

Screening in antenatal care in Nigeria using the integrated panel: Data sources

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May 14, 2026

1 OBJECTIVE

In 2025 Abbott received pre-qualification from the World Health Organization (WHO) for its Determine™ Antenatal Care Panel, which combines rapid diagnostic tests for HIV, syphilis and hepatitis B into an integrated panel (WHO, 2025). The authors have been asked to project the cost-effectiveness of this integrated test in Nigeria. One of the kit's innovative components is a fourth generation HIV rapid test that can detect the P24 antigen, a marker of acute HIV infection. Another innovation is incorporating testing for hepatitis B virus (HBV) into the same panel as HIV and syphilis. To explain the health and economic implications of these new capabilities, this document presents the results of the authors' review of the literature and internal data.

2 HIV SCREENING

2.1 HIV prevalence

2.1.1 Nigerian studies on prevalence and detection of acute-phase HIV infection

Abbott's fourth generation HIV test received prequalification from the WHO in 2016 (WHO, 2016). According to Abbott, the specificity of this HIV test is 99.7%. In a study by Ndeh et al (2020) conducted in Nigeria the Abbott Determine test kit was used to detect HIV in 400 women attending antenatal care. All the women were first tested for HIV 1/2 antibodies using the Determine™ HIV-1/2 test kit and then retested for p24 antigen using the Determine™ HIV-1/2 p24 Ag/Ab Combo test kit. Out of the 400 women, 3.75% (15 out of 400) tested positive only for the p24 antigen test (i.e., negative on the antibody test). This is the share of women who would benefit from the p24 test. In addition, 3.0% (12 out of 400) women tested positive for the antibody test. Out of the 12 who tested positive for the antibody test 2 also tested positive for the p24 antigen test. This is consistent with another study by Adamu et al (2023) in Nigeria, which reported a 3.5% (9 out of 261) prevalence of p24 HIV infection amongst blood donors. This result shows the conventional algorithm missed the 15 women who tested negative for Determine antibody test but were positive for p24. Though this study did not report rates of mother-to-child transmission (MTCT), another study (Ugochukwu et al., 2020) in Nigeria, reported that out of 3784 HIV positive ANC women in a 14 year period, there was a 52.10% rate of MTCT where neither the mother nor the child were covered by anti-retroviral therapy (ART), 24.10% where the infant only was covered by ART, 9.3% where the mother only was covered by ART and 1.4% MTCT where both the mother and the infant were covered. We can estimate therefore that amongst the 15 p24 positive women who were undetected by the antibody test 52.1% (8) of them would transmit it to the infant under current conditions.

In seeking to use this study, we should examine its strengths and limitations. The strengths are the only study of which we are aware reporting p24 in ANC. Its results appear plausible. However, it has two limitations. First, the study was published in the *Indo American Journal of Pharmaceutical Research*. This journal is not indexed in Pub Med and the paper has had minimal citations since its publication 6 years ago. Second, the article is not clearly organized, so the results were slightly ambiguous. The study uses three different types of test kits pathways for the antibody test, Determine™ HIV-1/2, Stat-Pak HIV-1/2 and HIV UniGold rapid test kit on the same sample of 400 women in ANC. In the reporting of results, the study does not clearly segregate the overlaps of the results, that is. whether the exact same positive cases were uniform across the three different pathways. In view of these limitations, we also examined other sub-Saharan African studies.

2.1.2 Kenyan study

In comparative Kenyan research study by Ochwoto et al (2024), there were 5 of 577 women tested in antenatal care in Kenya with the fourth generation HIV test who tested positive for acute HIV infection. In follow up exchanges, Dr Ochwoto explained that of these 5 women, the combination test showed that 2 also had HIV antibodies (chronic HIV infection) at the time of testing. While the antibody test used Abbott's HIV Combo RDT 4th generation HIV test, a comparative study concluded that it "showed high sensitivity and specificity in detecting HIV antibodies with performance similar to 3rd-generation RDTs" (Manjate et al., 2024). Therefore, those 2 would have been detected from antenatal care (ANC) screening using conventional antibody tests. There were thus 3 (i.e., 5 – 2) of 577 women (i.e., 0.52%) who were positive only for acute HIV when tested at the same time with a conventional antibody test.

