Protocol

Knowledge, Attitudes, and Practices of Pregnant Women and Health Care Workers Regarding Antenatal Testing for HIV, Hepatitis B Virus, and Syphilis in Vietnam: Protocol for a Multicenter Cross-Sectional Study

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Abstract

Background: Mother-to-child transmission (MTCT) of HIV, hepatitis B virus, and syphilis remains a preventable cause of fetal loss, neonatal morbidity, and long-term disability. In Vietnam (Viet Nam), although antenatal care coverage is high, gaps persist in the timing, uptake, and completion of screening and follow-up services for these infections.

Objective: This study has 2 parallel population-specific objectives. Among women who recently gave birth, we will estimate completion of antenatal testing for HIV, hepatitis B virus, and syphilis and its associated factors with study-defined optimal testing (completion of all 3 tests during the first trimester). Among health care workers (HCWs), we will assess knowledge, attitudes, and reported practices and identify professional factors associated with good practice regarding antenatal screening and MTCT prevention.

Methods: This multicenter, hospital-based cross-sectional study was conducted from June to September 2026 in 4 provincial hospitals in northern Vietnam. Women completed an interviewer-administered questionnaire after delivery, once clinically stable and before discharge. Antenatal testing was verified from maternal records, laboratory reports, or electronic records whenever available. HCWs completed a separate anonymous self-administered questionnaire during the same study period. The 2 participant groups were not matched. The primary outcome for women is completion of all 3 antenatal tests during the first trimester (study-defined optimal testing). The primary outcome for HCWs is good practice regarding the prevention of MTCT. The minimum target sample sizes were 601 women and 601 HCWs. Data will be analyzed separately for each group. Descriptive analyses will summarize knowledge, attitudes, and practices indicators and service uptake. Modified Poisson regression with robust variance will be used to identify factors independently associated with the primary outcomes.

Results: The protocol received ethics approval on February 9, 2026. The study is funded by Thai Binh University of Medicine and Pharmacy, Hung Yen, Vietnam. Recruitment was conducted from June to September 2026. As of manuscript submission, 601 patients and 601 health care workers had been recruited. Data cleaning is planned for October 2026, followed by statistical analysis from November to December 2026. Dissemination of the first study results is planned for the first quarter of 2027.

Conclusions: The study will provide hospital-based evidence on completion of antenatal triple screening and provider practices. By prespecifying distinct outcomes for women and HCWs, the study is designed to identify actionable gaps while avoiding causal interpretation of cross-sectional associations.

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Introduction

Background

Mother-to-child transmission (MTCT) of HIV, hepatitis B virus (HBV), and syphilis remains a preventable cause of fetal loss, neonatal morbidity, and long-term disability. Without timely diagnosis and effective interventions during pregnancy, intrapartum, and early postnatal care, these infections can be transmitted vertically and lead to severe outcomes [1,2]. For HIV, MTCT can occur during pregnancy, delivery, and breastfeeding, and prevention relies on early maternal diagnosis and prompt antiretroviral therapy (ART) initiation and maintenance. Evidence from Vietnam (Viet Nam) shows that when women are diagnosed and treated appropriately, MTCT can be substantially reduced, but missed opportunities still occur when diagnosis is delayed or linkage to ART is incomplete [3]. For HBV, MTCT is a major driver of chronic infection in endemic settings, particularly among infants born to mothers with high viral load. Prevention requires antenatal identification of infected mothers plus timely birth-dose vaccination (and hepatitis B immunoglobulin where indicated/available) and, for high-risk pregnancies, maternal antiviral prophylaxis in late pregnancy [4-6]. For syphilis, untreated infection in pregnancy is associated with stillbirth, neonatal death, prematurity, and congenital syphilis, and the disease burden remains substantial globally despite inexpensive tests and curative treatment [7,8].

Vietnam is an HBV-endemic country, and studies in pregnant women consistently report a meaningful prevalence of hepatitis B surface antigen (HBsAg), implying a persistent risk of perinatal transmission if prevention is incomplete [4,9]. In a Vietnamese birth cohort, congenital HBV infection was uncommon when prevention steps were implemented. However, residual risk remained and was linked to gaps in immunoprophylaxis and maternal risk factors [4]. In contrast, HIV and syphilis prevalence among pregnant women is often reported as lower than HBV prevalence. Nevertheless, even low prevalence can translate into avoidable congenital infections if screening coverage and treatment linkage are suboptimal, especially when the absolute number of pregnancies is large. In a pilot implementation in Thai Nguyen Province, pregnant women had relatively high HBV prevalence but low HIV and syphilis prevalence. These findings support integrated screening and suggest that program impact depends more on coverage and timeliness than on prevalence alone [10].

Antenatal care (ANC) coverage in Vietnam is high, but the content and quality of ANC can be heterogeneous across settings and provider types [11,12]. Peer-reviewed work describing ANC practice in Vietnam indicates that testing for infections such as HIV, syphilis, and hepatitis is recommended as part of routine ANC [13]. Screening should occur early enough to enable effective preventive actions [13]. In practical terms, triple-elimination frameworks emphasize testing at the first ANC contact, rapid return of results, and confirmatory testing when required. Effective interventions should be initiated promptly, including ART for HIV, penicillin treatment for syphilis, and HBV prevention package, including newborn immunization and targeted maternal antiviral prophylaxis. When testing occurs late in pregnancy or is deferred to the intrapartum period, prevention becomes less effective. This is most obvious for syphilis, where treatment during pregnancy is the key to preventing fetal infection, and detection at delivery is often too late to prevent in-utero harms [7].

Despite guidance and program goals, there is often a mismatch between recommendations and real-world uptake. In Vietnam, access pathways are complex. Many pregnant women seek ANC in multiple facilities, including private providers, and out-of-pocket payments are common for parts of routine maternity care. These features can reduce test uptake, delay testing, or fragment follow-up after a positive screening result [14,15]. Evidence from Vietnam also suggests socioeconomic and structural inequities in the uptake of HIV testing during pregnancy, which can serve as a tracer for broader barriers affecting integrated testing [16,17]. In addition, health financing arrangements matter. Even when test kits are available in some public programs, the perceived and actual costs of testing, confirmatory diagnostics, transport, repeat visits, and treatment can discourage timely screening and completion of the care cascade. Implementation work in Vietnam has explicitly highlighted the importance of integrating services and addressing financing barriers to improve the performance of the elimination of MTCT program [18].

