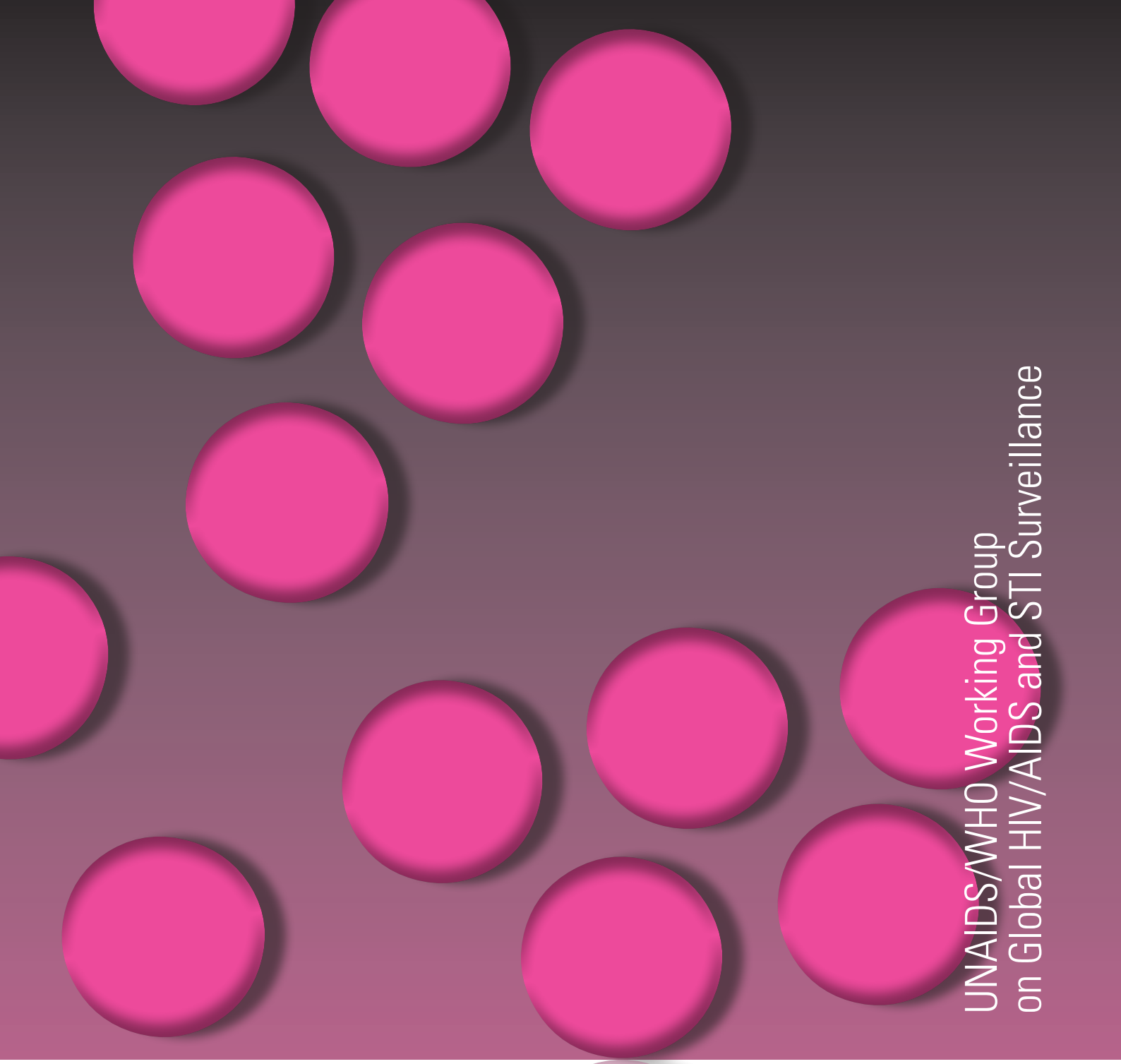

UNAIDS/WHO Working Group
on Global HIV/AIDS and STI Surveillance

Guidelines for assessing the utility of data from prevention of mother-to-child transmission (PMTCT) programmes for HIV sentinel surveillance among pregnant women

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Contents

Abbreviations

AIDS	acquired immunodeficiency syndrome
AFRO	World Health Organization Regional Office for Africa
ANC	antenatal clinic
ANC HSS	antenatal clinic HIV sentinel surveillance
ART	antiretroviral therapy
CDC	United States Centers for Disease Control and Prevention
DBS	dried blood spot
DQA	data quality assessment
ELISA	enzyme-linked immunosorbent assay
EPP	Estimation and Projection Package
ERB	ethical review board
EQA	external quality assessment
FEFO	first-to-expire, first-out
HIV	human immunodeficiency virus
HSS	HIV sentinel surveillance
M&E	monitoring and evaluation
MCH	maternal and child health
MOH	Ministry of Health
PCR	polymerase chain reaction
PEPFAR	the United States President's Emergency Plan for AIDS Relief
PMTCT	prevention of mother-to-child transmission
QA	quality assurance
QC	quality control
SSA	sub-Saharan Africa
SOP	standard operating procedure
STI	sexually transmitted infection
UAT	unlinked anonymous testing
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
VCT	voluntary counselling and testing
WHO	World Health Organization

1. Purpose of the guidance document

This document provides guidance to countries for assessing the utility of data from programmes for prevention of mother-to-child transmission (PMTCT) of human immunodeficiency virus (HIV) for HIV sentinel surveillance (HSS) among pregnant women. The objectives of these guidelines are as follows:

1. Describe the context and rationale for transitioning from traditional HSS based on unlinked anonymous testing (UAT) in antenatal clinics (ANCs) to a system of HSS based on routine PMTCT programme data.
2. Describe robust methods for assessing the quality of PMTCT programme data for use in HSS.
3. Describe general standards for evaluating the readiness of PMTCT programme data to serve as the basis for HSS among pregnant women.

This information is provided in the form of general principles and standards to guide local discussions among the technical body charged with directing the assessment, including government public health actors, partners and subject matter experts. Though not strict targets, the suggested general standards presented in this document represent a high level of programme performance, which may serve as a point of reference to aid countries in interpreting assessment results.

For the purpose of these guidelines, the term "ANC HSS" will be used to refer to traditional periodic serosurveys of pregnant women at sentinel sites based on UAT, while "PMTCT-based HSS" will refer to HSS among pregnant women using routinely collected information from PMTCT programme records as its data source. "PMTCT data" refers to routinely collected data at sites that offer PMTCT programmes, and "PMTCT surveillance assessment" refers to assessment of the utility of data from PMTCT programmes for HSS.

A description of the methods and implementation of PMTCT-based HSS is beyond the scope of this document. However, a brief discussion on this topic is provided for the purpose of informing and planning the PMTCT surveillance assessment.

This guidance document is written for national HIV/acquired immunodeficiency syndrome (AIDS) programme managers, surveillance officers and epidemiologists responsible for monitoring HIV trends in low- and middle-income countries.

2. Background

Information about trends in HIV prevalence is necessary for countries to monitor the course of their epidemics, measure the effectiveness of control and prevention interventions, and plan further HIV control efforts. Timely and reliable data on HIV prevalence are gathered by HIV surveillance systems through the ongoing systematic collection, analysis and reporting of data at different points in the HIV disease process. *(1)*

2.1 HSS among pregnant women

Over the past two decades, HSS among pregnant women who routinely attend ANC sentinel sites has provided valuable information about the burden of HIV and trends in HIV prevalence. Antenatal clinics provide an accessible cross-section of healthy, sexually active women in the general population, and data from ANC HSS are considered to be generally representative of the underlying community.*(2)* In many countries, national HIV prevalence estimates are substantially based on annual or biennial ANC HSS.*(3,4)* ANC HSS data serve as one of the data sources used to construct mathematical models of HIV prevalence and trends using Estimation and Projection Package (EPP)/Spectrum analysis tools developed by the Joint United Nations Programme on HIV/AIDS (UNAIDS).*(5,6)*

The UNAIDS/World Health Organization (WHO) 2000 and 2013 guidelines on second generation HIV surveillance recommend conducting serosurveys among pregnant women as a core surveillance activity in concentrated and generalized HIV epidemics.*(7,8)* The 2003 UNAIDS/WHO *Guidelines for conducting HIV sentinel serosurveys among pregnant women and other groups* describe the method of UAT, in which leftover blood from routine ANC testing (usually syphilis testing) is stripped of all information that could permit personal identification and used for HIV surveillance.*(4)* In UAT-based ANC HSS, informed consent is usually not obtained from pregnant women and test results are not returned, thus eliminating a potential source of selection bias.

2.2 Ethical considerations associated with UAT-based ANC HSS

HIV programmes have improved dramatically in the past decade. There is more widespread access to HIV testing in ANC settings, higher coverage of PMTCT and antiretroviral therapy (ART) programmes, and transition to PMTCT Option B+ (initiating immediate, lifelong ART treatment) for HIV-positive pregnant women. At the end of 2010, an estimated 6.6 million HIV-positive persons in low- and middle-income countries were receiving ART, compared with 400 000 in 2003.*(9,10)* Additionally, to meet the targets of the United Nations General Assembly Special Session on HIV/AIDS (UNGASS) and UNAIDS to reduce mother-to-child transmission of HIV, many countries have rapidly expanded coverage of PMTCT services.*(11,12)* Because many women attending ANC services can now access HIV testing, PMTCT and ART services, the conduct of UAT-based ANC HSS raises ethical concerns. ANC HSS based on UAT does not obtain informed consent from pregnant women who are HIV tested for surveillance, provide them with their HIV test results, or refer them to available HIV care, treatment and prevention interventions if the test results are positive. *(13,14)*

In the context of expanding coverage of HIV testing, PMTCT and ART, alternative surveillance methods and data sources are increasingly available and should be explored to address concerns about UAT-based ANC HSS. Forthcoming WHO guidelines on ethical issues in HIV surveillance recommend that UAT-based ANC HSS should be used only when data from clinical settings and other studies cannot provide the information necessary for surveillance.*(15)*

2.3 PMTCT programmes in the context of HSS

As PMTCT programmes expand coverage and capture sociodemographic, syphilis and HIV testing data similar to those collected by ANC HSS, many countries are considering the use of routinely collected PMTCT programme data to complement or replace ANC HSS.[1] During the WHO Regional Office for Africa (AFRO) Network Meeting held in Addis Ababa, Ethiopia in July 2009, the assessment and strengthening of PMTCT programmes and programme data was identified as a priority surveillance activity.[2]

High-quality PMTCT programme data could provide a cost-effective alternative to ANC HSS. The population of women captured by both systems should be the same (i.e. pregnant women from the communities surrounding ANC HSS sites).[3] In most countries, pregnant women attending ANC facilities with PMTCT programmes are routinely provided HIV testing with the right to opt out, pregnant women receive pre- and post-test counseling, HIV testing is performed in accordance with national standards, and test results are provided during the same visit. Pregnant women routinely tested for HIV through PMTCT programmes are offered interventions, including prevention, treatment, care and support based on their test results.

2.3.1 A PMTCT-based system of HSS among pregnant women

In a PMTCT-based system of HSS among pregnant women, routinely collected PMTCT programme data would serve as the single source of surveillance data to monitor HIV prevalence and trends among pregnant women. PMTCT-based HSS will be possible if PMTCT HIV testing services are consistently available at all ANC HSS sites; PMTCT HIV testing is accurate; routinely recorded sociodemographic, syphilis and HIV testing data are of high quality; and selection bias inherent in PMTCT HIV testing data is minimal.*(16,17)*

The method by which PMTCT programme data would be collected and used for HSS would need to be developed and implemented in accordance with each country's PMTCT data collection system, programme infrastructure and available resources.

2.3.2 Potential advantages and limitations of PMTCT-based HSS

There are several potential advantages to replacing ANC HSS with a system of PMTCT-based HSS:

- In PMTCT HIV testing, pregnant women are informed that they will be tested for HIV with the opportunity to opt out. They receive pre- and post-test counseling, are provided with their test results, and are referred to HIV care, treatment and prevention services if test results are positive.
- In most countries, variables required for HSS among pregnant women are routinely collected in PMTCT registries.
- PMTCT-based HSS could reduce the workload and financial costs associated with conducting ANC HSS.
- Transition to PMTCT-based HSS can contribute to a system and culture of using routine programme data for surveillance.
- Increased use of and improvements in PMTCT data can directly contribute to improved PMTCT programme implementation and monitoring, and broader health systems strengthening.
- PMTCT-based HSS has the potential to achieve broader geographical coverage, a larger sample size and more stable prevalence estimates by facilitating the expansion of the surveillance period and the number of HSS sites.

However, using PMTCT data for HSS could involve challenges or limitations:

- PMTCT HIV testing services may not be available at some ANC HSS sites, or service availability may be inconsistent due to stock-outs of HIV test kits or other factors.
- The quality of individual-level PMTCT programme data at ANC HSS sites may be of uncertain or varying quality.
- Quality assurance (QA) for PMTCT HIV testing at ANC HSS sites may not meet the required standards of rigour.
- Selection bias may be inherent in PMTCT HIV testing data due to potential associations between acceptance of PMTCT HIV testing and likelihood of being HIV-positive or of known HIV-positive status.
- Information on historical trends in HIV prevalence HIV prevalence from PMTCT programme data is not available.

1 Fifth meeting of the WHO/AFRO Technical Network on HIV/AIDS and STI Surveillance. Harare, Zimbabwe, 26–28 September 2006.

2 Sixth meeting of the WHO/AFRO Technical Network on HIV/AIDS and STI Surveillance. Addis Ababa, Ethiopia, 1–3 July 2009.

3 Fifth meeting of the WHO/AFRO Technical Network on HIV/AIDS and STI Surveillance. Harare, Zimbabwe, 26–28 September 2006.

2.4 Early assessments of the utility of PMTCT programme data for HSS

Until recently, few studies assessing the utility of PMTCT data for HSS had been conducted in the sub-Saharan Africa (SSA) region,[4] which continues to report the world's largest generalized HIV epidemics. *(18)* In part, this reflects the relatively slow expansion of PMTCT services to ANC facilities during the initial phase of implementation of PMTCT programmes. In addition, low or uneven participation levels in PMTCT programmes during the initial phases of programme expansion were seen as obstacles to deriving accurate HIV estimates and trends from PMTCT data.

Outside of SSA, Thailand has demonstrated the feasibility of using PMTCT programme data for HSS, leveraging on a high-performing PMTCT programme with a robust data system (Box 1).

Box 1. The experience of Thailand

Thailand has demonstrated the feasibility of using PMTCT data for HSS. In 2000, Thailand instituted a national PMTCT programme based on routine, opt out testing during ANC services and at delivery.*(19)* By 2002, coverage of ANC services reached 97% and uptake of PMTCT HIV testing among pregnant women attending ANC services was 96% (Figure 1).*(20)*

In 2002, the Thai Ministry of Public Health compared 2001 and 2002 ANC HSS results to PMTCT-based HIV data captured by the Perinatal HIV Intervention Monitoring System (PHIMS), which collects PMTCT HIV testing data for women attending all government hospitals.*(16)* This analysis found that PMTCT HIV data accurately reflected ANC HSS data (Figure 2). The strength of the PHIMS data system facilitated the comparison of ANC HSS and PMTCT data, and supported high-quality routine PMTCT data.