The 3 Kenyan women who tested positive in ANC only for antigen but negative for antibody were subsequently tested with different tests at different times. The results confirmed that all of the positive results were correct. That is, all 3 did have an acute HIV infection. One of the women sero-converted by the time of her next test, so she had HIV antibodies on that next test a week later. The other women did not sero-convert before the end of the follow up period of the study two weeks later. This time varied according to the point in the pregnancy of the acute test. Having started antenatal later in their pregnancy, these two women had received their acute test late in their pregnancy. Assuming the women had been infected shortly before their acute HIV test, it could take several weeks for them to sero-convert, so the negative antibody results were quite plausible. However, the two women who had not sero converted were positive for HIV when tested with a PCR (laboratory-based) test. These positive results also showed that Kenya's conventional testing algorithm at that time, based on antibody tests, would not have confirmed these 2 infections. It also shows that a potential strategy of waiting two weeks following a positive p24 and negative antibody combination would have missed 67% (2 of 3) women who were infected with HIV, virtually negating the value of the p24 test.

Some of these women in the study, by Ochwoto et al. (2024), commented that they were sexually active during pregnancy because they perceived little risk. Their major concern with unprotected sex had been pregnancy. However, since they were already pregnant at the

time of testing, they no longer had that concern. As pregnancy suppresses a woman's immune system, a high rate of acute infections is plausible.

2.1.3 Additional study of acute HIV testing

We are aware of only one other study that have tested for acute HIV infection in ANC following negative antibody tests. In a South African study, nucleic acid amplification testing (NAAT) (a more sensitive but more costly assay than p24) detected acute HIV infections in 49/8,208 (0.6% 95% CI: 0.5–0.8) of study participants (Mayaphi et al 2019). As that assay is not part of the integrated test being modeled, we did not use it.

2.1.4 Comparative prevalence of HIV in a clinical cohort. A study from Mozambique evaluating Abbott's rapid p24 antigen detection highlighted the short time for detecting acute HIV infection (Manjate et al., 2024). That study analyzed samples from 920 women enrolled at clinics for cervical cancer screening, family planning, and sexual health clinics. Most women had urogenital complaints and pregnant women were excluded. Although 17.8% (164/920) of samples were positive for HIV based on third generation antibody tests, only 1 of 920 women (0.11%) showed evidence of acute infection. The authors commented that variations among countries in the HIV-1-C subtype may further affect detection of p24 antigen.

2.1.5 Combined results from p24 tests

To provide the best estimate of the probable results of incorporating the p24 test in ANC in Nigeria, we felt the most accurate prediction was to calculate a weighted average of studies testing for p24 (Ochwoto et al and Ndheh et al). The weighting used the sample sizes of the respective studies, giving a pooled prevalence of 1.84% as our best estimate for Nigeria.

Under this pooled rate, out of 128,940 women who would test positive for p24, 117,854 (91.0%) would be true positives while 11,556 (9.0%) would be false positives. In other words, the predicted value positive is. 91.0%. If a woman tests positive for p24, the chances are 91.0% that she is actually infected with acute HIV.

2.2 Testing guidelines for HIV status

International and current Nigerian norms require that a positive HIV test be confirmed by another test with an independent sample (Pebody 2022). For antibody tests, a routine screening test (such as Abbott's) is usually followed by a Unigold test as a tie breaker. Similarly, Nigeria's current algorithm for antibody testing is that a woman must test positive with two tests to be considered positive. Nigeria's current guidelines for acute HIV testing requires that positive p24 cases be confirmed with NAT testing (PCR) or 4th generation enzyme-linked immunosorbent assay (ELISA) method.

2.3 Confirmation of acute-phase infections

2.3.1 Polymerase chain reaction (PCR) or enzyme-linked immunosorbent assay ELISA test

The positive p24 patient is sent for a confirmatory test at a private facility where they have to pay for it. Alternatively, the confirmatory sample is sent to a general or teaching hospital located in major city. The ELISA and NAT test takes an average 5.2 days for the results to be out in the US (Wesolowski et al., 2015). The authors estimate the average time will be longer for a LIC like Nigeria, due to the downtime of the testing and the travel time with other sub-Saharan countries reporting up to three weeks turn around (Labcare Malawi 2026). When the woman test positive for PCR, she would be initiated on ART treatment.

PCR tests and platforms used in Nigeria are the Roche test and the Roche TaqMan test. Two publications have evaluated these tests in sub-Saharan Africa. They reported sensitivity and specificity both of 100% in Zimbabwe (Ziejenah et al 1999) and Central African Republic (Mossoro-Kpinde, 2016). Other options are the Cepheid GeneXpert® - Rapid PCR Diagnostic Testing and Roche TaqMan test. In Botswana, Cepheid GeneXpert had a sensitivity and specificity of 93.3% and 100% respectively (Ibrahim et al 2017). The high accuracy of PCR tests should eliminate virtually all false positives, making it an effective confirmatory test.