These gaps can produce a pattern in which screening is performed late, sometimes during labor or at admission for delivery, or results are returned after the window for optimal prevention has passed. Late detection reduces the benefit of ART initiation for HIV before delivery, prevents adequate maternal penicillin treatment courses for syphilis, and limits the opportunity to triage HBV-infected mothers for high-risk management [4]. The consequence is avoidable MTCT, missed prevention opportunities, and preventable neonatal morbidity, even in a context of high ANC contact.

For these reasons, understanding knowledge, attitudes, and practices (KAP) among both pregnant women and health care workers (HCWs) is essential. KAP influences whether women accept early testing, return for results, disclose risk, adhere to referral, and complete treatment. It also shapes whether providers consistently recommend testing, counsel effectively, manage positive results according to guidance, and navigate cost and logistical barriers. Accordingly, the questionnaire was designed to assess not only knowledge of HIV, HBV, syphilis, MTCT, and available preventive measures, but also attitudes toward antenatal screening. It also examines perceived benefits and barriers to testing,

previous screening experience, access to ANC services, cost and affordability, and actual screening-related practices. For HCWs, the questionnaire additionally considers professional characteristics, training and experience, familiarity with national recommendations, availability of tests and treatment, counseling practices, referral pathways, perceived patient-level barriers, workload, and health-facility constraints. These factors were selected because screening behavior is likely to reflect interactions between individual knowledge and perceptions, previous experience, service accessibility, and the capacity of health care facilities to provide timely testing and follow-up.

We hypothesize that, among women, higher knowledge of MTCT and its prevention, greater perceived benefits of screening, previous receipt of counseling, earlier and more frequent ANC contact, and better access to affordable services will be associated with a higher rate of testing. Conversely, concerns about cost, stigma, fear of a positive result, limited awareness, and difficulties accessing services are expected to be associated with poorer screening practices. Sociodemographic characteristics, including age, education, socioeconomic circumstances, parity, place of residence, and previous pregnancy or screening experience, may also contribute to differences in optimal screening.

Among HCWs, we hypothesize that better knowledge of MTCT prevention will be associated with better practices. Previous training, greater clinical experience, familiarity with guidelines, and access to diagnostic and treatment resources may also improve adherence to recommended screening, counseling, referral, and management. In contrast, limited training and uncertainty about guidelines may lead to poorer practices. Limited availability of tests or treatment, weak referral systems, and financial barriers for patients may also affect care. Professional role, type and level of health facility, and frequency of providing ANC services may further influence these outcomes. These hypotheses guided the selection of explanatory variables in the questionnaire and the planned analyses of factors associated with KAP.

Integrated triple screening has been shown to be feasible in Vietnam under program conditions. Wider implementation requires alignment between guidelines, provider practice, and women's demand and acceptability, particularly in settings where payment mechanisms and service fragmentation can undermine timely uptake [10]. Therefore, this protocol proposes a study to assess KAP related to HIV, HBV, and syphilis screening in pregnancy and to examine individual and perceived service-related factors associated with optimal antenatal screening among women and good MTCT-prevention practice among HCWs. We also aim to identify reported barriers and facilitators that may inform future efforts to improve alignment between national recommendations and routine practice.

Objectives

The study aimed to assess KAP regarding the prevention of MTCT of HIV, HBV, and syphilis among women and HCWs in 4 provincial hospitals in northern Vietnam and to identify factors associated with optimal screening among women and good practices regarding the prevention of MTCT among HCWs.

The study objectives are specifically as follows: (1) to measure levels of knowledge about MTCT prevention, including transmission routes, consequences, recommended timing of antenatal testing, and available prevention and treatment interventions; (2) to describe attitudes toward MTCT prevention and routine antenatal screening, including perceived necessity, perceived benefits and harms, stigma-related concerns, trust in testing, and willingness to test and receive treatment/referral if indicated; (3) to characterize MTCT prevention-related practice and cascade indicators, including uptake of antenatal testing, timing and place of testing, receipt and understanding of results, counseling, and linkage to follow-up actions. Cascade indicators will refer to service-delivery milestones among women, including uptake and timing of antenatal testing, receipt and understanding of results, counseling, and linkage to appropriate follow-up actions; and (4) to determine individual and perceived service-related factors associated with optimal antenatal triple screening among women and good MTCT screening and prevention practice among HCWs.

Methods

Study Design

This was a hospital-based cross-sectional study conducted from June to September 2026. Two participant groups were included: women who had recently given birth and HCWs involved in antenatal screening and MTCT prevention services.

Women were surveyed after delivery, once they were clinically stable and before hospital discharge. Their responses referred to the pregnancy that had just ended, including ANC, screening for HIV, HBV, and syphilis, and related knowledge, attitudes, experiences, and perceived barriers. This timing allowed screening uptake during the completed pregnancy to be assessed without interviewing women during labor or before their ANC pathway had been completed.

HCWs completed a separate questionnaire during the same data-collection period. Their survey assessed knowledge, attitudes, self-reported practice, training, and perceived barriers related to antenatal screening and MTCT prevention for HIV, HBV, and syphilis.