In 2003, the Thai Ministry of Public Health transitioned to a system of using routine PMTCT HIV testing data for HSS. Surveillance is conducted for two months each year, and all public hospitals are included in the HSS system.

During the surveillance period, individual-level routine PMTCT data on women making their first ANC visit are collected and used for HSS. Variables captured from routine data include age, parity, gravidity, race, syphilis test result and PMTCT HIV test result. These data are abstracted from site logbooks by ANC nurses onto paper surveillance forms. These forms are forwarded to Provincial Health Offices, where the data are entered into a national HIV serosurvey database for use at the provincial and national levels.

Figure 1. Uptake of PMTCT HIV testing in government hospitals, Thailand, 2001–2011*(20)*

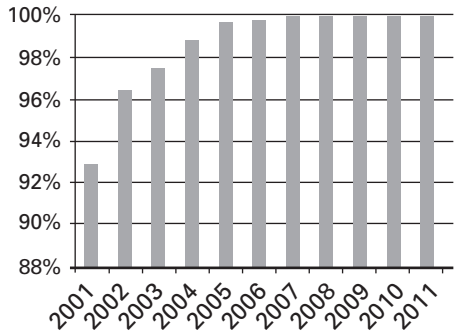
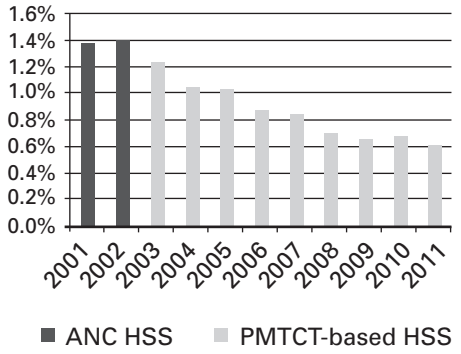


Figure 2. HIV prevalence from ANC HSS and PMTCT-based HSS, Thailand, 2001–2011*(21)*



With the transition from ANC HSS to PMTCT-based HSS, the Thai Ministry of Public Health eliminated duplication of HIV testing for surveillance and realized budget savings.

4 Fifth meeting of the WHO/AFRO Technical Network on HIV/AIDS and STI Surveillance. Harare, Zimbabwe, 26–28 September 2006.

To date, no country in SSA has replaced ANC HSS with PMTCT-based HSS. However, many countries have conducted or are actively planning assessments to explore the potential for transition.

Currently published findings from studies conducted in SSA provide mixed evidence regarding the quality of PMTCT programme data for HIV surveillance purposes. Studies in Botswana (2005–2007),*(22)* Cameroon (2003) *(23)* and Uganda (2001–2003, 2004–2005)*(24,25)* found that PMTCT data could be adequate for HSS purposes. These studies cited similarities in ANC HSS and PMTCT prevalence estimates as the primary reason for supporting the use of PMTCT data for surveillance. Other reasons included high levels of PMTCT HIV testing uptake, representativeness of PMTCT programme data and adequate PMTCT data quality.

However, studies in Kenya (2003, 2005, 2006, 2008, 2010) (Box 2),*(17,26,27,28)* Burkina Faso (1996),*(29)* Zimbabwe (2004),*(30)* Uganda (2002–2003, 2004),(31)[5] Ethiopia (2005),*(28)* and Rwanda (2007)*(32)* reported substantial obstacles to using PMTCT programme data for HSS. In general, these studies found overall HIV prevalence estimates from PMTCT data to be similar to those from ANC HSS. However, these studies reported substantial challenges to transitioning to PMTCT-based HSS, including:

- differences in age-specific estimates between the two data sources;
- low uptake of PMTCT HIV testing;
- differences in estimates when PMTCT HIV testing uptake was low or when PMTCT services had been recently introduced at the ANC;
- limited PMTCT data quality;
- site-level differences in HIV prevalence estimates between ANC HSS and PMTCT data.

A more detailed summary of published findings from studies conducted in SSA assessing the utility of PMTCT data for surveillance is provided in Appendix A.*(33)*

Box 2. The experience of Kenya

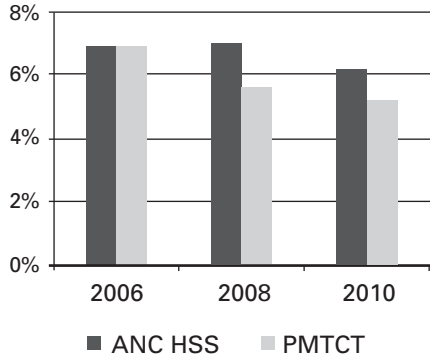
Kenya started biennial ANC HSS in 1990 and rolled out PMTCT services in 1999. Kenya has conducted multiple studies to assess the utility of PMTCT data for HSS, including studies comparing ANC HSS and PMTCT HIV test results among pregnant women sampled by ANC HSS in 2006, 2008 and 2010.*(26,27)* These evaluations have shown significant progress in the quality of PMTCT HIV data:

- Coverage of PMTCT services at ANC HSS sites increased from 15% in 2003 to 100% in 2005.
- Uptake of PMTCT HIV testing among women attending ANC services increased from 56% in 2003 to 99% in 2010.
- National HIV prevalence estimates from ANC HSS and PMTCT-based HSS have been similar (Figure 3).

However, studies have also revealed ongoing challenges to the suitability of using PMTCT data for HSS:

- The quality of data in PMTCT records was inconsistent. In 2010, a third of the PMTCT logbooks at ANC HSS sites were mising more than 10% of the HIV test results.

Figure 3. HIV prevalence from ANC HSS and PMTCT among pregnant women sampled by ANC HSS, Kenya, 2006, 2008 and 2010*(26,27)*



- Individual level agreement between ANC HSS and PMTCT HIV testing results was inconsistent.
- PMTCT logbooks at ANC HSS sites do not adequately document pregnant women who are not HIV tested because they already know that their HIV status is positive.

Based on the assessment findings, Kenya formulated strategies to address these challenges and plans to conduct another PMTCT surveillance assessment in 2013.

5 Finkbeiner T et al. Effect of PMTCT program on sampling for unlinked anonymous testing, Uganda, 2004. WHO/AFRO Surveillance Officers Technical Network on HIV/AIDS and STI Surveillance Meeting; Harare, Zimbabwe, 26–28 September 2006

3. Overview of assessing the utility of PMTCT programme data for surveillance

3.1 Elements of a PMTCT surveillance assessment

The decision to transition to a PMTCT-based system of HSS among pregnant women should be supported by a robust and comprehensive evidence base. In order for PMTCT data to serve as the basis for HSS, PMTCT HIV testing services need to be consistently available at all ANC HSS sites, PMTCT HIV testing needs to be accurate, PMTCT data need to be of high quality, and PMTCT-based HIV prevalence estimates need to be unbiased. The objective of a surveillance assessment is to evaluate the ability of PMTCT HIV testing and programme data to meet the needs of HSS.

To achieve this objective, a comprehensive assessment would address five areas of PMTCT HIV testing and data quality:

1. Agreement between ANC HSS and PMTCT HIV test results;
2. The magnitude of selection bias inherent in PMTCT HIV testing data compared to ANC HSS data;
3. The proportion of ANC HSS sites that provide PMTCT HIV testing services;
4. The quality of routinely collected PMTCT programme data at ANC HSS sites, including the minimum dataset of variables for surveillance;
5. The state of QA practices for PMTCT HIV testing at ANC HSS sites.

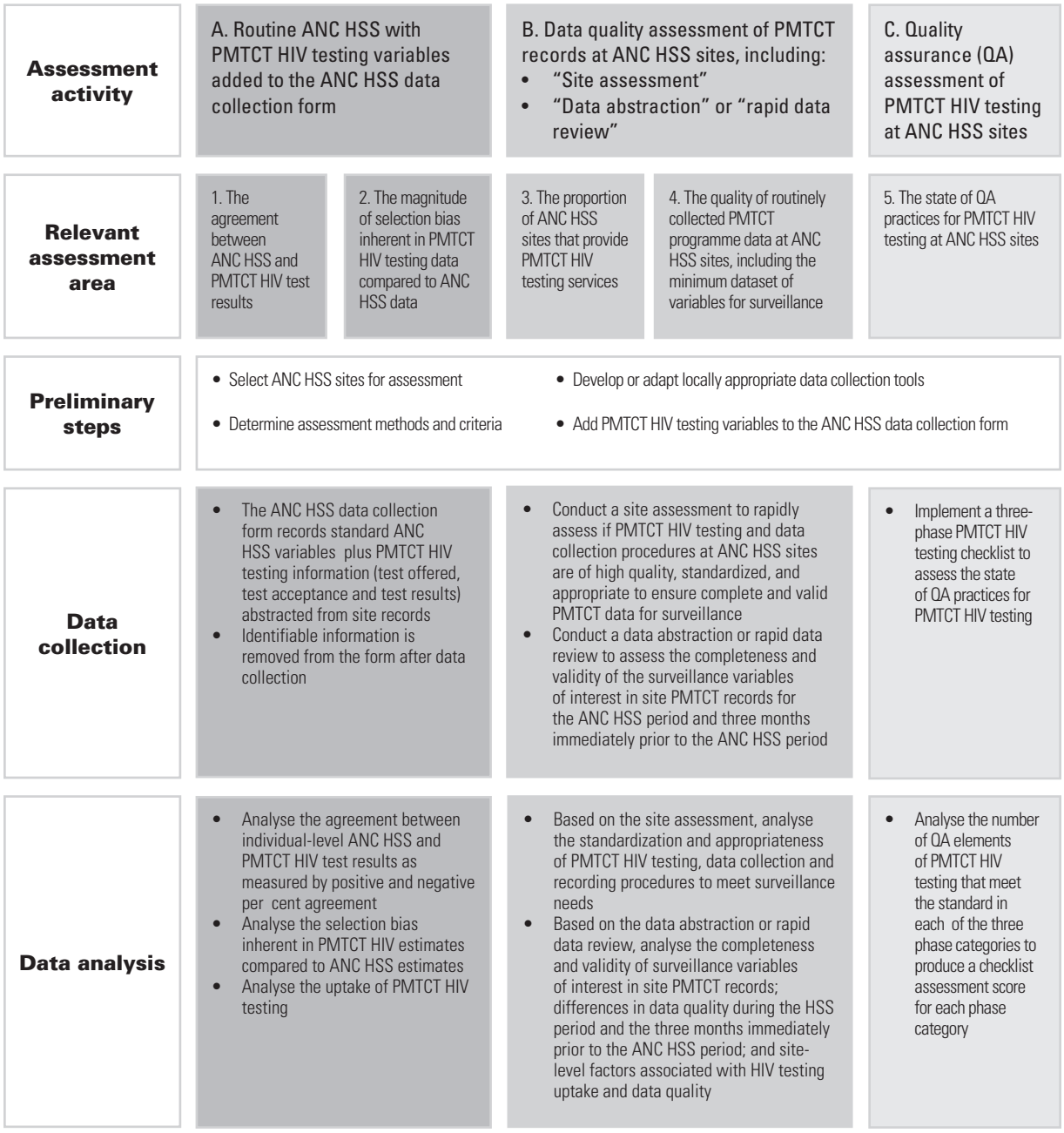
Figure 4 outlines the process flow for conducting a PMTCT surveillance assessment. The three principal assessment activities are as follows:

A. Routine ANC HSS with PMTCT HIV testing variables added to the ANC HSS data collection form (addresses assessment areas 1 and 2);
B. A data quality assessment (DQA) of PMTCT data and data recording practices at ANC HSS sites (addresses assessment areas 3 and 4). The DQA has two components:
    - "site assessment": a questionnaire to rapidly assess if PMTCT HIV testing and data collection procedures at the ANC HSS site are of high quality, standardized, and appropriate to ensure complete and valid PMTCT data for surveillance;
    - "data abstraction" or "rapid data review": systematic examinations of the completeness and validity of routinely collected PMTCT data at ANC HSS sites;
C. A QA assessment of PMTCT HIV testing at ANC HSS sites (addresses assessment area 5).

Assessing the utility of PMTCT data for HSS involves a cycle of assessment, actions to improve programme performance and further assessment. The results of each assessment serve to identify limitations in PMTCT HIV testing and data quality, and inform recommendations for improvement. Strategies to address these limitations can be developed and implemented before conducting another assessment. This cycle may continue until assessment findings show that PMTCT programme data are suitable for surveillance.

Assessing and improving PMTCT programme data for HIV surveillance requires a collaborative effort among all relevant agencies and stakeholders, including surveillance and monitoring and evaluation (M&E) staff, maternal and child health (MCH) and PMTCT programmes, the national HIV/AIDS control programme, the national HIV reference laboratory and key partners. To ensure that the results of the assessment are translated into actions to improve PMTCT programme performance and data, it is advisable that all of these stakeholders form a technical body charged with directing the assessment. In this way, all important stakeholders will be actively engaged in the design and implementation of the assessment, interpretation of assessment results, and generation and implementation of recommendations for programme improvement.

Figure 4. Process flow for conducting a PMTCT surveillance assessment



3.2 Deciding to conduct a PMTCT surveillance assessment

It is suggested that all countries currently conducting ANC HSS implement a PMTCT surveillance assessment. In countries where PMTCT HIV testing or programme data are known to be of substandard quality, an assessment will help to identify and quantify programme gaps and inform strengthening measures. In countries where PMTCT services in ANC HSS sites are limited but expanding, an assessment can inform the immediate improvement of existing sites in anticipation of future transition to PMTCT-based HSS.

3.3 Preparing to conduct a PMTCT surveillance assessment

3.3.1 Site selection

A PMTCT surveillance assessment seeks to understand the true condition of PMTCT HIV testing services and programme data at ANC HSS sites. It is suggested that all ANC HSS sites offering PMTCT HIV testing services be included in the assessment. Restricting selection to those sites with well-established or high-performing PMTCT programmes would bias the assessment.

Some countries may face significant challenges to including all ANC HSS sites offering PMTCT HIV testing services in the assessment (due to resource constraints or the number or accessibility of ANC HSS sites). These countries may consider an alternative site selection strategy in which activities B (DQA of PMTCT data) and C (QA assessment of PMTCT HIV testing) of the assessment are conducted at a subset of ANC HSS sites (Table 1). Such a subset could be selected to achieve a representative sample of the various settings in which ANC HSS is conducted (urban/rural, geographical regions, etc.). Conducting activities B and C at a sample of ANC HSS sites can provide an estimate of the overall quality of PMTCT data and QA of HIV testing at ANC HSS sites. However, it is suggested that the final assessment before making the decision to transition to PMTCT-based HSS include all three activities at all ANC HSS sites to ensure the readiness of all sites for transition.