Nevertheless, according to GHSC-PSM (2022) only about 60 public health laboratories can conduct PCR tests, and just 17 are actively supported to provide free viral load testing against a population of 1.9 million people living with HIV in Nigeria and in this case against a backdrop of 4.2 million women screened for p24 in ANC. This shows that PCR testing would not be readily available for the confirmatory tests.

Studies indicate that ELISA testing is virtually not available in the Nigerian public health system and therefore would not be considered as a practical confirmatory test for p24 in Nigeria for ANC women.

2.3.2 Antibody test after two weeks

The positive patient is asked to return in two weeks for a confirmatory antibody test following the current antibody testing guidelines with the assumption that the true positive mothers would have seroconverted by then. If the woman tests positive to antibody then she would initiated on ART therapy, if she tests Negative and p24 would be repeated and if its still positive then she would be asked to return back in two weeks for another antibody test until she either tests positive for antibody or test negative for both antibody and antigen. In Kenyan study by Ochwoto et al, as noted above, 2 of the 3 women never sero-converted by the end of the study period, 2 weeks later. Thus, this strategy does not guarantee confirmation and may lead to substantial delay.

2.3.3 Challenges with confirmatory testing

These testing protocols would create challenges and downgrade the benefit of p24 testing as follows. First, both confirmatory tests are not readily available in the Nigerian health system with availability limited to private laboratories and general and teaching hospitals in

major cities. This would translate to a waiting time of up to between 5 to 21 days thereby increasing the chance of MTCT since the acute phase has a 26-times higher transmission likelihood than the chronic phase of HIV infection (Cheret et al, 2025). Second, a woman in ANC in Nigeria would generally need to pay out of pocket for such confirmatory tests. Discussions with public health experts suggest most women would be unwilling or unable to pay out of pocket. Third, the two-week confirmatory with antibody test does not guarantee confirmation and may lead to further delay. And lastly, delaying the start of treatment would violate Nigeria's policy of "test and treat."

The authors, therefore, think that the current Nigerian testing guidelines for p24 would therefore undermine the benefit of p24 testing if treatment is not initiated promptly due to the availability, waiting time and the cost constraint of confirmatory testing. Additionally, delaying treatment would be particularly dangerous for women who do not attend pre-natal care regularly. Such women would experience a substantial delay and might miss the opportunity for ANC testing altogether.

2.4 PEP-based strategy for positive acute-phase results

To preserve the value from early detection through p24 testing, the authors propose initiating treatment immediately after a p24 positive result in line with the Nigerian post-exposure prophylaxis (PEP) guidelines.

The authors have proposed that a woman with a positive acute-phase result but a negative antibody test be given 28 days of anti-retroviral therapy (ART) using the current treatment regimen and counseled about avoiding future exposure to her and partners. In accordance with PEP, she should be tested with a standard antibody test at the end of the 28-day period. If that test is negative, PEP can be stopped. If the test is positive, ART should be continued. She should periodically be retested, with ART continued as long as she tests positive, possibly for her lifetime.

This proposal is consistent with WHO recommendations that individuals exposed to HIV infection be initiated on PEP, ideally within 24 hours and not later than 72 hours (WHO, 2024, pp 5, Allan-Blitz et al, 2024). Unprotected sex with an HIV-positive partner is one source of such exposure. The PEP guidelines of both Nigeria and the WHO indicate that daily dosing of the three antiretroviral drugs should continue for 28 days after exposure has ended and until the person tests negative (Nigeria guidelines 2020, pp99-101; WHO, 2024, pp 6-8).