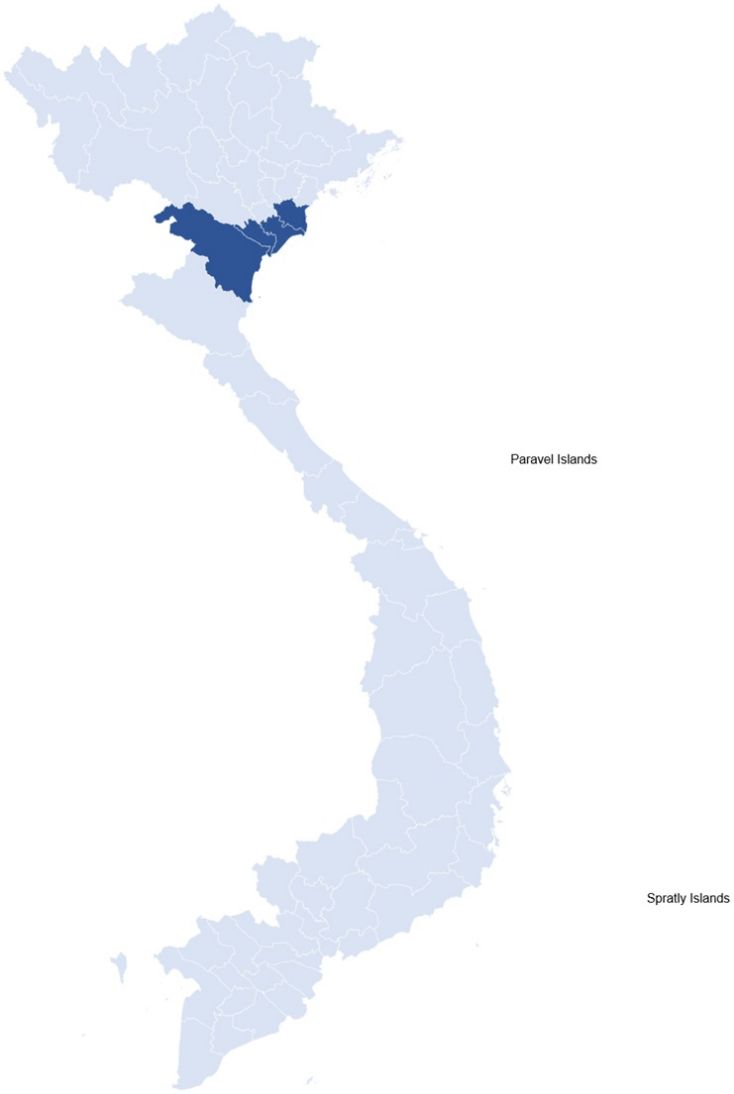
The 2 participant groups were not paired or matched. A participating HCW was therefore not linked to or assumed to have provided care for any participating woman. Data from women and HCWs will be analyzed separately according to the prespecified outcomes for each group. Findings from the 2 components will be interpreted together only at a descriptive and contextual level to provide complementary perspectives on antenatal screening from service users and health care providers. No individual-level association between health care-worker characteristics and women's screening outcomes will be estimated.

This protocol was prepared with reference to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) Checklist 1 guideline for cross-sectional studies (Multimedia Appendix 1).

Study Setting

The study was conducted in 4 provincial hospitals in northern Vietnam: Thai Binh Obstetrics and Gynecology Hospital, Nam Dinh Obstetrics and Gynecology Hospital, Ninh Binh Obstetrics-Gynecology and Pediatrics Hospital, and Thanh Hoa Obstetrics-Gynecology and Pediatrics Hospital (Figure 1).

Figure 1. Study sites (shown in dark blue).



The 4 hospitals were selected purposively as provincial-level hospitals providing maternity and antenatal services in northern Vietnam. They were chosen based on their involvement in antenatal screening and MTCT prevention services, sufficient numbers of deliveries and eligible HCWs to support recruitment, and feasibility of study implementation. The hospitals were not selected to represent different levels of the health system. Rather, they provide a multicenter sample of provincial hospital settings.

Because participants were recruited from 4 provincial hospitals, the findings will primarily reflect women delivering at these hospitals and HCWs providing relevant services within them. The study is not intended to produce nationally representative estimates for all women who have recently given birth or HCWs in Vietnam, particularly those receiving or providing care in district hospitals, commune health stations, private facilities, or outside health facilities.

Eligibility Criteria

Eligible women were those who gave birth at 1 of the 4 study hospitals during the data-collection period, were able to communicate in Vietnamese, and were willing to provide informed consent. Women were approached only

after delivery, once clinically stable and considered able to participate, and before hospital discharge. They were not interviewed during active labor. The questionnaire referred specifically to the pregnancy that had just ended. Women were asked about ANC and screening undertaken during that pregnancy, including whether and where they were tested for HIV, HBV, and syphilis before admission for childbirth. The testing timing reported in the questionnaire was a general timing item and was not used alone to assign infection-specific timing for the primary outcome.

Questionnaire administration was postponed if the woman required clinical care, experienced significant discomfort or fatigue, was breastfeeding or undergoing a procedure, or did not have adequate privacy. Women were excluded if they were clinically unstable, had a condition that precluded participation at the time of recruitment, or had cognitive or communication limitations that prevented questionnaire completion.

Testing conducted after admission for childbirth, including intrapartum testing, was recorded separately and was not classified as antenatal screening for the primary outcome.

Eligible HCWs were staff at the study hospitals who were involved in offering, counseling, ordering, performing, or reporting testing for HIV, HBV, and syphilis for pregnant women, were able to communicate in Vietnamese, and were willing to provide informed consent. HCWs were recruited and completed the anonymous self-administered questionnaire between June and September 2026, during the same data-collection period as the women's component. HCWs were excluded if they were not actively working in relevant services during recruitment or were not involved in routine screening-related activities.

Sampling and Recruitment

Women were recruited consecutively from among eligible women who gave birth at the participating hospitals until the required sample size was reached. The target number at each hospital was based on delivery volume. For HCWs, recruitment used a target-limited census approach among staff involved in prevention of mother-to-child transmission screening: all identified HCWs who met the eligibility criteria at each participating hospital were approached rather than selectively sampled. Recruitment proceeded across the 4 hospitals and stopped once the overall HCW sample-size target of 601 participants was reached.

Sample Size Calculation

The sample size was calculated separately for women and HCWs using the single-population proportion formula [19]. A standard normal deviate corresponding to a 95% CI was used, and the margin of error was set at 4%. Because reliable prior estimates of the prevalence of the prespecified primary outcomes were unavailable, we assumed P=.50. The minimum required sample size was 601 participants per group. Accordingly, the recruitment target was at least 601 women and 601 HCWs across the 4 participating hospitals, and recruitment stopped once the required target was achieved.

The study also includes multivariable analyses. Because reliable prior estimates of the prevalence of the prespecified primary outcomes are not available, a separate conventional power calculation for each regression coefficient would require assumptions that cannot be justified before data collection. Instead, model complexity will be constrained according to the number of participants in the less frequent outcome category. As a pragmatic rule, the number of estimated regression parameters will be kept sufficiently small relative to the number of observed outcome events/nonevents, with approximately 10 observations in the less frequent outcome category per estimated parameter used as a minimum guide for model stability [20]. Candidate variables will therefore be prespecified, and models will remain parsimonious. If the observed prevalence of a primary outcome provides insufficient information for the originally planned number of predictors, the model will be reduced to the core prespecified covariates rather than selecting variables on the basis of bivariable statistical significance.

The primary purpose of the sample-size calculation remains estimation of the principal proportions with adequate precision. The multivariable analyses are intended to evaluate associations rather than to develop a clinical prediction model.

Questionnaire

Data were collected using 2 structured, Vietnamese-language questionnaires tailored to the 2 participant groups.