PMTCT-based HSS has the potential to facilitate expansion of the number of HSS sites to additional sites providing PMTCT HIV testing services. However, it is suggested that initial efforts focus on assessing and transitioning existing ANC HSS sites. Expansion of PMTCT-based HSS to include additional sites may be considered at a future date. Additional sites would need to be rigorously assessed to ensure that PMTCT HIV testing and data are of sufficient quality to support surveillance.

Table 1. Comprehensive and alternative* site selection approaches for the three principal activities of the PMTCT surveillance assessment

Assessment activity	Site selection: comprehensive strategy	Site selection: alternative* strategy
A. Routine ANC HSS with PMTCT HIV testing variables added to the ANC HSS data collection form	Conduct at all ANC HSS sites offering PMTCT HIV testing services	Conduct at all ANC HSS sites offering PMTCT HIV testing services
B. Data quality assessment (DQA)	Conduct at all ANC HSS sites offering PMTCT HIV testing services	Conduct at a subset of ANC HSS sites selected to achieve representation of diverse settings
C. Quality assurance assessment of PMTCT HIV testing	Conduct at all ANC HSS sites offering PMTCT HIV testing services	Conduct at a subset of ANC HSS sites selected to achieve representation of diverse settings

* The alternative strategy may be appropriate for countries that face considerable challenges to including all ANC HSS sites offering PMTCT HIV testing services in the assessment. However, it is suggested that, before making the decision to transition to PMTCT programme-based HSS, the final assessment involve a comprehensive site selection strategy.

3.3.2 Standards for interpreting assessment results

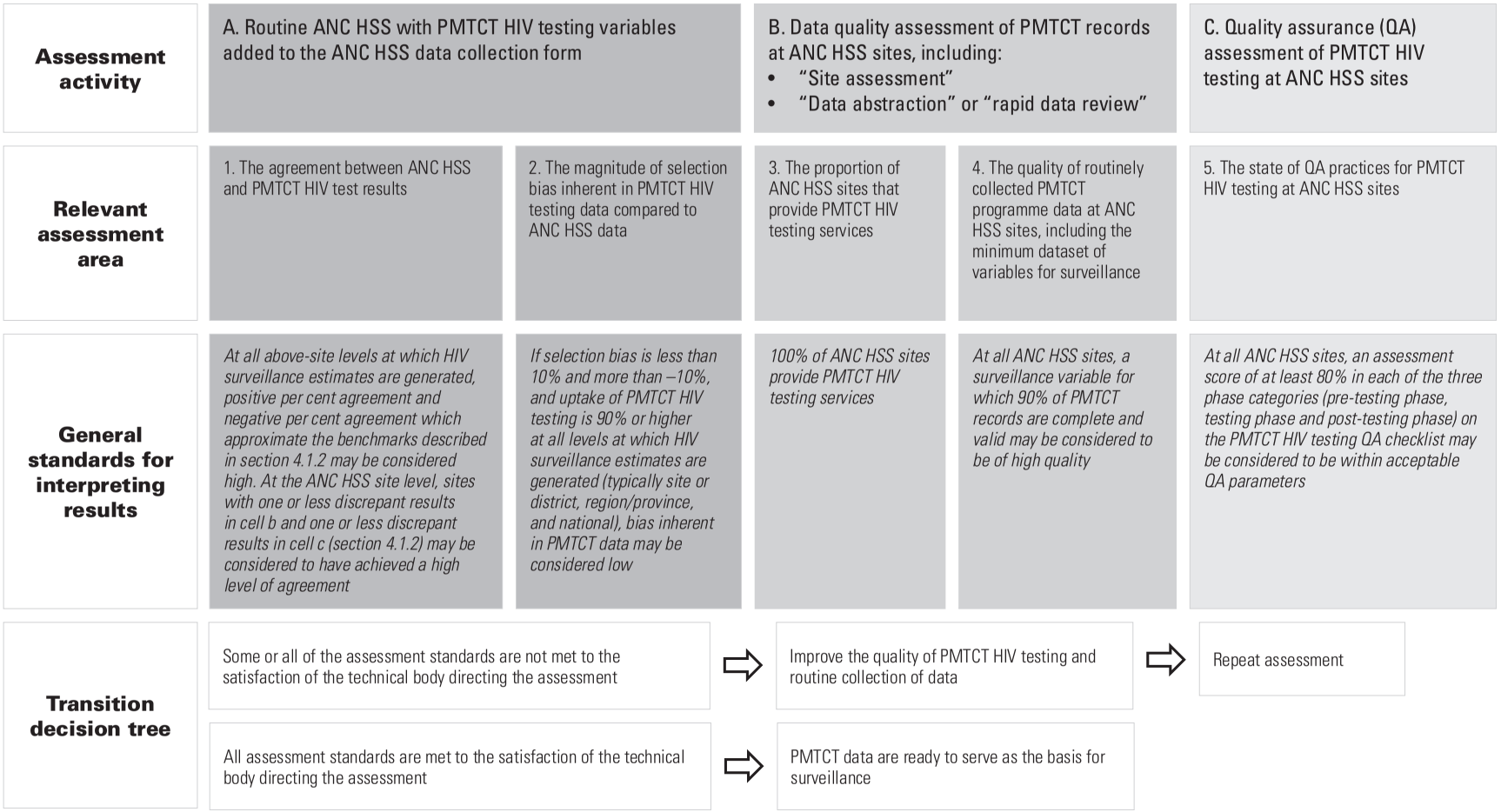
It is necessary that PMTCT HIV testing and programme data meet high standards to be considered ready to serve as the basis for HSS. These standards should reflect the consensus of the technical body charged with directing the PMTCT surveillance assessment, including government public health actors, partners and subject matter experts.

As general guidance, this document suggests the following general standards for the five assessment areas (described in section 3.1). Though not strict targets, these standards represent a high level of programme performance that may serve as a point of reference to aid countries in the interpretation of assessment results and guide local discussions on the readiness to transition to PMTCT-based HSS.

1. The agreement between ANC HSS and PMTCT HIV test results
   It is important to achieve a high level of agreement between individual-level ANC HSS and PMTCT HIV test results. As a general standard, positive per cent agreement and negative per cent agreement between ANC HSS and PMTCT HIV test results which approximate the benchmarks described in section 4.1.2 at all above-site levels at which HIV surveillance estimates are generated (typically district/regional/provincial and national levels) may be considered high. At the ANC HSS site level, sites with one or less discrepant results in cell b (negative as per ANC HSS and positive as per PMTCT) and one or less discrepant results in cell c (positive as per ANC HSS and negative as per PMTCT) may be considered to have achieved a high level of agreement (section 4.1.2).
   - *At sites with a larger sample size and a higher HIV prevalence (sites with a sample size of 400 and an HIV prevalence of ≥18%, and sites with a sample size of 500 and an HIV prevalence of ≥14%), two or less discrepant results in cell b (negative as per ANC HSS and positive as per PMTCT) and two or less discrepant results in cell c (positive as per ANC HSS and negative as per PMTCT) may be considered to have achieved a high degree agreement (section 4.1.2).*
2. The magnitude of selection bias inherent in PMTCT HIV testing data compared to ANC HSS data
   It is important that the bias inherent in PMTCT data be low at all ANC HSS sites. As a general standard, if the selection bias is less than 10% and more than –10% at all levels at which HIV surveillance estimates are generated (typically site or district, region/province and national), the bias inherent in PMTCT data may be considered low. For the purpose of these guidelines, selection bias is defined as the per cent relative change (positive or negative) from the total HIV prevalence (among pregnant women who do and do not receive PMTCT HIV testing) to the observed HIV prevalence (among pregnant women who receive PMTCT HIV testing). To ensure the continuing ability of PMTCT-based HSS to limit bias to acceptable levels, it is important that the uptake of PMTCT HIV testing be high at all ANC HSS sites. As a general standard, an uptake of PMTCT HIV testing of 90% or greater may be considered high (Appendix C).
3. The proportion of ANC HSS sites that provide PMTCT HIV testing services
   It is important that 100% of ANC HSS sites provide PMTCT HIV testing services.
4. The quality of routinely collected PMTCT programme data, including the minimum dataset of variables for surveillance (age, date of visit and HIV test result)
   It is important that all surveillance variables of interest, including the minimum dataset of variables for surveillance (age, date of visit and PMTCT HIV test result), be of high quality in site records at all ANC HSS sites. As a general standard, a variable for which 90% of site records are complete and valid may be considered to be of high quality.
5. The state of QA practices for PMTCT HIV testing
   It is important to maintain a robust system of QA supporting routine PMTCT HIV testing at all HSS sites. As a general standard, an assessment score of at least 80% in each of the three phase categories (pre-testing phase, testing phase and post-testing phase) on the QA checklist for PMTCT HIV testing" to be consistent. (Appendix E) May be considered to be within acceptable QA parameters.

Should the assessment findings show that standards are not met to the satisfaction of the technical body charged with directing the assessment, the country would not be considered ready to transition to PMTCT-based HSS. In this scenario, the results of the assessment can be used to generate recommendations for improvement of PMTCT programmes and data quality. Strategies to realize these improvements may be implemented before the next PMTCT surveillance assessment. This process of assessment, programme improvement and re-assessment would continue until all standards are met. Figure 5 shows PMTCT surveillance assessment activities, assessment areas, general standards for interpreting assessment results and a decision tree for transitioning from ANC HSS to PMTCT-based HSS among pregnant women.

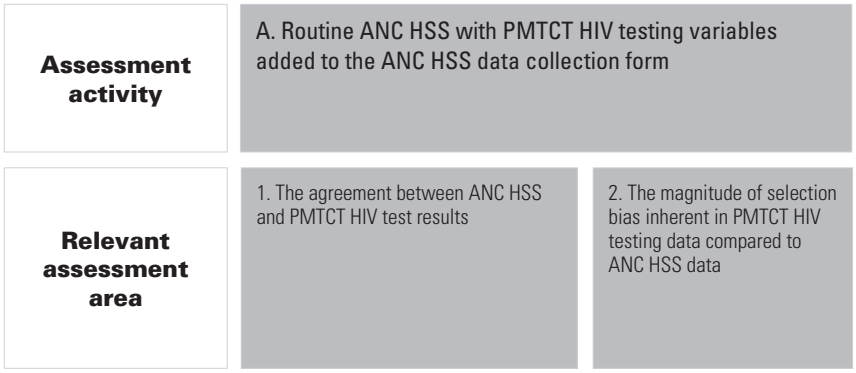
Figure 5. PMTCT surveillance assessment activities, assessment areas, general standards for interpreting results and transition decision tree



4. Assessment activity A: Routine ANC HSS with PMTCT HIV testing variables added to the ANC HSS data collection form

This section describes methods for the conduct of routine ANC HSS with PMTCT HIV testing variables added to the ANC HSS data collection form (Figure 6). This activity addresses assessment areas 1 (the agreement between ANC HSS and PMTCT HIV test results) and 2 (the magnitude of selection bias inherent in PMTCT HIV testing data compared to ANC HSS data).

Figure 6: Assessment Activity A



4.1 Comparison of HIV test results from ANC HSS and PMTCT programme data

For PMTCT programme data to serve as the basis for HSS, it is important that there be a high level of agreement between ANC HSS and PMTCT HIV test results. A comparison of ANC HSS and PMTCT HIV test results is essential to assess the utility of PMTCT data for surveillance.

Individual-level comparison of ANC HSS and PMTCT HIV test results offers a rigorous method to assess the agreement between the two data sources. Previous studies comparing ANC HSS and PMTCT HIV data have largely relied on comparisons of aggregate HIV prevalence estimates.*(16,17,24,25,31)* Although aggregate HIV prevalence estimates from ANC HSS and PMTCT programme data may be similar, a direct comparison of the individual HIV test results between ANC HSS and PMTCT programme data may reveal important discrepancies. Table 2 presents an example comparison of ANC HSS and PMTCT HIV test results in which aggregate prevalence estimates are identical—20% as per ANC HSS and 20% as per PMTCT—but individual HIV test results are highly discrepant—positive per cent agreement is 70%. In this example, of the 100 women testing HIV-positive by ANC HSS, only 70 are identified as HIV-positive by PMTCT HIV testing.

Table 2. Comparison of discrepant ANC HSS and PMTCT HIV test results that produce identical prevalence estimates

	ANC HSS HIV test		
PMTCT HIV test	HIV+	HIV-	Total
HIV+	70	30	100
HIV-	30	370	400
Total	100	400	500

ANC HSS HIV prevalence = 20%
PMTCT HIV prevalence = 20%
Positive per cent agreement =70%
Negative per cent agreement = 93%

4.1.1 Collection of PMTCT HIV testing variables using the ANC HSS data collection form

To compare ANC HSS and PMTCT HIV test results, variables can be added to the ANC HSS data collection form to capture PMTCT HIV testing uptake and results. This method allows countries to collect and compare ANC HSS and PMTCT HIV test results for each pregnant woman sampled by ANC HSS, quantify PMTCT HIV testing uptake and explore potential bias in PMTCT-based HIV prevalence estimates. This method also maintains the anonymity of pregnant women whose data are examined.

To collect these data, the following questions and response options can be added to the ANC HSS data collection form:

1. Was a PMTCT HIV test offered during this visit?
   - Yes (if Yes, go to question 2)
   - No (If No, stop here)
2. Was a PMTCT HIV test accepted?
   - Yes (if Yes, go to question 3)
   - No: previously tested positive (If No, stop here)
   - No (If No, stop here)
3. What were the PMTCT HIV test results?
   - Test 1 result: __ Positive __ Negative __ Missing
   - Test 2 result: __ Positive __ Negative __ Missing __ Not applicable
   - Test 3 result: __ Positive __ Negative __ Missing __ Not applicable
   - Other: __ Positive __ Negative __ Missing __ Not applicable

Question two includes a response option for pregnant women who were not tested because they already knew that they were HIV-positive. Pregnant women attending ANC services who know their status to be HIV-positive would be sampled by ANC HSS. If HIV information on these women is not documented in PMTCT records, these data would falsely underestimate HIV prevalence. For PMTCT programme data to serve as the basis for HSS, it will be imperative to ensure that the serostatus of known HIV-positive pregnant women is recorded and that this information is available for surveillance (see also sections 4.1.3 and 5.2).