While there are potential grounds for concern for drug resistance during PEP, several factors minimize that risk. First, the use of three drugs, as in other treatments, is highly effective in controlling HIV infection. Second, because the P24 rapid assay is 99.7% specific, the chances are 99.7% that the person actually has an HIV infection. Third, studies show that prompt treatment restricts HIV reservoir expansion at its earliest stage, which may delay viral rebound and improve the feasibility of future remission strategies (Shelton et al., 2020, p. 7,8). The substantial protective benefits to patients far outweighs the risks hence its continued use (Powell et al., 2019, p. 1). In persons exposed to HIV, Grant and Liegler (2015, p. 1203) found that 25 HIV infections were prevented for every single drug resistance and

that preventing HIV infections also prevented drug resistance. On this basis, we can argue then that covering the positive infections with HIV treatment would not only be beneficial, but have a lower chance of resistance, as it will be a far more focused treatment than PEP. Additionally, Early initiation of antiretroviral therapy during acute HIV infection is also critical for limiting the establishment of HIV reservoirs in anatomical sanctuary sites, particularly the central nervous system and lymphoid tissues (Whitney et al., 2019; Arts & Hazuda, 2024). Patients who start treatment during acute infection exhibit significantly smaller reservoir sizes compared to those who delay treatment, as HIV establishes these sanctuaries within the first few days of infection behind barriers like the blood-brain barrier where drug penetration and immune surveillance are limited (Namazi et al., 2021). Therefore, the benefit of starting the treatment in an antigen positive patient far outweighs the risks.

2.5 Repeat testing for HIV during pregnancy

With the 1.7% prevalence of HIV infection noted above, Nigeria, average pregnant women could be considered a low-risk population. In such settings, the WHO's guidelines indicated only that repeat testing "could be considered" (WHO, 2024). Nigeria's 2020 national guidelines on HIV testing services advised retesting all HIV-negative pregnant women in the 3rd trimester, postpartum or during labor because of the risk of acquiring HIV infection during pregnancy (Nigeria, 2020).

A study by Ejikunle S.D. et al (2019) reported a seroconversion of 3.7% in ANC mothers who had earlier tested negative and treatment prompt initiation of therapy in both the mother and child eliminated 100% MTCT. The study also highlighted the risk factors ranging from multiple sex partners to sex for money and blood transfusion. Since retesting uses the conventional algorithm which is readily available and does not add considerable cost, the benefit from retesting would be substantial and would be encouraged as complimentary to the p24 testing.

2.6 Cost of screening

We estimated that the cost of testing per infection screened is \$1.07 for p24 antigen/antibody screening using the triple combo test kit (HIV/syphilis/hepatitis B), based on materials at \$0.87 per infection (derived from a \$2.60 product cost split across three infections; Abbott, 2025) and laboratory technician labor at an adjusted wage of \$1.48/hour. This compares with \$0.78 per infection for the dual test (HIV/syphilis) and \$1.51 per infection for conventional single testing, making the combo approach about \$0.44 cheaper per infection than running three single tests, driven largely by a 27% reduction in laboratory technician time.

For confirmatory testing of reactive screens, we estimated a cost of \$2.21 for a Uni-Gold HIV antibody confirmatory test, inclusive of materials and labor (Folorunsho-Francis, 2020), and \$29.47 for a PCR test to confirm acute HIV infection (Dr. Kingsely, 2025). All costs are expressed in 2025 US dollars using a conversion rate of ₦1,609 per USD.

2.7. Cost of treatment

The main treatment for HIV infection for adults is Tenofovir + Lamivudine (or Emtricitabine) + Dolutegravir (TLD) (Nigerian HIV guidelines, 2024). We estimated that the cost of this antiretroviral regimen plus associated clinic visits is \$107 per year, based on the Global Fund's negotiated price of \$45 per year for TLD (Global Fund, 2023) plus \$62 per year for diagnostic tests, follow-up, and clinic visits. For shorter treatment durations, the TLD drug cost prorates to \$33.75 for the 9 months of pregnancy and \$3.45 for a 28-day course. The discounted remaining life expectancy from the average age of pregnancy is 20.77 years.

2.8 Chronic HIV prevalence

2.8.1 Chronic HIV prevalence (General Population)

Because of the difference in detection procedures, it is useful to distinguish chronic versus acute HIV infections. Chronic infections are ones that have been present in the body for months so that the person has had time to form antibodies. Acute infections are more recent ones, detectable only through antigens or viral particles. In Nigeria, the NAHS (2018) is considered the best estimate of the overall prevalence of chronic HIV among women of reproductive age (15-49 years). It reports a prevalence of 1.7% in women in that age bracket. We assume that rate is applicable to chronic infection among women in antenatal care (ANC), who fall in that age range.

The latest meta-analysis (Ozim et al, 2023) showed a much higher rate for pregnant women (7.22%). However, that meta-analysis synthesized older studies from 2008 through 2016. The older vintage of these studies limits the current usefulness of that meta-analysis, as the prevalence had been falling over those years. Given the robustness of the NAHS study and our inability to locate a representative seroprevalence study of women in ANC in Nigeria, we have used its 1.7% prevalence among women of reproductive age in NAHS in Nigeria as our estimate of the prevalence of chronic HIV infection.