The questionnaires were developed specifically for this study using current Vietnamese national recommendations for the prevention of MTCT and relevant World Health Organization (WHO) guidance on the triple elimination of MTCT of HIV, syphilis, and HBV [21,22]. Questionnaire items were mapped to the principal domains addressed by these guidelines, including recommended antenatal screening, timing of testing, MTCT risk, preventive interventions, counseling, referral, and management following positive results. Published evidence on barriers to antenatal screening and service uptake was also considered when developing items concerning access, cost, stigma, and other perceived barriers.

Draft questionnaires were reviewed by experts with relevant clinical and public-health expertise. The expert review assessed whether the items were clinically correct, relevant to the study objectives, consistent with national and WHO recommendations, understandable in the Vietnamese context, and sufficiently comprehensive to cover the intended KAP domains. Items considered unclear, redundant, clinically inaccurate, or outside the study scope were revised or removed. Content validity was therefore assessed qualitatively through expert review; a formal quantitative content-validity index was not calculated.

Before the main study, both questionnaires were pilot-tested among 30 participants from each target group. The pilot assessed comprehension, wording, response options, questionnaire flow and skip patterns, acceptability, completion time, and the practical feasibility of administration. Feedback and difficulties identified during the pilot were reviewed by the study team and used to finalize the questionnaires before the main data collection. Pilot participants were not included in the main analytical dataset.

Formal psychometric validation, including construct-validity analysis and calculation of Cronbach α, was not performed. This decision reflects the primarily criterion-referenced nature of the instruments: the knowledge questions assess several distinct factual recommendations rather than a single underlying latent construct.

Questionnaire Scoring

Knowledge items will be scored using a prespecified answer key aligned with Vietnamese Decision 678/QĐ-BYT (2025) and WHO guidance (Multimedia Appendix 1) [21,22]. For women, question 9 is an awareness item and will not be scored. Question 10 will be scored as correct only if HIV, HBV, and syphilis are all selected, and "none of these" is not selected. Question 11 will be scored as correct only if both "helps detect infection early so that treatment can be started" and "reduces the risk of transmission to the child" are selected and neither "no benefit" nor "do not know" is selected. Question 12 will be summarized separately as knowledge of testing timing and will not contribute to a composite score because national guidance recommends testing at the first antenatal visit or as early as possible rather than defining a specific trimester.

For HCWs, the guideline-concordant knowledge score will include 4 items with unambiguous answers: question 8 (HIV, HBV, and syphilis all selected, without "uncertain" or an incorrect option), question 12 (HBsAg), question 13 (syphilis, HBV, and HIV all selected, without "none of these" or "uncertain"), and question 14 ("yes, for all 3 infections"). Questions 9 to 11 will be reported item by item and will not contribute to the composite score because the national guidance specifies early testing rather than a trimester-specific rule and permits more than 1 acceptable testing technology or algorithm. Each scored item will receive 1 point only for a fully correct response and 0 otherwise; no partial credit will be given for multiple-response items. Explicit "uncertain" or "do not know" responses will be coded as incorrect, whereas blank responses will be coded as missing. The HCW knowledge percentage score will be calculated as (sum of the 4 scored items/4) × 100 only if all 4 scored items are complete.

Attitude items will be summarized individually and no composite attitude-domain score will be calculated; therefore, an internal-consistency threshold such as Cronbach α will not be used for the attitude domain. The five-item HCW practice score will be calculated only when all 5 practice items are completed; otherwise, the primary HCW practice outcome will be coded as missing.

Questionnaire for Women

The women's questionnaire was administered in the delivery services and is organized into 5 sections. It first captures sociodemographic and obstetric characteristics, including age, education, occupation, household income, gravidity, and patterns of ANC seeking. It then assesses knowledge related to MTCT prevention and screening for syphilis, HBV, and HIV, including awareness of MTCT, perceived benefits of screening, and understanding of the recommended timing for testing. The next section measures attitudes toward screening, covering the perceived necessity of universal testing, worries or concerns about testing, willingness to accept treatment if positive, and trust in test results. The practice section records whether the woman was tested for syphilis, HBV, and HIV during the current pregnancy before admission for delivery and it captures where and when testing occurred as well as reasons for not testing. The final section documents perceived barriers and preferred supports, such as cost, distance, waiting time, stigma, and counseling needs, and it includes documentation of any screening performed during labor, with test dates and recorded results when available.

Questionnaire for HCWs

The HCW questionnaire collects demographic and professional characteristics such as age group, sex, cadre, years of experience, facility and department, and prior training. It assesses knowledge of screening recommendations, including which infections should be screened for in pregnancy, recommended timing, and appropriate tests for syphilis, HIV, and HBV, alongside knowledge of MTCT risks and awareness of prevention options. It then measures attitudes toward routine screening, including perceived necessity of integrated screening, confidence in interpreting results, views on universal screening irrespective of risk, and perceived barriers to implementation. The clinical practice section captures self-reported frequency of recommending screening, counseling practices, and intended actions in response to positive results for syphilis, HBV, and HIV. The final section assesses training needs and preferred training modalities.

Questionnaire Administration and Confidentiality

The women's questionnaire was interviewer-administered in Vietnamese by trained study staff in the postpartum setting. Interviews were conducted, as far as possible, in a location where responses could not be overheard by other patients, family members, or clinical staff not involved in the study. Participation occurred only when the woman was clinically stable and felt able to complete the interview.

To minimize mode effects and social desirability bias, the HCW questionnaire used one standardized mode: anonymous self-administration. HCWs completed the questionnaire privately and were not required to provide names, employee identification numbers, or other direct identifiers. Completed questionnaires were not made available to department heads, supervisors, or hospital management in identifiable form. Study staff emphasized that participation or

nonparticipation had no employment consequences and that individual responses would not be reported to supervisors.

Verification of Screening Uptake and Timing

Because recall of testing throughout pregnancy may be imperfect, self-reported screening information from women was verified whenever documentary information was available. With participant consent and according to hospital procedures, study staff reviewed available antenatal records, maternal health books, laboratory reports, and/or hospital electronic or paper medical records for evidence of HIV, HBV, and syphilis testing. The original questionnaire did not contain separate infection-specific date or timing fields, and its general timing question (question 20) was not used by itself to determine infection-specific timing. During source verification and data cleaning, trained field workers will review the available documentary sources and complete derived trimester-specific fields separately for HIV, HBsAg, and syphilis as first, second, or third trimester, or unknown.