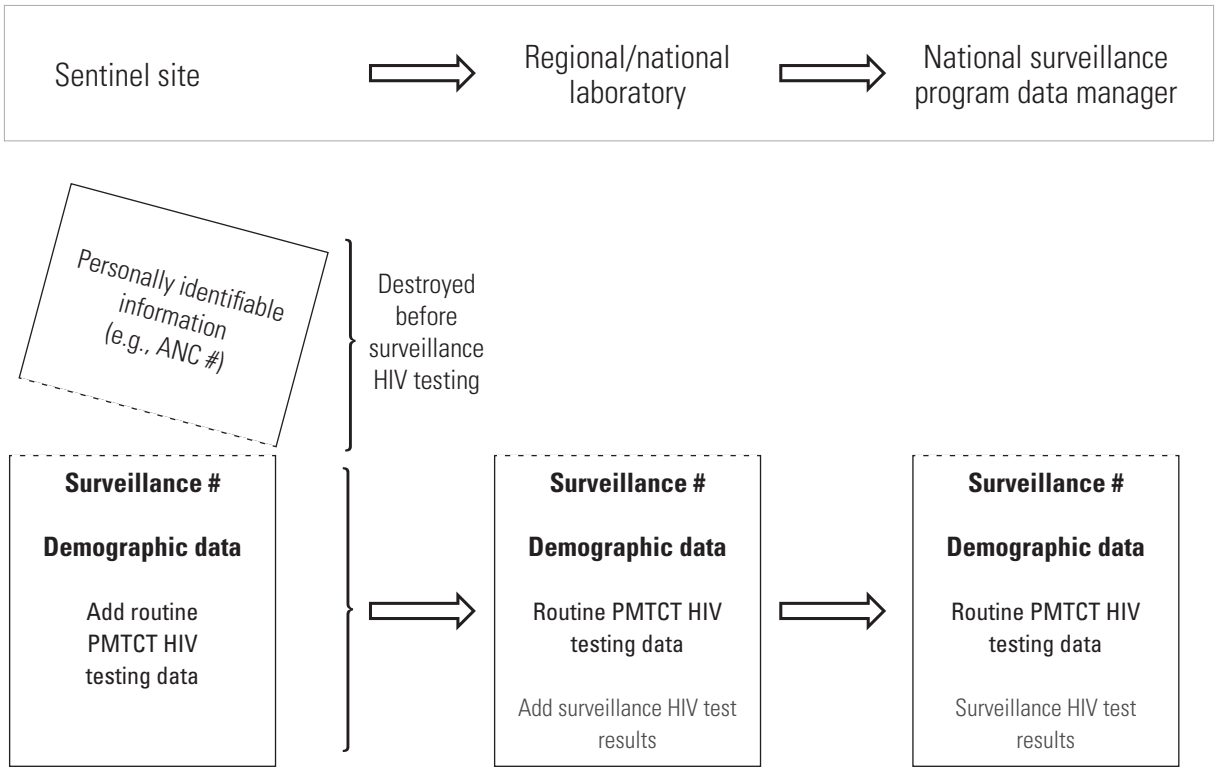
Question three may be adapted to suit the country's PMTCT HIV testing algorithm and ensure that the final HIV status determination is captured by the question. A sample ANC HSS data collection form with additional PMTCT HIV testing variables is provided in Appendix B.

Implementation of ANC HSS using a revised data collection form that captures PMTCT HIV testing variables should meet the same rigorous ethical and methodological standards as routine ANC HSS. The collection of PMTCT HIV testing variables would need to be incorporated into existing standard operating procedures (SOPs) for ANC HSS in a way that ensures the security and anonymity of PMTCT HIV testing information. Figure 7 shows a possible data collection flow for the ANC HSS data collection form. In this approach, a surveillance identification number is assigned to each pregnant woman. Sociodemographic, syphilis testing and PMTCT HIV testing information is abstracted from ANC and PMTCT programme records and recorded on the data collection form. A detachable section of the form containing personal identifiable information is removed and properly destroyed. The form and the ANC HSS blood specimen are sent to the regional or

national laboratory responsible for ANC HSS HIV testing. The laboratory technician who tests the specimen records the HIV test results on the form and sends the completed form to the regional or national data manager.

A more detailed description of methods for conducting ANC HSS can be found in WHO's *Guidelines for conducting sentinel serosurveys among pregnant women and other groups.(4)*

Figure 7. Possible flow of ANC HSS data collection forms for the PMTCT surveillance assessment



4.1.2 Analysis of ANC HSS and PMTCT HIV test results

A comprehensive analysis of ANC HSS and PMTCT HIV test results would occur at multiple levels: site, district/region/province, residence (i.e. rural versus urban) and national. It is important to conduct analysis at the ANC HSS site level. Site-level analysis allows countries to more precisely identify suboptimal performance of PMTCT programmes. Further, some countries may report ANC HSS site-level HIV estimates and use these estimates to inform HIV control efforts. Finally, EPP/Spectrum requires accurate site-level ANC HSS data as one of the inputs used to model national HIV estimates.*(5,6)*

In some countries, ANC HSS may use "satellite" facilities to augment the sampling of pregnant women around ANC HSS sites in low-population density areas. These guidelines suggest conducting analysis at the ANC HSS site level, including data contributed by satellite facilities. Sample sizes at the satellite level may be too small for meaningful analysis.

Method for analysis

Individual-level data are used to calculate positive per cent agreement and negative per cent agreement of ANC HSS and PMTCT HIV testing, as shown in Table 3.

Table 3. Calculation of positive per cent agreement and negative per cent agreement of ANC HSS and PMTCT HIV testing data

	ANC HSS HIV test*		
PMTCT HIV test	HIV+	HIV-	Total
HIV+	a	b	a + b
HIV-	c	d	c + d
Total	a + c	b + d	a + b + c +d

$$Positive\ per\ cent\ agreement = 100 \times \frac{a}{a+c}$$

$$Negative\ per\ cent\ agreement = 100 \times \frac{d}{b+d}$$

* Non-reference standard

The calculations for positive per cent agreement and negative per cent agreement are identical to those of sensitivity and specificity, respectively. However, because ANC HSS HIV testing is not a reference standard (i.e. the ANC HSS HIV testing algorithm has imperfect performance characteristics—less than 100% sensitivity and specificity), the terms positive per cent agreement and negative per cent agreement are used. These measures are used in this context because they provide a nuanced picture of the relationship between the two testing algorithms and where disagreement may be occurring.

Assessment standards for agreement between ANC HSS and PMTCT HIV test results

It is suggested that analysis of ANC HSS and PMTCT HIV test results address two general standards:

- *It is important to achieve a high level of agreement between ANC HSS and PMTCT HIV testing results at all above-site levels at which HIV surveillance estimates are generated (typically district/regional/provincial and national levels). As a general standard, positive per cent agreement and negative per cent agreement that approximate the benchmarks described in Table 4 may be considered high.* Benchmarks differ according to the HIV prevalence. Countries may find their HIV prevalence according to ANC HSS and read across the table to identify the positive and negative per cent agreement benchmarks that correspond to the prevalence level.

Table 4. Benchmarks for positive per cent agreement and negative per cent agreement OF ANC HSS and PMTCT HIV testing at all above-site levels at which HIV surveillance estimates are generated, by ANC HSS HIV prevalence (see Appendix C for details on the generation of these benchmarks)

HIV prevalence according to ANC HSS (%)	Benchmark for positive per cent agreement (%)	Benchmark for negative per cent agreement (%)
0.5	94.7	99.9
1.0	96.6	99.9
1.5	97.0	99.9
2.0	97.2	99.9
2.5	97.3	99.9
3.0	97.3	99.9
3.5	97.4	99.9
4.0	97.4	99.9
6.0	97.5	99.8
8.0	97.6	99.8
9.0–16.0	97.6	99.7
17.0–26.0	97.6	99.5

- *It is important to achieve a high level of agreement between ANC HSS and PMTCT HIV test results at the ANC HSS site level. As a general standard, sites with one or less discrepant result in cell b (negative as per ANC HSS and positive as per PMTCT HIV testing) and one or less discrepant result in cell c (positive as per ANC HSS and negative as per PMTCT HIV testing) (Table 5) may be considered to have achieved a high level of agreement.*
  - At sites with larger sample sizes and higher HIV prevalence, slightly more discrepant results would be expected. This includes sites with a sample size of 400 and an HIV prevalence of ≥18%, and sites with a sample size of 500 and an HIV prevalence of ≥14% (see Appendix C for further information). *As a general standard for such scenarios, sites with two or less discrepant results in cell b (negative as per ANC HSS and positive as per PMTCT HIV testing) and two or less discrepant results in cell c (positive as per ANC HSS and negative as per PMTCT HIV testing) (Table 5) may be considered to have achieved a high level of agreement.*

Table 5. Benchmarks for discrepant results in cells b and c for site-level comparisons of ANC HSS and PMTCT HIV test results*

	ANC HSS HIV test	
PMTCT HIV test	HIV+	HIV-
HIV+	a	b ≤1
HIV-	c ≤1	d

* At sites with larger sample sizes and higher HIV prevalence (sites with a sample size of 400 and an HIV prevalence of ≥18%, and sites with a sample size of 500 and an HIV prevalence of ≥14%), the benchmark is b ≤2 and c ≤2.

These benchmarks were developed to characterize a high level of agreement between ANC HSS and PMTCT HIV test results while taking into account the performance characteristics of the two testing algorithms and expected statistical variability in test performance. These benchmarks represent expected results in the absence of human error. Though not strict targets, these benchmarks are provided as points of reference to aid countries in interpreting the results of comparison.

A level of agreement between ANC HSS and PMTCT HIV testing that does not approximate the benchmarks listed in Tables 4 and 5 signifies that the disagreement exceeds what would be expected based on statistical variability and the performance characteristics of the two testing algorithms .Such disagreement is likely to be due to human error in operating ANC HSS or PMTCT HIV tests. If ANC HSS enzyme-linked immunosorbent assay (ELISA) testing is subject to appropriately rigorous QA and quality control (QC) measures,*(4)* it may be inferred that substantial disagreement between ANC HSS and PMTCT HIV testing is due to suboptimal operation of PMTCT HIV test kits. Appendix C contains further information on the statistical methods used to generate these benchmarks.

Impact of testing technologies on the agreement between ANC HSS and PMTCT HIV test results

Differences in testing technologies between ANC HSS and PMTCT HIV testing can affect comparisons. ANC HSS HIV testing may be done using a fourth-generation ELISA that detects both HIV antigen and antibody, while most rapid tests used in PMTCT programme settings detect only HIV antibody. This difference can result in a slight discordance between ANC HSS and PMTCT HIV testing results.

A careful evaluation of the optical density values produced by ELISA (whether third- or fourth generation) for specimens found to be discordant between the two algorithms can be informative. If the ELISA optical density results are above the cut-off threshold but low, they are more likely to be ELISA false-positive. Countries may consider further testing of such specimens by Western blot or polymerase chain reaction (PCR) to confirm or rule out HIV infection.

4.1.3 Analysis of the impact of selection bias

Because some pregnant women sampled by ANC HSS may opt out of PMTCT HIV testing, PMTCT-based HIV estimates could be vulnerable to selection bias. Previous studies have identified several factors that may introduce selection bias into PMTCT-based estimates.*(34,35,36,37,38,39,40)* Pregnant women who perceive that they have an increased risk of being infected may be more likely to opt out of PMTCT testing, resulting in an underestimate of HIV prevalence. Other factors—including reluctance to test without a partner's consent, educational level, age, parity, gravidity and employment—have also been found to be associated with opting out of HIV testing, although the direction of bias introduced by these factors is unclear. Pregnant women who are not tested because they already know their HIV status to be positive can also contribute to selection bias, and it is essential to consider these women when conducting an assessment (Box 3).

Box 3. Selection bias and pregnant women who already know they are HIV-positive

Pregnant women who already know their HIV status to be positive may not receive PMTCT HIV testing. Such women may opt out of testing, or they may not be offered HIV testing. If the HIV serostatus of known HIV-positive women is not recorded in PMTCT records, these women could be a systematic source of selection bias. If known HIV-positive women are not included in PMTCT programme data, surveillance estimates based on these data would falsely underestimate HIV prevalence. For PMTCT programme data to serve as the basis for HSS, it is imperative for PMTCT programmes to record the serostatus of known HIV-positive pregnant women and to make this information available for surveillance (see also section 5.2).

This section describes methods for the following:

- Measuring the impact of selection bias on PMTCT-based HIV prevalence estimates;
- Determining if the selection bias is small enough to consider PMTCT data suitable for HSS;
- Assessing the factors driving bias to inform future actions to reduce bias.

Measuring the impact of selection bias

For the purpose of these guidelines, selection bias is defined as the per cent relative change (positive or negative) from the total HIV prevalence (among pregnant women who do and do not receive PMTCT HIV testing) to the observed HIV prevalence (among pregnant women who receive PMTCT HIV testing). Examples of selection bias are presented in Table 6. Usually, the total HIV prevalence is not known. However, in this assessment, ANC HSS will provide HIV test results for pregnant women who do and do not receive PMTCT HIV testing.

Table 6. Examples of selection bias in PMTCT-based HIV prevalence estimates

Total HIV prevalence (pregnant women who receive PMTCT HIV testing and women who do not receive PMTCT HIV testing)	Observed HIV prevalence (pregnant women who receive PMTCT HIV testing)	Selection bias
10%	9%	–10%
10%	8%	–20%

The formula for selection bias is given below.

$$Selection\ bias = \frac{\left(\begin{array}{c}HIV\ prevalence\ among\ pregnant\\ women\ sampled\ by\ ANC\ HSS\ who\\ consent\ to\ PMTCT\ HIV\ testing\end{array}\right) - \left(\begin{array}{c}HIV\ prevalence\ among\\ all\ pregnant\ women\\ sampled\ by\ ANC\ HSS\end{array}\right)}{HIV\ prevalence\ among\ all\ pregnant\ women\ sampled\ by\ ANC\ HSS} \times 100$$

Determining if the selection bias is small enough to consider PMTCT data suitable for HSS

For PMTCT data to serve as the basis for HSS, it is important that the bias inherent in these data be low. As a general standard, if the selection bias is less than 10% and more than –10% at all levels at which HIV surveillance estimates are generated (typically site or district, region/province and national), bias inherent in PMTCT data may be considered low.

Assessing the factors driving selection bias

An analysis of the components of selection bias can provide a better understanding of PMTCT-based HIV prevalence estimates and the potential for bias. Assessing the factors driving selection bias can also provide information on the role of previously known HIV-positive pregnant women in generating bias.

From the information collected on the revised ANC HSS data collection form (section 4.1.1), countries can estimate two parameters that together determine the magnitude and direction of selection bias:

A. Uptake of PMTCT HIV testing: This is the proportion of pregnant women sampled by ANC HSS who receive PMTCT HIV testing.

$$Uptake\ of\ PMTCT\ HIV\ testing = \frac{\begin{array}{c}number\ of\ pregnant\ women\ sampled\ by\\ ANC\ HSS\ who\ receive\ PMTCT\ HIV\ testing\end{array}}{total\ number\ of\ pregnant\ women\ sampled\ by\ ANC\ HSS}$$

B. Differential prevalence ratio: This is the ratio of the HIV prevalence among pregnant women sampled by ANC HSS who receive PMTCT HIV testing to the HIV prevalence among pregnant women sampled by ANC HSS who do not receive PMTCT HIV testing. When the differential prevalence ratio is close to one, HIV prevalence among pregnant women who do and do not receive PMTCT HIV testing is very similar. As the differential prevalence ratio moves away from one (in either the positive or negative direction), HIV prevalence among pregnant women who do and do not receive PMTCT HIV testing becomes more dissimilar.