2.8.2 Prevalence of HIV infection in the ANC cohort.

The Ndeh et al (2020) study from Nigeria reported a chronic HIV prevalence of 3.0% (12/400) with the overall prevalence being 6.75% (27/400). The contemporaneous studies from Kenya suggest that the prevalence among women in ANC may be higher than women of reproductive age in the general population. The overall prevalence among women 15-49 in Kenya was 6.4% in 2022 (Perplexity, 2025). By contrast, the prevalence in a multi-site cohort study of women in ANC by Ochwoto et al (2024) of 8.15%, i.e., 47/577, about a quarter higher. While the difference is not statistically significant and could also be due to site selection, an undeniable consideration is the fact that all the women in antenatal care were pregnant, so they were necessarily engaging in unprotected sex. That fact probably does not apply to their demographic cohort. To incorporate the difference between the ANC and demographic cohorts, our model treats acute HIV infection as additional infections on top of chronic HIV infections for modeling purposes.

3 HBV SCREENING

3.1 HBV prevalence

The estimated prevalence of HBV in women in ANC in Nigeria is 6.49% (Olakunde et al., 2021).

3.2 Higher HBV testing rate

The integration of HBV into the same test as HIV is expected to substantially increase coverage and lower out-of-pocket costs to pregnant women in ANC in Nigeria. As HIV screening in ANC is part of Nigeria's public health program, services closely integrated with HIV should become part of the national program. Thus, women who receive the integrated panel should obtain HBV testing at no additional cost to them. In addition to the financial advantages, integration provides programmatic and logistic advantages. The programmatic value means that women will generally expect to receive an HBV test whenever they are tested for HIV. As a senior official in Nigeria's HBV testing program, Dr. Kingsley estimates that the current and future rates of HBV testing in ANC are 13% and 67%, respectively.

3.3 Vaccination against treatment of HBV

The birth dose vaccine of HBV is recommended for all infants, regardless of whether the mother is tested and the outcome of any test. To give maximal protection, the dose should be administered within 24 hours of birth – i.e. on day 0 or day 1 of the infant's life. A meta-analysis of rates and timing of birth doses for sub-Saharan Africa listed 8 studies from Nigeria (Solomon-Rakiep et al, 2024). Their rate of vaccination in days 0-1 averaged 26%.

3.4 Treatment for HBV

We assumed treatment in pregnancy consisted of an immunoglobulin shot for the baby and tenofovir for the woman. For a woman infected with HBV the options (and associated risks to the infant of chronic HBV to the baby are: baby vaccinated receives immunoglobulin and woman treated with tenofovir (1.5%), vaccination only (20%), no vaccination but immunoglobulin and tenofovir treatment (7.2%), and no vaccination and no treatment(80%) (Mast et al. 2005; Li 2005).

While Nigeria's public program does not pay for treatment of women and infants related to HBV infection, testing for HBV alongside testing for HIV increases awareness and the salience of treatment of HBV. Dr Kingsley estimates that the current rate of treatment against HVB is 7.5% while the future rate is 30%. If treatment were publicly financed, the treatment rate would be higher.

4 SYPHILIS SCREENING AND TREATMENT

Available evidence from blood-test-based cross-sectional studies conducted in Nigerian antenatal care (ANC) settings between 2020 and the present documents a syphilis seroprevalence ranging from 0.0% to 3.9%, with a pooled prevalence of 2.64% across 2,574 ANC attendees. This variation highlights the heterogeneity associated with geographically dispersed, single facility estimates (Abraham, 2025). The reported prevalence has

substantial public health implications. The World Health Organization estimates up to 2,000 congenital syphilis cases per 100,000 live births in Nigeria, indicating that the current maternal seroprevalence, if not addressed through systematic antenatal screening, may result in preventable neonatal morbidity and mortality (World Health Organization, 2024).

Syphilis is not currently part of Nigeria's public program, so it is not generally publicly financed. If it were publicly financed, the authors believe the treatment rate would be higher.

5 CONCLUSIONS

This document provides the authors best estimate of the parameters and outcomes of alternative strategies relevant to the cost-effectiveness of the integrated test in ANC in Nigeria. An operational research study across several sites in Nigeria providing ANC could generate real-world evidence of the relevant parameters and feasibility of the policies under discussion.

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