For primary-outcome derivation, "optimal testing" will be classified as yes only when infection-specific documentary information confirms that all 3 tests were completed during the first trimester. It will be classified as no when at least 1 of the 3 tests is documented as not performed antenatally or as performed only after the first trimester. If infection-specific timing remains unavailable for one or more tests and the available information is insufficient to establish either yes or no, the primary outcome will be classified as unknown/missing. Self-report alone may contribute to secondary descriptions of test uptake but will not establish the primary outcome when only the general, noninfection-specific timing response is available. When self-report and a documentary source disagree, the documentary information will be used. If documentary sources conflict and the discrepancy cannot be resolved from the source records, timing will be classified as unknown rather than adjudicated subjectively.

Testing performed after admission for childbirth will be abstracted separately from hospital clinical and laboratory records, when available. Such testing will be classified as intrapartum testing and will not satisfy the primary antenatal screening outcome.

Primary and Secondary Outcomes

Women

Current Vietnamese national guidance and WHO recommendations support testing all pregnant women for HIV, HBV, and syphilis early in pregnancy. WHO recommends testing for all 3 infections at least once, and as early as possible, ideally at the first ANC visit. Vietnamese Decision 678/QĐ-BYT (2025) similarly recommends testing at the first antenatal care visit or as early as possible during pregnancy [21,22]. This national recommendation is not a trimester-specific definition. For this study, completion of all 3 tests during the first trimester was prespecified as the study-specific operational definition of optimal antenatal triple screening. The yes/no/unknown classification will follow the infection-specific source-verification rules described above. Testing performed only after the first trimester or at admission for childbirth will not satisfy the primary outcome.

Secondary outcomes will include antenatal testing for HIV, HBV, and syphilis separately; timing of the test; and intrapartum testing among women not screened antenatally. These secondary indicators will not replace the prespecified primary outcome.

HCWs

The single prespecified primary outcome for HCWs will be "good practice" in antenatal screening and prevention of MTCT of HIV, HBV, and syphilis. Five prespecified practice items will each be rated on a 5-point Likert scale: 1=never, 2=rarely, 3=occasionally, 4=often, and 5=always. A percentage practice score will be calculated as (sum of the 5 item scores/25) × 100. "Good practice" will be defined a priori as a percentage score of ≥80%. This threshold will be specified before data analysis and will not be modified based on the observed distribution of practice scores.

Scope of Service-Level Factors

The questionnaires capture participants' perceptions of service-related barriers, including cost, access, waiting time, availability of counseling, and perceived implementation constraints. However, the study does not independently measure facility-level health-system characteristics such as stock-out records, staffing ratios, facility budgets, or longitudinal availability of diagnostic commodities. Accordingly, analyses will refer to "individual and perceived service-related factors" rather than claiming to identify independent health-system determinants. Facility-level causal effects will not be estimated.

Data Management

All questionnaires will be checked for completeness and internal consistency at the point of collection. Each participant will be assigned a unique study identification code, and no direct personal identifiers will be included in the analytical dataset. Data will be entered into a dedicated electronic database using double data entry or built-in validation checks to minimize transcription errors. Paper questionnaires will be stored in locked cabinets in a secure office at each site and transferred to the coordinating center following standard operating procedures. A data dictionary, codebook, and version-controlled analysis scripts will be maintained to support reproducibility. Any data transfer between the sites and the coordinating center will be encrypted, and access logs will be maintained.

Data Analysis Plan

Data analysis will be conducted separately for women and HCWs because the main outcome differs by group. No statistical linkage will be made between individual women and individual HCWs. Among women, the primary outcome is completion of screening for all 3 infections during the first trimester of the current pregnancy. Among HCWs, the

primary outcome is good practice regarding the prevention of MTCT. Analyses will be performed using RStudio (Posit PBC).

Data preparation will start with data cleaning and validation. All variables will be checked for completeness, allowable ranges, and internal consistency according to questionnaire skip patterns. Duplicate records will be identified using study identification codes and key demographic fields, then reconciled against source questionnaires where necessary. Inconsistent testing responses or trimester classifications will be checked against available source records through a documented query process. Categorical variables will use explicit reference categories. Knowledge, attitude, and practice responses will be coded according to the prespecified scoring rules described above.

For HCWs, both item-level knowledge responses and the prespecified four-item percentage knowledge score will be summarized. Attitudes will be presented as item-level distributions without a composite attitude score. Practice indicators and the five-item practice score will be derived from questionnaire responses as described above. Among women, practice will be operationalized primarily through measured service uptake during pregnancy, with the primary outcome derived from infection-specific source verification.

Descriptive statistics will summarize participant characteristics and outcomes overall and by hospital. Categorical variables will be presented as frequencies and percentages, and continuous variables will be summarized using means and SDs or medians and IQRs depending on the distribution.

For women, optimal screening proportions for each infection and for the 3 infections combined will be reported with 95% CIs, and variations across hospitals and key participant characteristics such as education, parity, and ANC patterns will be described. For HCWs, practice score distribution and the proportion meeting the good practice threshold will be reported with 95% CIs, and differences across cadres, hospitals, departments, years of experience, and prior training will be described.

Bivariable analyses will explore associations between candidate explanatory variables and outcomes. For binary outcomes, crude prevalence ratios will be estimated, and chi-square or Fisher exact tests will be used, as appropriate, for hypothesis testing. Candidate variables associated with optimal testing among women will be selected based on a conceptual framework and will include sociodemographic characteristics, obstetric history, ANC use and care-seeking patterns, including use of multiple facilities, and reported barriers such as cost, distance, waiting times, stigma, and counseling access. Candidate variables for HCWs' practice regarding prevention of MTCT will include cadre, years of experience, department, prior MTCT prevention-related training, knowledge regarding prevention of MTCT, and hospital.

Multivariable models will be fitted to identify factors independently associated with the primary outcomes, and effect estimates will be reported as prevalence ratios and adjusted prevalence ratios with 95% CIs.

Because participants were recruited from only 4 hospitals, hospital will be included as a categorical fixed effect in the multivariable models to account for systematic differences in baseline outcome prevalence between study sites. The modified Poisson models will therefore estimate individual-level associations conditional on hospital [23]. Robust sandwich standard errors will be used for the modified Poisson models but will not be clustered by hospital, because cluster-robust variance estimation is unreliable with only 4 clusters. We acknowledge that residual within-hospital correlation may remain after adjustment for hospital and that the precision of the estimated associations may therefore be affected. Hospital-specific estimates will be presented descriptively where appropriate, but coefficients for individual hospitals will not be interpreted as generalizable hospital-level effects. Comparisons between hospitals will therefore be interpreted cautiously.