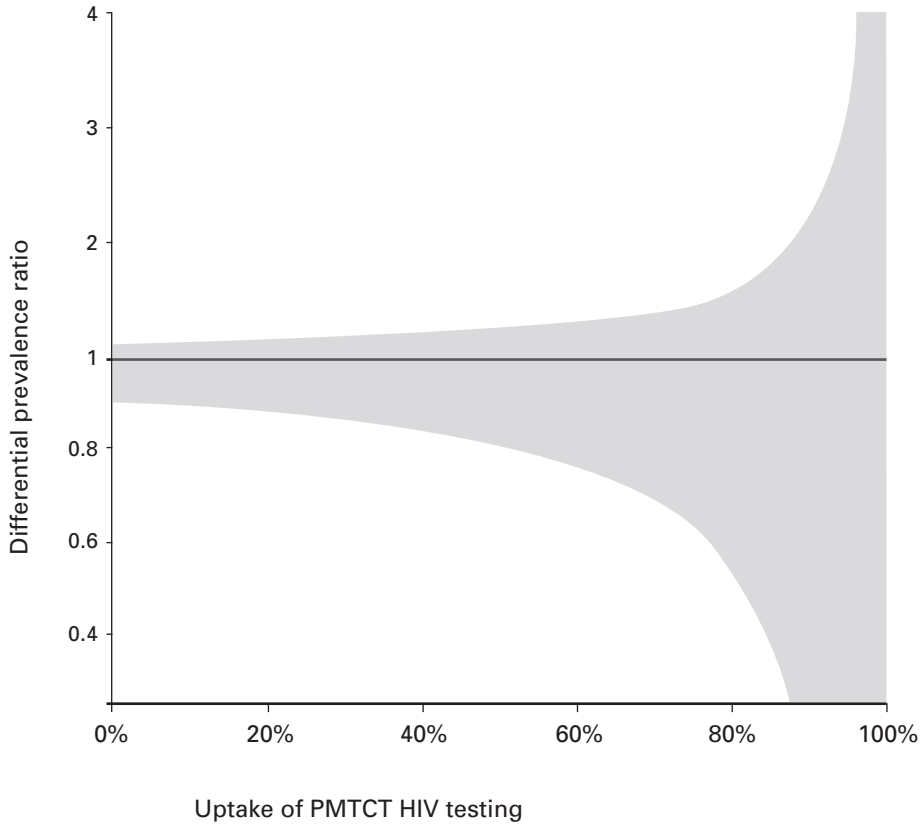
$$Differential\ prevalence\ ratio = \frac{\left(\begin{array}{c}number\ of\ pregnant\ \ women\ sampled\ by\ ANC\ HSS\ who\\ receive\ PMTCT\ HIV\ testing\ and\ are\ HIV\text{-}positive\\ \hline total\ number\ of\ pregnant\ women\ sampled\ by\ ANC\ HSS\\ who\ receive\ PMTCT\ HIV\ testing\end{array}\right)}{\left(\begin{array}{c}number\ of\ \ pregnant\ women\ sampled\ by\ ANC\ HSS\ who\\ do\ not\ receive\ PMTCT\ HIV\ \ testing\ and\ are\ HIV\text{-}positive\\ \hline total\ number\ of\ pregnant\ women\ sampled\ by\\ ANC\ HSS\ who\ do\ not\ receive\ PMTCT\ HIV\ testing\end{array}\right)}$$

An examination of the interplay between the uptake of PMTCT HIV testing and differential prevalence ratio can reveal the cause of selection bias and suggest opportunities to reduce it. A differential prevalence ratio substantially below one may suggest that the serostatus of previously known HIV-positive pregnant women is not being captured by PMTCT data. Such a result should focus attention on recording PMTCT data on previously known HIV-positive pregnant women.

Figure 8 demonstrates combinations of the uptake of PMTCT HIV testing and differential prevalence ratio which reduce the selection bias to less than 10% and more than –10%. If the uptake of PMTCT HIV testing is high, a substantial difference in HIV prevalence between pregnant women who do and do not receive PMTCT HIV testing can be tolerated while still minimizing the selection bias. However, as the uptake of PMTCT HIV testing drops, the difference in HIV prevalence between pregnant women who do and do not receive PMTCT HIV testing must remain small to avoid substantial bias.

To limit bias in PMTCT-based HIV prevalence estimates it is important that the uptake of PMTCT HIV testing be high at all ANC HSS sites. As a general standard, an uptake of PMTCT HIV testing of 90% or more may be considered high. Appendix C contains further information on the statistical methods used to generate this general standard.

Figure 8. Combinations of differential prevalence ratio and uptake of PMTCT HIV testing which limit selection bias to less than 10% and more than –10%, represented by the shaded area



5. Assessment activity B: Data quality assessment of PMTCT programme data and recording pratices at ANC HSS sites

This section describes methods for the conduct of a DQA of PMTCT data and data recording practices at ANC HSS sites (Figure 9). This activity addressed assessment areas 3 (the proportion of ANC HSS sites that provide PMTCT HIV testing services) and 4 (the quality of routinely collected PMTCT programme data at ANC HSS sites, including the minimum dataset of variables for surveillance).

Figure 9: Assessment Activity B

Assessment activity	B. Data quality assessment of PMTCT records at ANC HSS sites, including: • "Site assessment" • "Data abstraction" or "rapid data review"	
Relevant assessment area	3. The proportion of ANC HSS sites that provide PMTCT HIV testing services	4. The quality of routinely collected PMTCT programme data at ANC HSS sites, including the minimum dataset of variables for surveillance

A review of PMTCT programme data and data collection practices can reveal challenges and barriers to PMTCT HIV testing uptake and data capture at ANC HSS sites. A DQA of PMTCT programme data quality and data collection tools and practices will help to determine whether PMTCT programmes collect high-quality data that can be used for HSS.

5.1 Variables of interest for assessing PMTCT programme data quality

For the purpose of assessing the utility of PMTCT programme data for HSS, the term "minimum dataset" is used to refer to the three core variables essential for conducting HSS among pregnant women. This is the minimum set of variables to be evaluated in a DQA, including:

- age
- date of visit
- PMTCT HIV test result.

Countries may add additional surveillance variables to the DQA at their discretion based on the local context. The following variables are also of interest for HSS and could be included in a DQA:

- residence
- gravidity
- parity
- education level
- occupation
- PMTCT HIV test offered
- PMTCT HIV test accepted
- syphilis test result
- previously known HIV-positive status

The collection of a patient record number, such as an ANC number, may be required to facilitate data collection. Such a number may be needed in settings where it is necessary to link data sources at two sites to collect all the desired variables of interest for each pregnant woman. For example, the ANC number may be needed if the ANC register contains demographic information but a separate register is used to record HIV testing information. A patient record number may also be needed to identify duplicate records so as to avoid sampling the same pregnant women twice. After data collection, patient record numbers should be destroyed as this information can identify the person and could be used to link assessment data to specific individuals.

5.2 Methods for assessing PMTCT programme data through a DQA

The DQA presented in these guidelines consists of two parts:

- "site assessment": a questionnaire to rapidly assess if PMTCT HIV testing and data collection procedures at ANC HSS sites are of high quality, standardized and appropriate to ensure complete and valid PMTCT data for surveillance;
- "data abstraction" or "rapid data review": systematic examinations of the completeness and validity of routinely collected PMTCT programme data at ANC HSS sites.

Site assessment

The purpose of a site assessment is to determine whether the procedures for PMTCT HIV testing, data collection and data recording at the site level are of high quality, standardized and appropriate to ensure complete and valid PMTCT data for surveillance. It is suggested that the site assessment be conducted by an assessment staff member (not an ANC or PMTCT site staff member) a structured data collection tool using to collect quantitative and qualitative data on:

- basic features of and PMTCT HIV testing procedures at the ANC HSS site
- types of registers used for PMTCT data collection
- what PMTCT data are collected
- when and how PMTCT data are recorded.

A sample site assessment tool has been developed for these guidelines (Appendix D).This tool may be adapted to the local country context and piloted before implementation.

Pregnant women receiving ANC services who already know that they are HIV-positive would be sampled by ANC HSS. For PMTCT programme data to serve as the basis for HSS, it is imperative to ensure that the serostatus of known HIV-positive pregnant women is recorded and available for surveillance. It is important that the site assessment tool contains questions regarding if and how the serostatus of known HIV-positive pregnant women is recorded.

Data abstraction or rapid data review

Assessment of the quality of routinely collected PMTCT data in site registers may be based on two parameters: completeness and validity.

- A value is considered complete if it is present and legible in the field. If the data field is blank or illegible, the value is considered incomplete. If a variable is not contained in any register under examination, the value is also considered incomplete.
- A value is considered valid if it is within the expected range of values for that field and invalid if it is not within that range. The expected range of values is determined by local policy. For example, in country A, the SOP dictates that the variable "HIV test result" should be recorded as "positive" or "negative". Either of these is a valid value. However, the values "—"or "x" are considered invalid.

These guidelines describe two methods to examine data quality:"data abstraction" (more intensive) and "rapid data review" (less intensive), summarized in Table 7. The rapid data review option is presented in recognition of the fact that country resources to conduct a DQA will vary. However, it is advisable to conduct a data abstraction before making the decision to transition to PMTCT-based HSS. This will ensure that PMTCT data have undergone a comprehensive and rigorous assessment of data quality.

Countries, and ANC HSS sites within countries, may use different types and numbers of registers to record surveillance variables of interest: ANC registers, PMTCT registers, integrated ANC/PMTCT registers or laboratory registers. The minimum dataset (and other optional variables of interest) may be spread across more than one register. It is suggested that countries determine which registers will be examined by the data abstraction or rapid data review to ensure that all the variables in the minimum dataset (and other optional variables of interest) are abstracted or rapidly reviewed. If the variables of interest appear in more than one register, countries may select the most appropriate and comprehensive register as the single data source for those variables.

For both data abstraction and rapid data review, there are two study periods: the period of ANC HSS and the three months immediately prior to the ANC HSS period. Records from before the surveillance period are examined because site data collection practices during the sentinel surveillance period may be of a higher quality than normal due to increased training and supervision during the surveillance period. This has the potential to introduce bias. For both data abstraction and rapid data review, eligible pregnant women are defined using the same criteria as for ANC HSS (i.e. pregnant women making their first ANC visit in their current pregnancy during the study period) so as to avoid double counting of pregnant women.

Table 7. Summary of DQA activity options: data abstraction and rapid data review

Element	Data abstraction	Rapid data review
Study periods	There are two study periods: (1) the ANC HSS period and (2) the three months prior to the ANC HSS period	There are two study periods: (1) the ANC HSS period and (2) the three months prior to the ANC HSS period
Eligibility criteria	Records of pregnant women making their first ANC visit in their current pregnancy during the two study periods	Records of pregnant women making their first ANC visit in their current pregnancy during the two study periods
Sample size	Sample size for each study period matches site sample size attained for ANC HSS	Small sample to provide a snapshot of data quality. A suggested sample size for each study period is 40
Sampling method	Consecutive selection of records of all eligible pregnant women until sample size is met	Systematic random sampling of records of eligible pregnant women until sample size is met
Data collection	For all sampled records in designated site registers, the study staff member abstracts (copies) data values for all surveillance variables of interest (including the minimum dataset and other optional variables of interest)	For all sampled records in designated site registers, the study staff member assesses the completeness and validity of data values for all surveillance variables of interest (including the minimum dataset and other optional variables of interest) and records the determination
Advantages / disadvantages	Advantages: Comprehensive; rich data; large sample size provides reliable estimates Disadvantages: Time and resource intensive	Advantages: Time and resource inexpensive Disadvantages: Data not as rich; smaller sample size provides less reliable estimates
Comments	It is advisable to conduct a data abstraction before making the decision to transition to PMTCT-based HSS. This will ensure that PMTCT data have undergone a comprehensive and rigorous assessment of data quality.	

Data abstraction involves the retrospective abstraction of the surveillance variables of interest (including the minimum dataset and other optional variables of interest) from designated site registers. The sample size for each of the two study periods is equal to the site sample size attained for ANC HSS. For example, if the ANC HSS site sample size was 300, 300 records would be abstracted from the ANC HSS period and 300 records would be abstracted from the three months prior to the ANC HSS period. For each of the two study periods, a study staff member (not a site staff member) abstracts (copies) the surveillance variables of interest for consecutive eligible pregnant women from designated registers until the sample size has been met. It is suggested that countries develop a data abstraction SOP to ensure that the data abstraction process is methodologically rigorous and involves quality control measures.

Rapid data review involves the retrospective evaluation of the surveillance variables of interest from a smaller sample of records in designated site registers. The sample size for the two study periods should be small enough to be resource-economical but sufficient to provide a reasonable estimate of data quality.

A suggested sample size is 40 records of eligible pregnant women for each study period, for a total of 80 records.[1] For each of the two study periods, a study staff member selects records of eligible pregnant women from designated registers using systematic random sampling until the sample size is met. For each surveillance variable of interest within each selected record, a rapid review will assess the completeness and validity of the data value and record the determination. A rapid data review may use a structured tool that captures the completeness and validity of each variable of interest for selected records. Table 8 presents an example of such a tool. It is suggested that countries develop a rapid data review SOP to ensure that the rapid data review process is methodologically rigorous and involves quality control measures.

Table 8. Example of a potential rapid data review tool with example data

Record	Age	Date of visit	HIV test result
1	1	0	1
2	0	0	0
3	0	0	0
4	0	1	0
5	2	0	1
6	0	0	0

Legend:
0: Complete and valid
1: Incomplete
2: Invalid

5.3 Analysis of data derived from a DQA of PMTCT data

This section describes the analysis of data collected during a DQA of PMTCT data, including site assessment and data abstraction/rapid data review.

Site assessment

Quantitative results of the site assessment may be entered into a database for simple descriptive analysis. The objective of this analysis is to describe the frequency of optimal and suboptimal PMTCT HIV testing and data recording practices at ANC HSS sites. Of particular interest are non-standard practices that could negatively affect the uptake of PMTCT testing, and the quality and completeness of PMTCT data required for surveillance. Site characteristics of interest for analysis would include (but not be limited to) those listed in Table 9. The qualitative data captured by the site assessment are intended to clarify and provide greater detail on site practices and validate the information captured by the quantitative questions.

1 This sample size was not based on statistical needs and is not intended to provide benefits for statistical analysis. Countries that wish to obtain data sufficient for statistical testing of data quality parameters should consider a larger sample size (such as that provided by a data abstraction) and consult a statistician.

