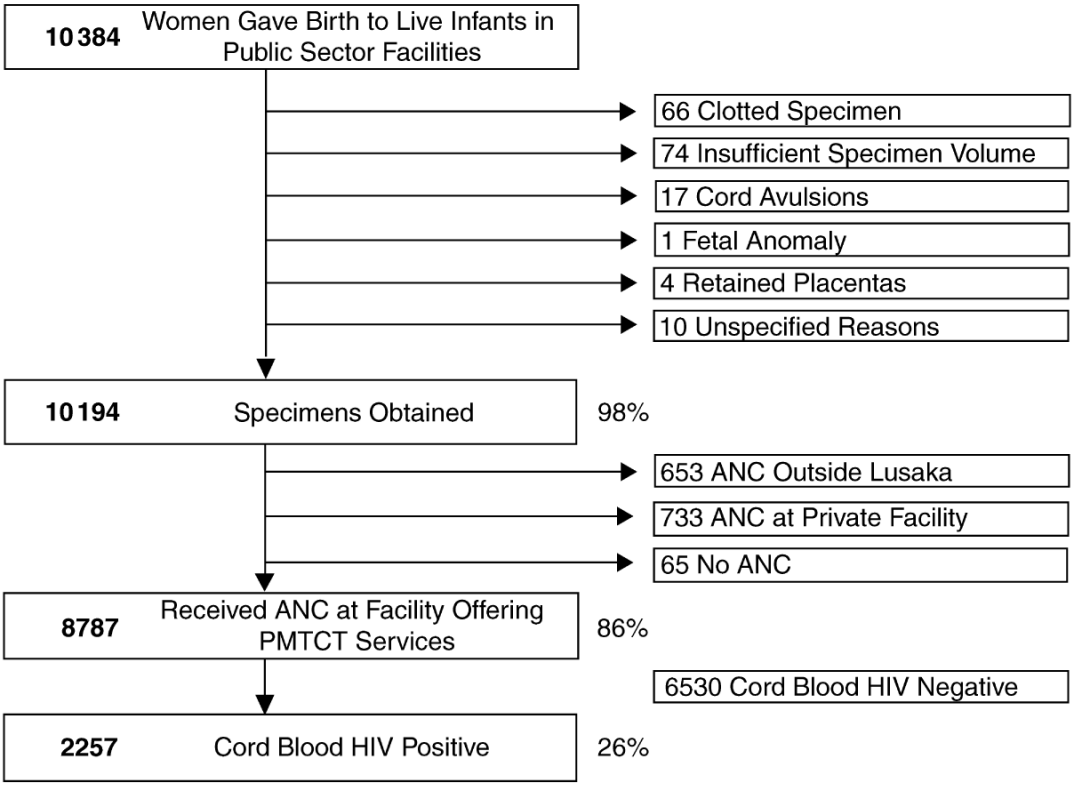

Fig. 1. Surveillance study profile

We obtained cord blood specimens from 98% of public sector deliveries in Lusaka during the 3-month surveillance period. Of these, 86% attended antenatal care within Lusaka and at a public-sector facility (and thus where prevention of mother-to-child HIV transmission services were being offered.) These 8787 women and their infants represent the 'surveillance population' to which we refer in the text. 26% of mothers in the surveillance population were HIV-infected as determined by cord blood serologic testing.