For women, multivariable optimal-screening models will include variables reflecting access and enabling factors and prespecified individual knowledge and attitude items where conceptually relevant; no composite attitude-domain score will be used. For HCWs, the four-item knowledge percentage score may be included as a continuous explanatory variable, with effect estimates reported per 25-percentage-point increase. Confounding control will be guided primarily by the conceptual framework rather than bivariable *P* values, and parsimonious models will be prioritized. Collinearity will be assessed using variance inflation factors and clinical plausibility, and highly correlated variables will not be included simultaneously in the same model.

Missing data will be described by variable and by hospital. For the women's primary outcome, cases classified as unknown because infection-specific timing cannot be established will be reported separately and excluded from the primary regression analysis; a sensitivity analysis will conservatively classify these cases as not meeting the study-defined optimal-testing outcome. For other key predictors, complete-case analysis will be used when missingness is low; if missingness is substantial, multiple imputation by chained equations may be considered under a missing-at-random assumption. All tests will be two-sided with a significance level of 0.05. Results will clearly define uptake indicators, timing definitions, and the good-practice threshold. The primary outcomes and overall analysis strategy were prespecified before data collection. The additional source-verification, unknown-outcome, and scoring rules described in this revision were finalized after recruitment but before statistical analysis and were not informed by observed effect estimates. Any subsequent protocol or analysis-plan deviations will be documented and reported with their rationale.

The overall schedule and timing of assessments for the 2 participant groups, together with the main measures and their relation to the planned analyses, is summarized in Figure 2 and Table 1.

Figure 2. Overall workflow of the study. HBV: hepatitis B virus; MTCT: mother-to-child transmission.

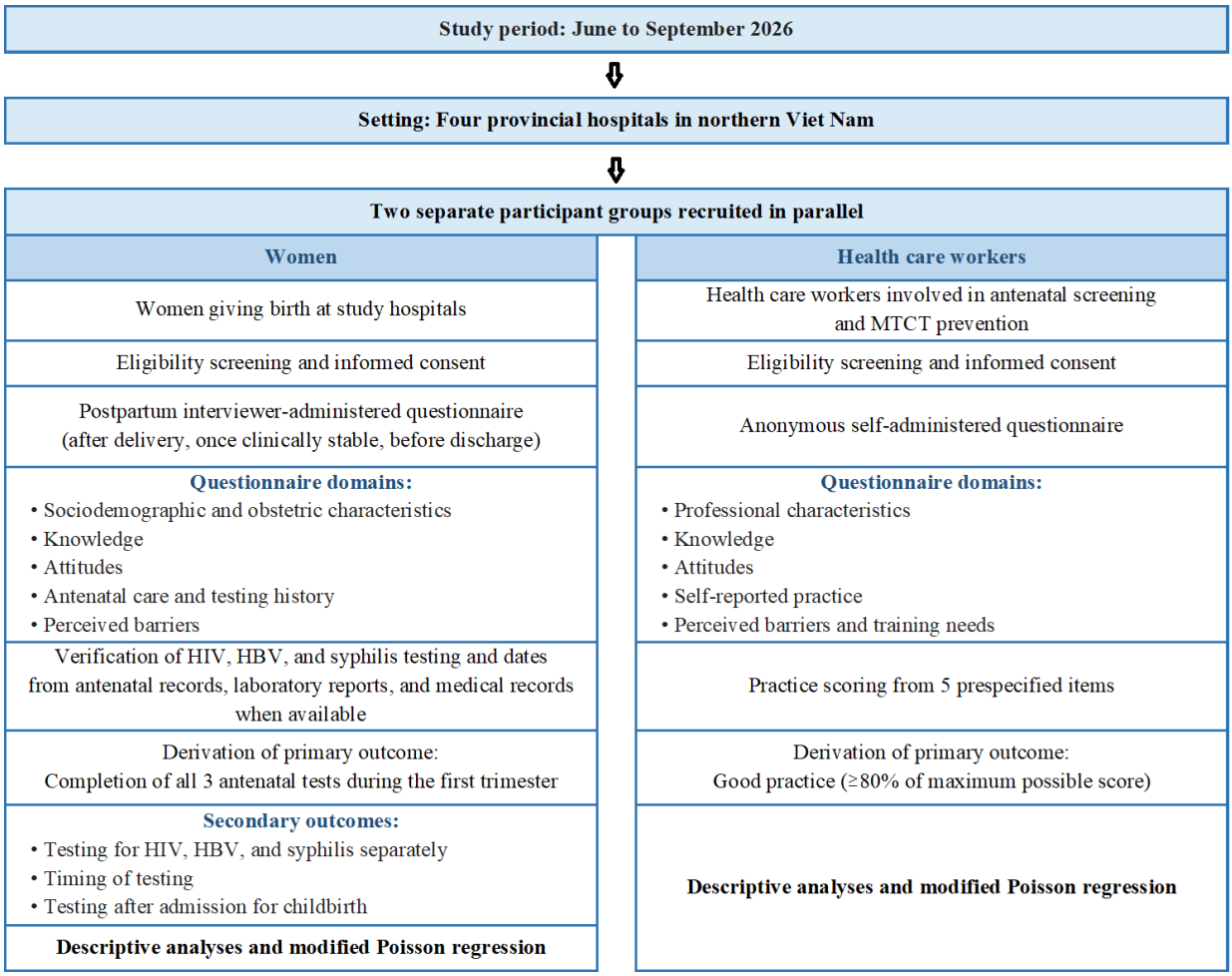


Table 1. Schedule and timing of assessments[a].