Table 9. ANC HSS site characteristics captured by the site assessment of potential interest for descriptive analysis

Characteristics that could negatively affect PMTCT HIV testing uptake	Characteristics that could negatively affect completeness of PMTCT data in site records
• PMTCT HIV testing is opt in • Syphilis testing is not routinely provided by the site • PMTCT HIV testing services are not free • PMTCT HIV (and/or syphilis) testing is done off-site • PMTCT HIV (and/or syphilis) testing is not done on the day of referral • PMTCT HIV (and/or syphilis) testing is affected by shortages of test kits	• PMTCT HIV (and/or syphilis) testing is done off-site • Off-site HIV (and/or syphilis) testing results are returned to the clinic by the pregnant woman • PMTCT HIV (and/or syphilis) testing is not done on the day of referral • Results of PMTCT HIV (and/or syphilis) testing results are not retrieved or received by the pregnant women on the day of referral • Nationally standard registers are not in use • Variables from the minimum dataset (or other variables of interest) are spread across multiple registers • Variables from the minimum dataset (or other variables of interest) are not captured in any register • Variables from the minimum dataset (or other variables of interest) are not always recorded on a pregnant woman's first visit • Previously known HIV-positive pregnant women are not distinctly recorded as known HIV-positive • Pregnant women who opt out of PMTCT HIV testing are not distinctly recorded as opting out of HIV testing

Data abstraction or rapid data review

Analysis of data from a data abstraction or rapid data review of site records may examine the quality of surveillance variables of interest (including the minimum dataset and other optional variables of interest) in three ways.

- Descriptive analysis of these data may estimate the frequency of completeness and validity. A comprehensive analysis would occur at multiple levels, including site, region/province, urban/rural and national. *In order for PMTCT data to serve as the basis for HSS among pregnant women, it is important that all surveillance variables of interest (including the minimum dataset of variables for surveillance) be of high quality in site records at all ANC HSS sites. As a general standard, a variable for which 90% of site records are complete and valid may be considered to be of high quality.* This data quality standard is in concert with the *Local Fund Agent Guidelines for on-site data verification and rapid services quality assessment implementation* used by the Global Fund to Fight AIDS, Tuberculosis, and Malaria.*(41)*
- Descriptive analysis of these data may examine the frequency of completeness and validity stratified by time period (ANC HSS period versus the three months immediately prior to the ANC HSS period). Data quality outside the ANC HSS period may more accurately reflect the true condition of data in site records, as there may be additional resources and supervision during ANC HSS. A comprehensive stratified analysis would occur at multiple levels, including site, region/province, rural/urban and national.
- Analysis of these data may examine whether data quality differs by site-level factors (e.g. tenure of PMTCT HIV testing services at site, HIV testing done on-site or off-site, urban/rural site, etc.) captured by the site assessment. This analysis would occur at the national level (using pooled data from all assessment sites) and calculate the proportion of records that are complete and valid, stratified by site-level factors.

6. Assessment activity C: Quality assurance assessment of PMTCT HIV testing at ANC HSS sites

This section describes methods for the conduct of a QA assessment of PMTCT HIV testing at ANC HSS sites (Figure 10). This activity addresses assessment area 5 (the state of QA practices for PMTCT HIV testing at ANC HSS sites).

In order for PMTCT data to serve as the basis for HSS, it is important to maintain a robust QA system to support routine PMTCT HIV testing, including training, supervision, adequate supplies and storage, appropriate record-keeping, infrastructure, available standards and guides, and external quality assurance.*(42,43,44)*

Figure 10: Assessment Activity C

Assessment activity	C. Quality assurance (QA) assessment of PMTCT HIV testing at ANC HSS sites
Relevant assessment area	5. The state of QA practices for PMTCT HIV testing at ANC HSS sites

6.1 Data collection for a QA assessment of PMTCT HIV testing

A sample QA checklist for PMTCT HIV testing has been developed to assess QA of all areas of PMTCT HIV testing (Appendix E). The checklist records the presence of QA elements in PMTCT HIV testing in three phase categories: pre-testing phase, testing phase and post-testing phase.

It is suggested that the QA checklist for PMTCT HIV testing be completed by an assessment study staff member (not a site staff member) with laboratory training. The study staff member completes the checklist by examining site PMTCT HIV testing procedures and interviewing site staff involved in conducting HIV rapid testing. Optimally, the checklist would be completed outside of the ANC HSS period to avoid any bias associated with improved resources, training and supervision provided during the ANC HSS period. The sample QA checklist for PMTCT HIV testing may be adapted to the local country context and piloted before implementation.

6.2 Analysis of data derived from a QA assessment of PMTCT HIV testing

The sample QA checklist for PMTCT HIV testing contains a built-in analysis function. Every QA element that meets the defined standard is worth one point. Within each of the checklist's three phase categories (pre-testing phase, testing phase and post-testing phase), the points are added and divided by the total number of possible points in that phase category to produce a phase category assessment score. *As a general standard, if the assessment score is at least 80% in each of the three phase categories, site PMTCT HIV testing may be considered to be within acceptable QA parameters.*

7. Other issues when considering PMTCT-based HSS

7.1 Economic assessment through top–down cost assessment

Using routine PMTCT data for HSS is expected to result in cost savings, but few systematic assessments have attempted to quantify the amount and nature of the potential savings. When conducting a PMTCT surveillance assessment, countries may include optional components to assess the costs of ANC HSS and PMTCT-based HSS.

PMTCT-based HSS is likely to yield savings by avoiding duplication of HIV testing and reducing training, supervision and logistics. An economic assessment can estimate the extent of potential savings. This information can aid ministries of health, donors, stakeholders and the global HIV surveillance community in making evidence-based decisions regarding the transition to PMTCT-based HSS.

An economic assessment may use a top–down cost assessment method, commonly referred to as an expenditure analysis approach. The goal of a top–down approach is to track why, where, when and for what expenditures are incurred. Such an approach estimates the cost per person surveyed for the surveillance activity, and describes the drivers of that cost.

In an expenditure analysis approach, expenditures are prospectively tracked throughout the surveillance activity. This analysis is facilitated by the fact that surveillance activities are often funded through independent budgets, and separate accounts are maintained to track surveillance-related expenditures. Incremental costs recorded for economic assessment could include planning, training, staff salaries, travel, fuel and vehicle maintenance, utilities, laboratory reagents, data management, and data entry and dissemination. Additional data may be needed to disaggregate expenditures by region and sources of funding support. All ANC HSS sites would be included in the analysis. The total expenditure is divided by the number or persons surveyed to estimate the cost per person surveyed.

Economic assessment could help countries to identify activities that drive surveillance costs, enabling them to devise ways to reduce the amounts spent. For example, preliminary single-point analysis of an economic assessment in Zanzibar indicates that moving from ANC HSS to PMTCT-based HSS could yield savings of up to 55%.[1] The majority of the projected savings were a result of reduced laboratory expenses, including reagents, operational costs, and collecting and transporting blood specimens. The extent of savings depended upon the degree to which expenses associated with sociodemographic data collection and reference laboratory-based HIV testing could be reduced in PMTCT-based HSS.

1 Written communication with Dr Mohammed Dahoma, Zanzibar AIDS Control Program (ZACP), Tanzania, 2011

7.2 PMTCT-based HSS in the context of other surveillance systems

Transition to a PMTCT-based system of HSS could impact other ANC-related services and surveillance activities. UAT-based ANC HSS uses remnant venous blood from routine ANC testing. Under PMTCT-based HSS, the need for remnant blood is eliminated. This could potentially affect syphilis testing and other data collection activities. Routine syphilis screening is recommended in nearly all countries, as untreated syphilis in pregnancy can result in stillbirth, prematurity, neonatal death and congenital malformations. It is important to ensure that syphilis testing and penicillin treatment of pregnant women (both of which are cost-effective even in low-prevalence settings) are universally available. Further, surveillance of syphilis provides important epidemiological information for HIV, sexually transmitted infection (STI) and MCH programmes. Many countries also currently use ANC-related blood draws to screen for hepatitis B and C, herpesvirus and other STIs. With the transition from ANC HSS to PMTCT-based HSS, there is a risk that the quality and coverage of testing for syphilis and other STIs may decrease. It will be important for countries to maintain high-quality testing, surveillance and monitoring for syphilis and other relevant STIs when transitioning to PMTCT-based HSS. Further guidance on STI surveillance will be provided in the forthcoming WHO guidelines *Strategies and laboratory methods for strengthening surveillance of sexually transmitted infections.*

In recent years, remnant ANC blood samples collected for ANC HSS have also provided specimens for HIV incidence and HIV drug resistance surveillance. It will be necessary for countries to identify methods to ensure the continuation of HIV incidence and HIV drug resistance surveillance in the era of PMTCT-based HSS.

8. Ethical considerations for implementing a PMTCT surveillance assessment

When assessing the utility of PMTCT data for HSS, ethical principles for the protection of the rights and welfare of human subjects should be respected.*(45)* The assessment process includes site assessments, PMTCT HIV testing assessments, and the collection or review of medical and personal identifiable information in ANC HSS site records. These data, in particular HIV test results, may be of a sensitive nature. Protocols and SOPs for conducting an assessment should establish measures and standards to ensure the security and confidentiality of assessment data during collection, transport, storage and analysis, including the following:

- All staff collecting or handling assessment data should sign a confidentiality agreement.
- All databases, laptops and forms used in the assessment must be secured with restricted access. Laptops and databases should be encrypted, password protected, and accessible only by appropriate assessment staff. All assessment forms should be maintained in locked file cabinets or drawers when not in use.
- The PMTCT surveillance assessment should not collect any personal identifiable information other than what is essential to meet the objectives of the assessment. The names of pregnant women attending ANC services are not required to meet assessment objectives.
- Implementation of ANC HSS using a revised data collection form that captures PMTCT HIV testing variables should include the same rigorous ethical protections as routine ANC HSS to ensure the security and anonymity of PMTCT HIV testing information. Importantly, these protections should include the permanent delinking (and subsequent destruction) of personal identifiable information from demographic, syphilis testing and HIV testing data collected for HSS and the PMTCT surveillance assessment.
- The collection of a patient record number, such as ANC number, may be needed to identify duplicate records or to link two routine data sources at ANC HSS sites. After data collection, ANC numbers should be destroyed as this information could be used to link surveillance data to specific individuals.

Assessment activities should be reviewed and approved by all appropriate ethical review boards (ERBs). Adding PMTCT HIV variables to an existing ANC HSS data collection form may warrant ERB approval of an amended surveillance protocol.

9. Next steps

Assessing a country's readiness to transition from ANC HSS to PMTCT-based HSS among pregnant women is an iterative and methodologically rigorous process that could require multiple years to complete. The decision to transition to PMTCT-based HSS should be carefully considered and fully supported by ample, high-quality data from PMTCT surveillance assessments.

Transitioning from ANC HSS to PMTCT-based HSS could provide countries with many benefits. PMTCT-based HSS has the potential to reduce the resource costs associated with HSS; ensure that pregnant women sampled by HSS are informed that they will be tested for HIV and have the opportunity to opt out, are provided with pre- and post-test counselling, receive their test result, and are referred to HIV care and treatment services if the test is positive. In addition, PMTCT-based HSS has the potential to achieve broader geographical coverage, a larger sample size, and more stable prevalence estimates for HSS; support improved PMTCT programme implementation and monitoring; contribute to a system and culture of using routine programme data for surveillance; and contribute to broader health systems strengthening.

Guidance on implementing a system for PMTCT-based HSS is beyond the scope of this document. Future work is required to develop guidance for this process. However, it is clear that future guidelines and country transition plans will need to address several key considerations:

- The design and implementation of a PMTCT-based HSS system will require the same scientific rigour, political commitment and structural support that have historically and widely been afforded to ANC HSS.
- To maintain the ability to monitor site, regional/provincial and national HIV trends over time, PMTCT-based HSS should include the same ANC sites used in previous ANC HSS rounds. PMTCT-based HSS may also be expanded to include additional ANC sites if PMTCT data and HIV testing at additional sites are rigorously assessed and found to be of sufficient quality.
- PMTCT-based HSS protocols will require review by the appropriate ERB.
- PMTCT-based HSS will require efforts to ensure the continuing suitability of PMTCT programme data to serve as the basis for HSS, including:
  - continued QA of PMTCT HIV testing
  - M&E of PMTCT-based HSS
  - development of methods to rapidly and accurately extract routine PMTCT data from site records for HSS
  - possible development of a calibration method to integrate PMTCT-based HIV estimates into historical trend data from ANC HSS.
- Although transition from ANC HSS to PMTCT-based HSS may resolve certain ethical concerns associated with UAT-based ANC HSS, the use of PMTCT programme data for HSS also involves ethical considerations. Ethical protections for pregnant women sampled by PMTCT-based HSS should be assured, and include rigorous efforts to protect the rights, welfare and confidentiality of pregnant women sampled by surveillance.

Appendix A: Summary of published findings of studies assessing the utility of PMTCT data for surveillance

Table 10. Summary of published findings from studies conducted in sub-Saharan Africa to assess the utility of PMTCT data for surveillance, by recommendation

Country	Year	Sites	Factors assessed			
			HIV prevalence estimate	HIV testing uptake*	PMTCT data quality	Representativeness
Findings support PMTCT data for HIV surveillance						
Botswana*(22)*	2005–2007	National system	Rural: 34.8% in ANC HSS vs 34.6% in PMTCT (p value=0.73) Urban: 34.9% in ANC HSS vs 32.8% in PMTCT (p value=0.9)	2005: 83% 2006: 81% 2007: 85%	Data quality challenges were identified	Possibly achieved a high level of national representation
Cameroon*(23)*	2003	National system	7.3% (95% CI: 7.5–7.9) in ANC HSS vs 7.8% (95% CI: 6.7–7.9) in PMTCT	69%	Not reported	Possibly achieved a high level of national representation
Uganda*(24)*	2004–2005	1 rural ANC	Crude, 2004: 10.5% in ANC HSS vs 9.0% in PMTCT Crude, 2005: 10.9% in ANC HSS vs 11.8% in PMTCT Adjusted, 2004: 10.5% in ANC HSS vs 10.1% in PMTCT Adjusted, 2005: 10.9% in ANC HSS vs 11.2% in PMTCT	2004: 49.9% 2005: 54.2%	Not reported	Probably not representative at the national level
Uganda*(25)*	2001–2003	1 rural ANC	11.1% in ANC HSS vs 10.9% in PMTCT (age standardized)		Not reported	Probably not representative at the national level
Findings do not support PMTCT data for HIV surveillance						
Burkina Faso*(29)*	1996	1 urban ANC	4% in ANC HSS vs 10.5% in PMTCT	18.3%	Not reported	Probably not representative at the national level
Ethiopia*(28)*	2005	National system	8.2% in ANC HSS among women who did not accept PMTCT HIV testing 6.4% in ANC HSS among women who accepted PMTCT HIV testing	47%	Not reported	Possibly achieved a high level of national representation
Kenya*(17)*	2003	6 ANC	12.8% (range: 8.1%–26.3%) in ANC HSS vs 14.4% (range: 7.0%–27.2%) in PMTCT	56% (range: 48%–69%)	Data quality challenges were identified	Probably not representative at the national level