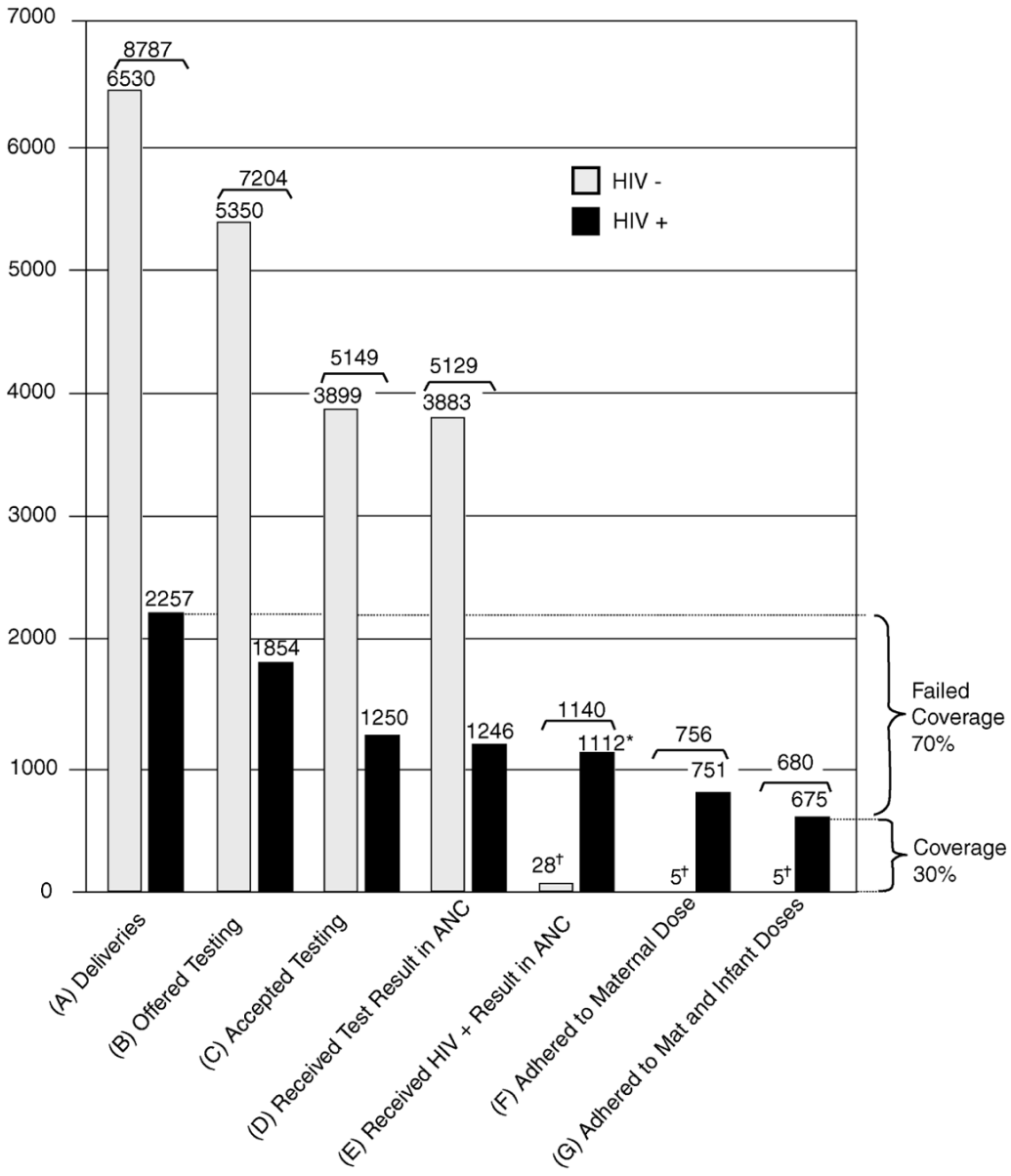

Fig. 2. Attrition cascade among women in the surveillance population

This Figure demonstrates the sequence of events that members of the surveillance population negotiated in order to achieve prevention of mother-to-child HIV transmission service coverage. Step A (leftmost bars) represents all the women in the surveillance population, stratified by HIV serostatus. Coverage, defined as the proportion of infected-exposed mother–infant pairs that received both the maternal and infant nevirapine (NVP) doses was 675/2257, or 30%. *Of 1246 cord blood seropositive women who received an HIV test result in antenatal care, 1112 received a positive test result. The remaining 134 comprise false-negative antenatal tests, false-positive cord blood tests, clerical errors, and seroconversions between the first test and delivery. †Twenty-eight women who were HIV seronegative on cord blood testing were given an HIV-positive test result and NVP tablet in antenatal care; five of these adhered to the maternal and infant dose. ANC, antenatal clinic.

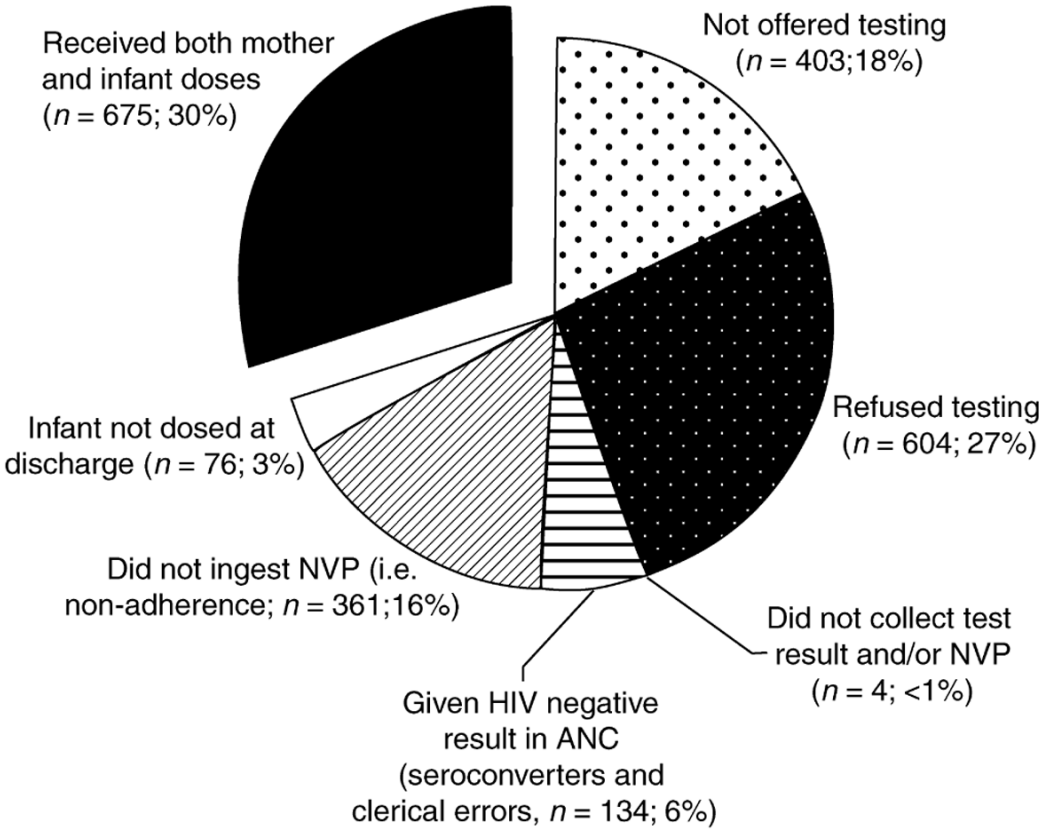

Fig. 3. Population nevirapine (NVP) coverage and reasons for failed coverage among 2257 cord blood seropositive mothers and infant in the surveillance population

ANC, antenatal clinic.