Study component	Women giving birth	HCWs[b]	Main variables/measures	Relation to outcomes and analysis
Eligibility screening	After delivery, before discharge, once clinically stable	During study period, among staff involved in antenatal screening and MTCT[c] prevention	• Eligibility criteria and consent	Defines study sample
Informed consent	At recruitment	At recruitment	• Written informed consent	Required before data collection
Sociodemographic and professional characteristics	At interview	At questionnaire completion	• Women: age, education, occupation, income, gravidity, and ANC[d] use • HCWs: age group, sex, cadre, years of experience, department, prior training	Candidate explanatory variables
Knowledge assessment	At postpartum interview and referring to the completed pregnancy	At self-administered questionnaire	• Knowledge of HIV, HBV[e], syphilis, MTCT, timing of testing, prevention and treatment	Descriptive KAP[f] analysis; possible explanatory variable
Attitude assessment	At postpartum interview	At self-administered questionnaire	• Perceived necessity, benefits, barriers, stigma, trust in testing, and willingness to test/treat	Descriptive KAP analysis; possible explanatory variable
Practice assessment	At postpartum interview	At self-administered questionnaire	• Women: self-reported uptake, timing, place of testing, reasons for nontesting • HCWs: frequency of recommending screening, counseling, and management actions	Basis for outcome derivation

Study component	Women giving birth	HCWs[b]	Main variables/measures	Relation to outcomes and analysis
Record verification	After women's interview, when records available	Not applicable	• Antenatal records, maternal book, lab reports, medical records	Verifies women's screening uptake and timing
Primary outcome derivation	After questionnaire and record verification	After questionnaire scoring	• Women: completion of HIV, HBV, and syphilis testing during first trimester • HCWs: good practice (≥80% of maximum score on 5 practice items)	Main outcome for regression analysis
Secondary outcome derivation	After questionnaire and verification	Not primary focus	• Women: separate testing by infection, timing of testing, intrapartum/delivery-admission testing • HCWs: distribution of practice score and item-level practice indicators	Descriptive and secondary analyses
Data analysis	After data cleaning	After data cleaning	• Descriptive statistics, bivariable analyses, and modified Poisson regression with robust variance	Separate analyses for women and HCWs

[a]Women and HCWs were recruited during the same study period but were not paired or matched, and analyses were conducted separately.
[b]HCWs: health care workers.
[c]MTCT: mother-to-child transmission.
[d]ANC: antenatal care.
[e]HBV: hepatitis B virus.
[f]KAP: knowledge, attitudes, and practices.

Access to Data

Access to study data will be restricted to authorized members of the research team and will follow the principle of least privilege. Site investigators will have access only to data collected at their hospital during the active data collection period for the purpose of quality control and query resolution. After data cleaning and harmonization, the coordinating center will maintain the master deidentified dataset and will control all dataset releases for analysis. Only the principal investigator and designated statisticians/data managers will have full access to the final deidentified analytical dataset. If any linkage file is created to support field operations, it will be stored separately from questionnaire data, protected with an additional password, and accessible only to the minimum number of staff required for operational purposes. For HCWs, the analytical database will contain no direct employee identifiers, and individual responses will not be provided to supervisors or hospital management. Any sharing of deidentified data with external collaborators will require ethics approval as applicable, a data-sharing agreement, and confirmation that data recipients will not attempt reidentification and will use the data only for the agreed scientific purposes.

Data Handling and Record Keeping

All study documents and datasets will be handled according to a written set of standard operating procedures. Paper questionnaires will be labeled only with study identification codes and stored in locked cabinets at each site, with access limited to study staff. Electronic data will be stored on password-protected computers with regular backups and controlled access. During data transfer between sites and the coordinating center, files will be encrypted and transmitted through secure channels. A complete audit trail will be maintained, including dated versions of the data dictionary, electronic case report forms/questionnaires, data-cleaning logs, query-resolution forms, and analysis scripts. Any modification to the dataset after initial entry will be documented with the reason for the change, the person responsible, and the date.

Study records will be retained for 5 years in accordance with institutional requirements and applicable Vietnamese regulations. After the retention period, records will be securely destroyed. Paper documents will be shredded or otherwise securely destroyed, and electronic files will be permanently deleted using methods appropriate for secure disposal.

Ethical Considerations

The protocol was reviewed and approved by the Institutional Review Board (IRB) of Thai Binh University of Medicine and Pharmacy (protocol code 09; approval date February 9, 2026). QTN is both a coauthor of this manuscript and President of the IRB. In his role as a coauthor, he contributed to the review and development of the study protocol and manuscript; however, he did not participate in the IRB evaluation, deliberation, or decision regarding the approval of this protocol. The approval decision was made by the other IRB members. In accordance with institutional procedures, he signed the final IRB approval decision in his administrative capacity as President of the IRB.

Written informed consent was obtained from all participants before enrollment. Participation was voluntary, and participants could withdraw at any time without consequences for their medical care or employment.

Participant privacy and confidentiality were protected throughout the study. Women were assigned unique study identification codes, direct personal identifiers were not included in the analytical dataset, and any operational linkage

file was stored separately with restricted access. For HCWs, names, employee identification numbers, and other direct identifiers were not collected. Paper and electronic study data are stored with physical, password, access-control, and encryption safeguards as described above.

No financial or material compensation was provided to participants.

Results

The study was funded by Thai Binh University of Medicine and Pharmacy, Hung Yen, Vietnam. The protocol received ethics approval on February 9, 2026. Recruitment and questionnaire data collection were completed between June and September 2026. As of manuscript submission, 601 patients and 601 health care workers had been recruited. Data cleaning and infection-specific source verification are planned for October 2026. Statistical analysis is planned for November to December 2026, with dissemination of the first study results in the first quarter of 2027. No inferential study findings are presented in this protocol manuscript. The primary outcomes and overall analysis framework were specified before data collection; the operational clarifications added during peer review were finalized before statistical analysis and were not based on observed effect estimates. The planned schedule is summarized in Table 2.

Table 2. Planned study status and timeline.

Activity	Planned period	Status
Ethics approval	February 9, 2026	Completed
Questionnaire finalization, cognitive testing, pilot, and staff training	March to May 2026	Completed
Participant recruitment and record verification	June to September 2026	Completed
Data cleaning and query resolution	October 2026	Planned
Statistical analysis	November to December 2026	Planned
Site feedback and first results manuscript	January to March 2027	Planned

Discussion

Principal Findings

This study is expected to quantify how often women giving birth at 4 provincial hospitals completed optimal antenatal testing for HIV, HBV, and syphilis before admission for delivery and to identify where gaps occur in timing, access, and provider recommendations. In parallel, it will characterize HCW-reported screening practices using a prespecified practice threshold. We anticipate that optimal screening will vary according to antenatal-care pathways and access barriers and that provider knowledge will vary with training and professional role; these are hypotheses rather than study findings.

Comparison With Prior Work

Previous Vietnamese work has demonstrated the feasibility and potential value of integrating HIV, HBV, and syphilis testing into ANC [10], while national and WHO guidance emphasize early testing and coordinated interventions [21,22]. The present study adds a multicenter hospital perspective that examines women's reported experiences and HCW KAP in the same 4 provincial settings. The 2 datasets are intentionally analyzed separately rather than treated as matched patient-provider observations.