Kenya*(28)*	2005	National system	5.1% in ANC HSS among women who did not participate in PMTCT HIV testing 4.7% in ANC HSS among women who participated in PMTCT HIV testing	76.4% of women offered and accepted test	Not reported	Possibly achieved a high level of national representation
Kenya*(26)*	2010	National system	6.2% (95% CI: 5.8–6.6) in ANC HSS vs 5.2% (95% CI: 4.8–5.6) in PMTCT	Not reported	Data quality challenges were identified	Possibly achieved a high level of national representation
Rwanda*(32)*	2007	National system	4.4%in ANC HSS vs 3.5% in PMTCT (p value=0.07)	100%	3% of PMTCT records did not have HIV test results	Possibly achieved a high level of national representation
Uganda*(31)*	2002– 2003	1 urban ANC	12% in ANC HSS vs 13% in PMTCT	73%	Not reported	Probably not representative at the national level
Ugandac	2004	7 ANC	8.3% in ANC HSS vs 9.8% in PMTCT; Similar median HIV prevalence but ANC HSS and PMTCT prevalence varied at 2 of 7 clinics	Not reported	Data quality challenges were identified	Probably not representative at the national level
Zimbabwe*(30)*	2004	19 ANC	21.3% in ANC HSS vs 21.87% in PMTCT; Similar overall levels, but differences in prevalence by site	44.6% (range: 2.3%–89.4%)	Not reported	Possibly achieved a high level of national representation
**Unless otherwise noted, uptake is the total number of pregnant women receiving a PMTCT HIV test divided by the total number of pregnant women attending ANC services or sampled by ANC HSS*						

Appendix B: Sample ANC HSS data collection form with additional PMTCT HIV testing variables

Ministry of Health
HIV surveillance data collection form for antenatal clinics[1]

Site:_____ District:_____

A. Sociodemographic Information

1. Survey ID code:_____
2. Date of patient visit (dd/mm/yyyy):_____/_____/_____
3. Age (in years):_____
4. Residence:
   a. Urban
   b. Rural
   c. Missing
5. Highest level of school attended:
   a. None
   b. Primary
   c. Secondary
   d. Higher
   e. Missing
6. Occupation (primary): (optional)
   a. Business
   b. Police/military
   c. Professional
   d. Labourer
   e. Farmer
   f. Domestic help
   g. Homemaker
   h. Student
   i. Not employed
   J. Other
   k. Missing
7. Total number of pregnancies, including this pregnancy: _____
8. Total number of live births: _____

B. PMTCT programme HIV testing information

9. Was a PMTCT HIV test offered during this visit?
   a. Yes (if Yes, go to next question)
   b. No (if No, skip to section C)

1 Adapted from the sample ANC HSS data collection form in: UNAIDS/WHO. *Guidelines for conducting HIV sentinel serosurveys among pregnant women and other groups.* Geneva, 2003. This form may be adapted to the local country context. If necessary, questions 11a–11d may be modified to suit the country PMTCT HIV testing algorithm.

10. Was a PMTCT HIV test accepted?
    a. Yes (if Yes, go to next question)
    b. No: previously tested positive (if No, skip to section C)
    c. No (if No, skip to section C)

11.a. What were the HIV test results?

Test 1 result:

    a. Positive
    b. Negative
    c. Missing

11.b. What were the HIV test results?

Test 2 result:

    a. Positive
    b. Negative
    c. Missing
    d. Not applicable

11.c. What were the HIV test results?

Test 3 result:

    a. Positive
    b. Negative
    c. Missing
    d. Not applicable

11.d. What were the HIV test results?

Other result:

    a. Positive
    b. Negative
    c. Missing
    d. Not applicable

C. Surveillance test result information

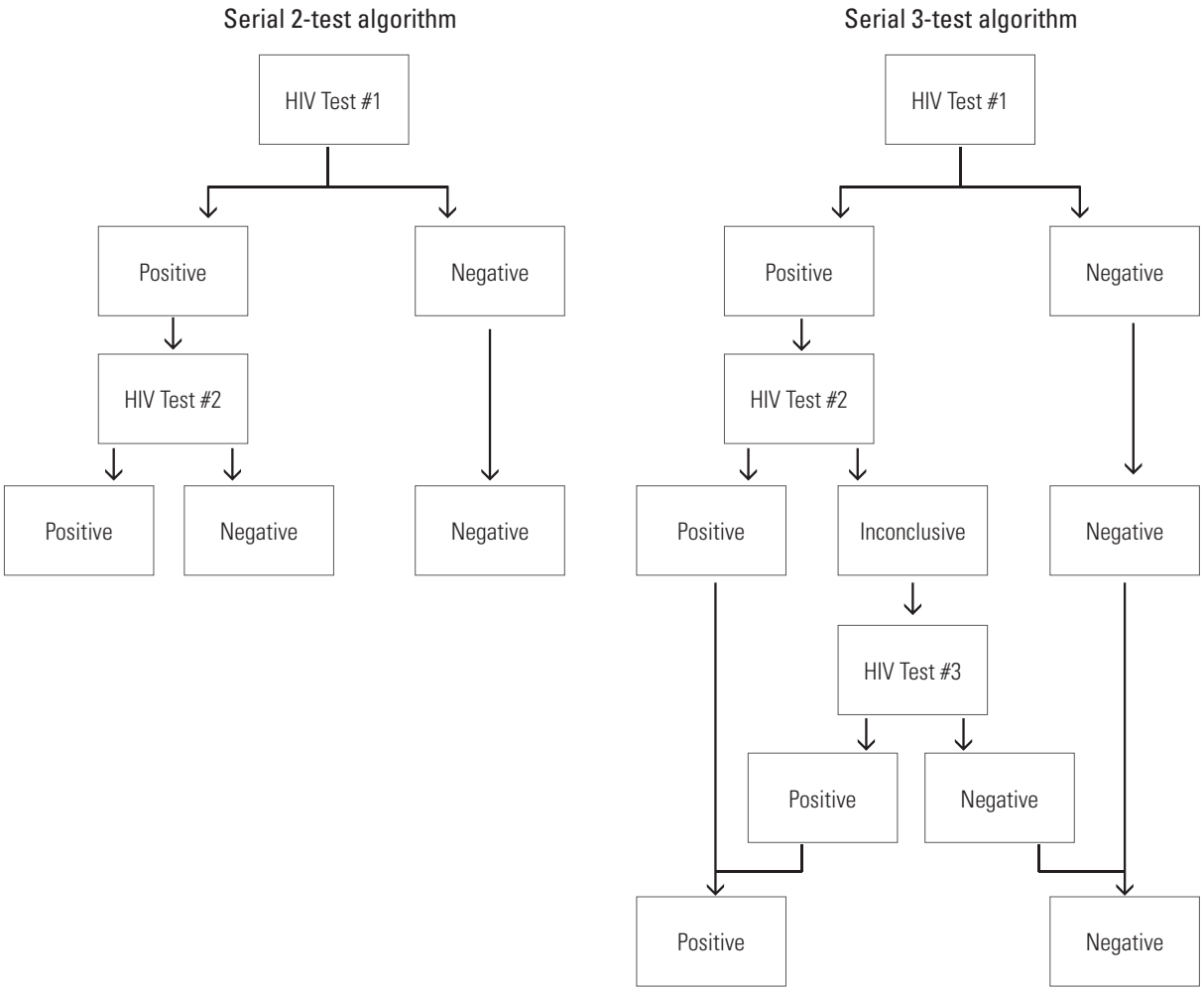
12. HIV screening (initial test) date: _____/_____/_____
13. HIV screening (initial test) result:
    a. Positive
    b. Negative
14. HIV confirmatory test date: _____/_____/_____
15. HIV confirmatory result:
    a. Positive
    b. Negative
16. Syphilis test date: _____/_____/_____
17. Syphilis test result:
    a. Positive
    b. Negative

Appendix C: Statistical appendix

Statistical methods for calculating agreement between ANC HSS and PMTCT HIV testing benchmarks
These guidelines suggest that the agreement between ANC HSS and PMTCT HIV test results be measured using individual-level data to calculate positive per cent agreement (PPA) and negative per cent agreement (NPA) of ANC HSS and PMTCT HIV testing. This section describes the statistical methods used to determine the benchmarks for PPA and NPA of ANC HSS and PMTCT HIV test results (described in section 4.1.2). These benchmarks were developed to characterize a high level of agreement between ANC HSS and PMTCT HIV test results while taking into account the performance characteristics of the two testing algorithms and potential statistical variability in test performance. These benchmarks represent expected results in the absence of human error, and thus are meant to serve as points of reference in interpreting assessment results, not as strict targets.

A simulation was performed to determine the benchmarks for PPA and NPA of ANC HSS and PMTCT HIV test results for various levels of ANC HSS prevalence. The first step in the simulation was to estimate net sensitivity and specificity for a typical two- and three-test serial HIV testing algorithm (Figure 11).

Figure 11. Two- and three-test serial HIV testing algorithms



Each of the HIV tests in the serial HIV testing algorithms were conservatively assumed to have sensitivities and specificities of 99.5%, based on WHO evaluations of rapid test kits and ELISA assays.*(46,47)* Net sensitivity and specificity for the two algorithms were calculated as follows:

Two-test serial algorithm:

$$Net\ sensitivity = Se_1 \times Se_2$$
$$Net\ specificity = Sp_1 + Sp_2 - (Sp_1 \times Sp_2)$$

Three-test serial algorithm:

$$Net\ sensitivity = Se_1 \times Se_2 + [Se_1 \times (1 - Se_2) \times Se_3]$$
$$Net\ specificity = Sp_1 + [(1 - Sp_1) \times Sp_2 \times Sp_3]$$

where

$Se_1 = Sensitivity\ of\ the\ first\ HIV\ test\ in\ the\ algorithm$
$Sp_1 = Specificity\ of\ the\ first\ HIV\ test\ in\ the\ algorithm$
$Se_2 = Sensitivity\ of\ the\ second\ HIV\ test\ in\ the\ algorithm$
$Sp_2 = Specificity\ of\ the\ second\ HIV\ test\ in\ the\ algorithm$
$Se_3 = Sensitivity\ of\ the\ third\ HIV\ test\ in\ the\ algorithm$
$Sp_3 = Specificity\ of\ the\ third\ HIV\ test\ in\ the\ algorithm$

This produced the following net sensitivities and specificities for the two- and three-test serial algorithms.

Two-test serial algorithm:

Net sensitivity = 99.003
Net specificity = 99.998

Three-test serial algorithm:

Net sensitivity = 99.498
Net specificity = 99.995

The next step in the process was to assess the uncertainty of the net sensitivity and specificity estimates. This was done by simulating a binomial distribution based on a sample size of 300—assuming sensitivities and specificities of 99.5%—for each HIV test and then solving the above equations for net sensitivity and specificity 10 000 times. The 10 000 net sensitivities and specificities were then sorted and the 2.5th and 97.5th percentiles were used as approximate 95% confidence limits.

Two-test serial algorithm:

Net sensitivity = 99.003 (97.680–100.000)
Net specificity = 99.998 (99.989–100.000)

Three-test serial algorithm:

Net sensitivity = 99.498 (98.660–100.000)
Net specificity = 99.995 (99.980–100.000)

Because the goal of this simulation was to estimate benchmarks for positive and negative per cent agreement, the lower bound net sensitivity (97.680%) and specificity (99.980%) estimates were used in the simulation as a "worst case" scenario for the respective sensitivities and specificities of the ANC HSS and PMTCT test algorithms, in the absence of human error.

The next step was to estimate what levels of PPA and NPA of ANC HSS and PMTCT test results could be expected by assuming the lower bound sensitivities and specificities described above. Following an approach described by Staquet and colleagues,*(48)* a series of 2X2 tables (Table 11) were generated for various levels of HIV prevalence using the following formulas. The lower bound net sensitivity (97.680%) was entered for Se_{ANC} and Se_{PMTCT}, and the lower bound net specificity (99.980%) was entered for Sp_{ANC} and Sp_{PMTCT}.

Table 11. Sample 2 X 2 table comparing ANC HSS and PMTCT HIV test results

	ANC HSS HIV test		
PMTCT HIV test	HIV+	HIV-	Total
HIV+	a	b	a + b
HIV-	c	d	c + d
Total	a + c	b + d	a + b + c +d

$$a = X \times Se_{ANC} \times Se_{PMTCT} + Y \times (1 - Sp_{ANC}) \times (1 - Sp_{PMTCT})$$
$$b = X \times (1 - Se_{ANC}) \times Se_{PMTCT} + Y \times Sp_{ANC} + (1 - Sp_{PMTCT})$$

$$c = X \times Se_{ANC} \times (1 - Se_{PMTCT}) + Y \times (1 - Sp_{ANC}) \times Sp_{PMTCT}$$
$$d = X \times (1 - Se_{ANC}) \times (1 - Se_{PMTCT}) + Y \times Sp_{ANC} \times Sp_{PMTCT}$$

where

$$X = HIV\ prevalence \times N$$
$$Y = (1 - HIV\ prevalence) \times N$$
$$N = X + Y$$
$$N = a + b + c + d$$
$$Se_{ANC} = Sensitivity\ of\ ANC\ HSS\ test\ algorithm$$
$$Sp_{ANC} = Specificity\ of\ ANC\ HSS\ test\ algorithm$$
$$Se_{PMTCT} = Sensitivity\ of\ PMTCT\ test\ algorithm$$
$$Sp_{PMTCT} = Specificity\ of\ PMTCT\ test\ algorithm$$

PPA, NPA, ANC HSS prevalence and PMTCT HIV prevalence were calculated for each of the simulated 2X2 tables using the following formulas:

$$Positive\ per\ cent\ agreement\ (PPA) = 100 \times \frac{a}{a + c}$$
$$Negative\ per\ cent\ agreement\ (NPA) = 100 \times \frac{d}{b + d}$$
$$ANC\ HSS\ HIV\ prevalence = 100 \times \frac{(a + c)}{N}$$
$$PMTCT\ HIV\ prevalence = 100 \times \frac{(a + b)}{N}$$

Based on the results of this simulation, benchmarks for positive and negative per cent agreement for both a two-test and three-test serial HIV testing algorithm were estimated (Table 12.). The final benchmarks for PPA and NPA (Table 4 in Section 4.1.2) were based on the lowest benchmark observed for each level of prevalence across the two testing strategies.

These benchmarks account for the potential statistical variability in the performance characteristics of both ANC HSS and PMTCT HIV testing. PPA or NPA below these benchmarks signifies that disagreement of the two testing results exceeds what would be expected due to statistical variability or the performance characteristics of the two testing algorithms, and is likely to be due to human error in operating ANC HSS or PMTCT HIV tests. If ANC HSS ELISA testing is subject to appropriately rigorous quality assurance (QA) and quality control (QC),*(4)* it may be inferred that sub-benchmark agreement between ANC HSS and PMTCT testing is possibly due to suboptimal operation of PMTCT HIV test kits.