Strengths and Limitations

This study has several strengths. First, it includes 2 complementary participant groups, women who have recently given birth and HCWs involved in antenatal screening and prevention of MTCT, allowing the study to describe antenatal screening from both service-user and provider perspectives. The 2 groups will be analyzed separately, avoiding inappropriate assumptions about individual patient–provider relationships. Second, a single primary outcome has been prespecified for each group, which reduces ambiguity in the main analyses. Third, women's reported HIV, HBV, and syphilis testing and the timing of testing will be verified using available antenatal records, laboratory reports, or medical records, which should reduce misclassification due to recall. In addition, standardized data collection across 4 provincial hospitals will allow comparison across different hospital settings. The HCW questionnaire will be completed anonymously and privately, which may reduce concerns about reporting practices that do not fully follow recommendations. Finally, the questionnaires were developed with reference to national and WHO recommendations, reviewed by experts, and pilot-tested in the target populations before the main study.

Several limitations should also be considered. First, participants are recruited from 4 provincial hospitals in northern Vietnam. The findings, therefore, may not be generalizable to women receiving care or giving birth in district hospitals, commune health stations, private facilities, or at home, or to HCWs in these settings. Second, the cross-sectional design limits assessment of temporal relationships and does not permit causal inference. Among women, knowledge, attitudes, and perceived barriers are measured after delivery and may have been influenced by their experiences during the pregnancy. Third, although screening information will be verified whenever records are available, some information may rely on self-report and therefore may remain subject to recall or reporting bias. Fourth, HCW practices are self-reported and may be affected by social desirability bias, despite anonymous questionnaire

administration. Fifth, women who are clinically unstable or otherwise unable to participate before discharge will not be included, which may introduce some selection bias. Sixth, the questionnaires were developed specifically for this study rather than using fully validated psychometric instruments. Expert review and pilot testing support their content and feasibility, but measurement error may remain. Finally, only 4 hospitals are included, limiting the ability to estimate hospital-level effects. In addition, service-related barriers are based mainly on participant perceptions rather than independent measurements of staffing, test availability, stock-outs, financing, or other facility-level characteristics. Therefore, these factors will be interpreted as perceived service-related factors rather than independent health-system determinants.

Future Directions

The study findings will be shared with participating hospitals and relevant provincial stakeholders to identify practical gaps in early antenatal screening, counseling, referral, and the prevention of MTCT. Particular attention will be given to potentially modifiable factors, such as gaps in provider knowledge or training, delayed recommendations for testing, financial or access barriers, and fragmented testing and referral pathways.

If important and consistent gaps are identified, subsequent studies could evaluate targeted interventions such as standardized screening protocols or reminders, HCW training, improved counseling materials, and more integrated pathways for HIV, HBV, and syphilis testing and follow-up. Future research could also extend the study to district hospitals, commune health stations, and private facilities to assess whether the findings are consistent across different levels of the health system. Longitudinal or implementation studies would be valuable to examine whether changes in service delivery lead to improvements in timely screening, linkage to care, and completion of recommended MTCT-prevention interventions. Further validation of the questionnaires in broader populations could also strengthen their use in future KAP and implementation research.

Conclusions

This multicenter study will provide hospital-based evidence on the timely completion of antenatal screening for HIV, HBV, and syphilis among women giving birth and on reported MTCT-prevention practices among HCWs. By using separate prespecified primary outcomes for the 2 participant groups and verifying women's screening histories whenever possible, the study is designed to provide a structured assessment of individual and perceived service-related factors associated with antenatal screening and provider practices.

Because the study is cross-sectional and hospital-based, the findings will be interpreted as associations rather than causal effects and will not be considered nationally representative. Nevertheless, the study may identify modifiable gaps in screening, counseling, referral, training, and access to services and provide evidence to guide future interventions aimed at improving timely antenatal triple screening and strengthening prevention of MTCT of HIV, HBV, and syphilis in Vietnam.

Generative AI Use

During the preparation of this work, the authors used GPT-5.4 (OpenAI) to check and improve grammar and clarity throughout manuscript development. After using this tool, the authors reviewed and edited the content as needed, and they take full responsibility for the content of the publication.

Funding

This study is funded by Thai Binh University of Medicine and Pharmacy, Hung Yen, Vietnam.

Data Availability

Deidentified data generated by this study may be made available to qualified researchers upon reasonable request to the corresponding author. Requests must describe the proposed scientific purpose and will be reviewed by the study leadership/coordinating center. Access will be granted only when the proposed use is approved and, where applicable, ethics approval and a data-sharing agreement are in place. Approved recipients must agree to use the data only for the agreed purpose and not attempt reidentification.

Authors' Contributions

TKN, MTB, TTTB, and TLD were responsible for conception and the funding application. TKN, MTB, TTTB, TLT, and TLD were in charge of the study design. TKN, MTB, TTTB, TLT, TLD, and VTH contributed to the development of the study protocol. TKN, MTB, TTTB, and TLD were responsible for preparing and submitting the ethics application and obtaining permission from local authorities. TKN, MTB, TTTB, QTN, DCN, TBN, TLT and TLD are responsible for coordinating study activities across sites. TKN, MTB, and TLD supervise the study implementation. VTH and TLD will lead the data analysis. Drafting of the study protocol manuscript was prepared by all authors. All authors contributed to the final revision and approved the submission.

Conflicts of Interest

QTN serves as President of the Institutional Review Board (IRB) that approved the study protocol and, as described in the Ethical Considerations section, he did not participate in the IRB evaluation, deliberation, or approval decision. The authors declare no other conflicts of interest.

Multimedia Appendix 1

Questionnaires assessing knowledge, attitudes, and practices regarding HIV, hepatitis B, and syphilis screening among pregnant women and health care workers.
[DOCX File (Microsoft Word File), 25 KB-Multimedia Appendix 1]

Checklist 1

STROBE checklist.
[DOCX File (Microsoft Word File), 44 KB-Checklist 1]

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Abbreviations

ANC: antenatal care
ART: antiretroviral therapy
HBsAg: hepatitis B surface antigen
HBV: hepatitis B virus
HCWs: health care workers
IRB: Institutional Review Board
KAP: knowledge, attitudes, and practice
MTCT: mother-to-child transmission
STROBE: Stengthening the Reporting of Observational Studies in Epidemiology
WHO: World Health Organization

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