Table 12.Benchmarks for positive per cent agreement and negative per cent agreement by ANC HSS prevalence for 2- and 3-test serial HIV testing algorithms

HIV prevalence according to ANC HSS (%)	2-test Serial algorithm		3-test Serial algorithm		2- or 3-test Serial algorithm	
	Benchmark for positive per cent agreement (%)	Benchmark for negative per cent agreement (%)	Benchmark for positive per cent agreement (%)	Benchmark for negative per cent agreement (%)	Benchmark for positive per cent agreement (%)	Benchmark for negative per cent agreement (%)
0.5	95.5	99.9	94.7	99.9	94.7	99.9
1.0	96.6	99.9	96.7	99.9	96.6	99.9
1.5	97.0	99.9	97.4	99.9	97.0	99.9
2.0	97.2	99.9	97.7	99.9	97.2	99.9
2.5	97.3	99.9	97.9	99.9	97.3	99.9
3.0	97.3	99.9	98.0	99.9	97.3	99.9
3.5	97.4	99.9	98.1	99.9	97.4	99.9
4.0	97.4	99.9	98.2	99.9	97.4	99.9
6.0	97.5	99.8	98.4	99.9	97.5	99.8
8.0	97.6	99.8	98.4	99.9	97.6	99.8
9.0-16.0	97.6	99.7	98.5	99.8	97.6	99.7
17.0-26.0	97.6	99.5	98.6	99.7	97.6	99.5

The above PPA and NPA benchmarks function well at the regional/provincial and national levels to describe a high level of agreement between ANC HSS and PMTCT HIV testing in the absence of human error.

It is important to examine agreement between ANC HSS and PMTCT test results at the ANC HSS site level to more precisely identify suboptimal PMTCT HIV testing performance, and because some countries may report ANC HSS site-level HIV estimates. However, the PPA and NPA benchmarks are not uniformly appropriate for analysis at the site level because of smaller sample sizes. Table 13 provides example data from a hypothetical country with an HIV prevalence of 2.0% (according to ANC HSS), an overall ANC HSS sample size of 10 000 and 30 ANC HSS sites.

Table 13. Example data showing the calculation of positive per cent agreement (PPA) and negative per cent agreement (NPA) between ANC HSS and PMTCT HIV testing at the national level in a low-prevalence country with an overall ANC HSS sample size of 10 000 and 30 ANC HSS sites

	ANC HSS HIV test		
PMTCT HIV test	HIV+	HIV-	Total
HIV+	195	10	205
HIV-	5	9 790	9 795
Total	200	9 800	10 000

HIV prevalence as per ANC HSS: 2.0%
PPA=97.5%
NPA=99.9%

Despite five discrepant results in cell c (positive as per ANC HSS but negative as per PMTCT HIV testing), this country exceeds the PPA benchmark for a country with 2.0% prevalence. However, when analysis is conducted at the site level, because of the smaller sample sizes, even one discrepant result in cell c drops the PPA well below the benchmark (Table 14). It would thus be impossible for low-prevalence countries to approximate the PPA benchmark at the site level for all sites. Some instances of single discrepant results at the site level are thus expected and must be tolerable.

Table 14. Example data showing the calculation of positive per cent agreement (PPA) and negative per cent agreement (NPA) between ANC HSS and PMTCT HIV testing at the site level in a low-prevalence country with an overall ANC HSS sample size of 10 000 and 30 ANC HSS sites

	ANC HSS HIV test		
PMTCT HIV test	HIV+	HIV-	Total
HIV+	6	10	16
HIV-	1	316	317
Total	7	326	333

HIV prevalence as per ANC HSS: 2.1%
PPA=87.5%
NPA=96.9%

To address this challenge, an alternative method of evaluating agreement between ANC HSS and PMTCT HIV test results at the site level was developed. The expected number of discrepant results for cell b (negative as per ANC HSS but positive as per PMTCTHIV testing) and cell c (positive as per ANC HSS but negative as per PMTCT HIV testing) were estimated for site-level sample sizes of 200, 300, 400 and 500 based on the PPA and NPA benchmarks described above and across a range of underlying HIV prevalence.

For most combinations of site-level sample size and HIV prevalence, the expected b and c cell sizes that would maintain agreement above the PPA and NPA benchmarks were less than 1.0 (Tables 15, 16, 17 and 18). Thus, these guidelines suggest that if an ANC HSS site has more than one cell b or cell c discrepant result, this result should be investigated as it exceeds what would be expected due to statistical variability or the performance characteristics of the two testing algorithms, and is likely to be due to human error in operating ANC HSS or PMTCT HIV tests (Table 5 in section 4.1.2). If ANC HSS ELISA testing is subject to appropriately rigorous QA and QC measures,*(4)* it may be inferred that more than one discrepant result in cell b or c is likely to be due to suboptimal operation of PMTCT HIV test kits.

In scenarios involving ANC HSS sites with larger sample sizes and higher HIV prevalence, slightly more discrepant results would be expected. This includes sites with a sample size of 400 and an HIV prevalence of ≥18%, and sites with a sample size of 500 and an HIV prevalence of ≥14%. In these scenarios, the expected cell b and cell c sizes that would maintain agreement above the PPA and NPA benchmarks were less than 2.0. Thus, these guidelines suggest that in these scenarios if an ANC HSS site has more than two discrepant results in cell b or cell c, respectively, this result should be investigated as it exceeds what would be expected due to statistical variability or the performance characteristics of the two testing algorithms, and is likely to be due to human error in operating PMTCT HIV tests.

At the site level, these benchmarks tolerate the expected occasional single discrepant result in cell b or cell c while flagging sites with excessive discrepant results. The PPA and NPA benchmarks at the regional/provincial and national levels ensure that only expected site-level discrepant results are tolerated.

Table 15. Expected cell b and cell c values of a cross-tabulation of ANC HSS and PMTCT HIV testing results for two- and three-test serial HIV testing algorithms, by ANC HSS prevalence for a sample size of 200

HIV prevalence according to ANC HSS (%)	Two-test serial algorithm		Three-test serial algorithm	
	Cell b	Cell c	Cell b	Cell c
3.0	0.16	0.16	0.12	0.12
6.0	0.30	0.30	0.20	0.20
9.0	0.44	0.44	0.28	0.28
12.0	0.58	0.58	0.36	0.36
15.0	0.71	0.71	0.44	0.44
18.0	0.85	0.85	0.51	0.51
21.0	0.99	0.99	0.59	0.59
24.0	1.13	1.13	0.67	0.67
6.0	97.5	99.8	98.4	99.9
8.0	97.6	99.8	98.4	99.9
9.0–16.0	97.6	99.7	98.5	99.8
17.0–26.0	97.6	99.5	98.6	99.7

Table 16. Expected cell b and cell c values of a cross-tabulation of ANC HSS and PMTCT HIV testing results for two- and three-test serial HIV testing algorithms, by ANC HSS prevalence for a sample size of 300

HIV prevalence according to ANC HSS (%)	Two-test serial algorithm		Three-test serial algorithm	
	Cell b	Cell c	Cell b	Cell c
3.0	0.24	0.24	0.18	0.18
6.0	0.45	0.45	0.30	0.30
9.0	0.66	0.66	0.42	0.42
12.0	0.86	0.86	0.53	0.53
15.0	1.07	1.07	0.65	0.65
18.0	1.28	1.28	0.77	0.77
21.0	1.49	1.49	0.89	0.89
24.0	1.70	1.70	1.01	1.01

Table 17. Expected cell b and cell c values of a cross-tabulation of ANC HSS and PMTCT HIV testing results for two- and three-test serial HIV testing algorithms, by ANC HSS prevalence for a sample size of 400

HIV prevalence according to ANC HSS (%)	Two-test serial algorithm		Three-test serial algorithm	
	Cell b	Cell c	Cell b	Cell c
3.0	0.32	0.32	0.24	0.24
6.0	0.60	0.60	0.40	0.40
9.0	0.87	0.87	0.55	0.55
12.0	1.15	1.15	0.71	0.71
15.0	1.43	1.43	0.87	0.87
18.0	1.71	1.71	1.03	1.03
21.0	1.98	1.98	1.19	1.19
24.0	2.26	2.26	1.35	1.35

Table 18. Expected cell b and cell c values of a cross-tabulation of ANC HSS and PMTCT HIV testing results for two- and three-test serial HIV testing algorithms, by ANC HSS prevalence for a sample size of 500

HIV prevalence according to ANC HSS (%)	Two-test serial algorithm		Three-test serial algorithm	
	Cell b	Cell c	Cell b	Cell c
3.0	0.40	0.40	0.30	0.30
6.0	0.75	0.75	0.49	0.49
9.0	1.09	1.09	0.69	0.69
12.0	1.44	1.44	0.89	0.89
15.0	1.79	1.79	1.09	1.09
18.0	2.13	2.13	1.29	1.29
21.0	2.48	2.48	1.48	1.48
24.0	2.82	2.82	1.68	1.68

Statistical methods for calculating the general standard for uptake of PMTCT HIV testing

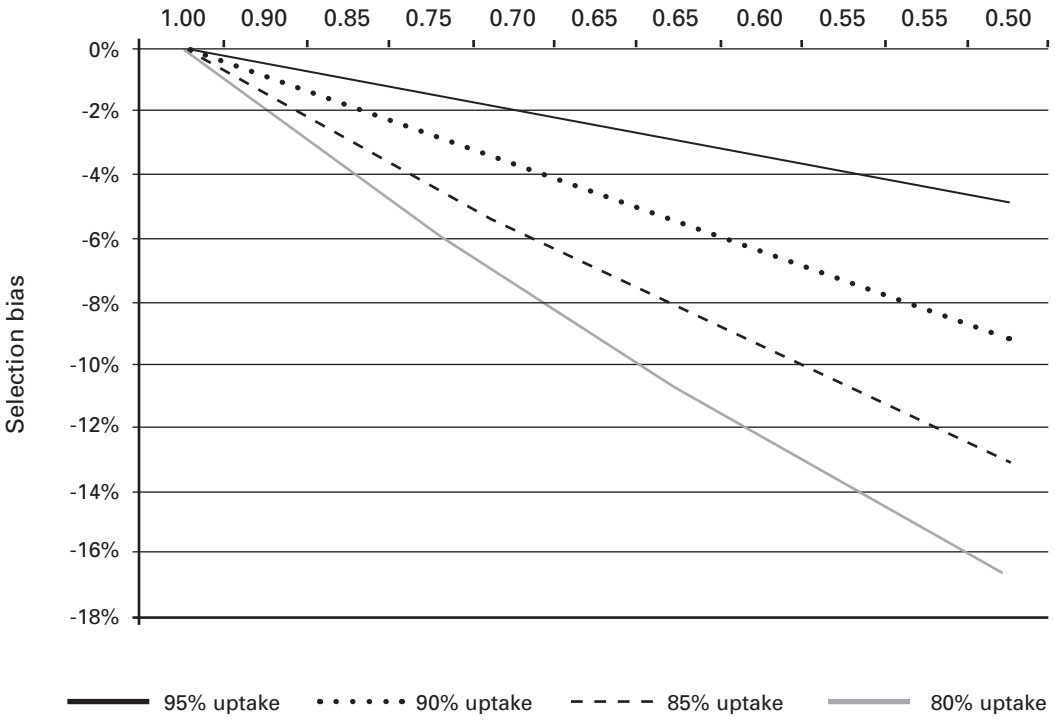
For PMTCT programme data to be used for HSS among pregnant women, it is important that the bias inherent in PMTCT data be low at all ANC HSS sites. In these guidelines, bias is measured by the parameter "selection bias", defined as the per cent relative change (positive or negative) from the total HIV prevalence (among pregnant women who do and do not receive PMTCT HIV testing) to the observed HIV prevalence (among pregnant women who receive PMTCT HIV testing). An important method to limit selection bias is to maintain high levels of PMTCT HIV testing uptake (defined as the proportion of pregnant women sampled by ANC HSS who receive PMTCT HIV testing) at all ANC HSS sites. This section describes the statistical methods used to determine the general standard for uptake of PMTCT HIV testing (section 3.3.2).

Uptake of PMTCT HIV testing and differential prevalence ratio (defined as the ratio of the HIV prevalence among pregnant women sampled by ANC HSS who receive PMTCT HIV testing to the HIV prevalence among pregnant women sampled by ANC HSS who do not receive PMTCT HIV testing) work together to determine the magnitude and direction of selection bias inherent in PMTCT HIV testing data (section 4.1.3). The object of the standard-setting process for uptake of PMTCT HIV testing was to identify a level of uptake that would limit selection bias even in the presence of substantial differences in prevalence.

Simulations of selection bias were conducted for decreasing differential prevalence ratios for four levels of uptake of PMTCT HIV testing: 95%, 90%, 85% and 80% (Figure 12). As differential prevalence ratios decreased (simulating increasingly higher prevalence among pregnant women who do not receive PMTCT

HIV testing compared to women who receive PMTCT HIV testing), the magnitude of selection bias grew. However, higher uptake of PMTCT HIV testing reduced the impact of differential prevalence ratio on selection bias. For example, at a differential prevalence ratio of 0.5, an uptake of PMTCT HIV testing of 95% limits selection bias to approximately –5%, whereas an uptake of PMTCT HIV testing of 80% limits selection bias to approximately –17%. Ninety per cent was chosen as the general standard for uptake of PMTCT HIV testing because it represented an achievable rate of uptake that limited selection bias to tolerable levels, even when the differential prevalence ratio is far from one. Even with a differential prevalence ration of 0.5, an uptake of PMTCT HIV testing of 90% limits selection bias to approximately 9%. This result is within the general standard for selection bias (less than 10% and more than –10%) outlined in section 3.3.2.

Figure 12. Magnitude of selection bias* produced by decreasing differential prevalence ratio,† by level of uptake of PMTCT HIV testing‡



* The per cent relative change (positive or negative) from the total HIV prevalence (among pregnant women who do and do not receive PMTCT HIV testing) to the observed HIV prevalence (among pregnant women who receive PMTCT HIV testing)

† The ratio of the HIV prevalence among pregnant women sampled by ANC HSS who receive PMTCT HIV testing to the HIV prevalence among pregnant women sampled by ANC HSS who do not receive PMTCT HIV testing

‡ The proportion of pregnant women sampled by ANC HSS who receive PMTCT HIV testing

Appendix D: Quality assessment of PMTCT data: sample site assessment tool

INSTRUCTIONS: Please complete this form with the staff member who provides PMTCT HIV testing services at the ANC HIV sentinel surveillance site. Provide the following information to the interviewee: "Today we would like to ask you some questions about this clinic, how PMTCT HIV testing services are delivered and data are recorded. We are not here to assess the clinic's or your performance, but rather to learn about the process of collecting information in PMTCT programmes. This process will take approximately 40 minutes to complete."

A. Site information	
INSTRUCTIONS: This section collects basic information about the interview and the site.	
1. Today's date	_ _ / _ _ / _ _ _ _ (m m / d d / y yyy)
2. Interviewer's name	
3. Interviewee's name and position	
4. Site name	
5. District	
6. Province/Region	
7. Setting	☐ Urban ☐ Rural ☐ Peri-urban
8. Average number of pregnant women enrolling in ANC services for a new pregnancy each month	___ pregnant women
B. PMTCT programme information	
INSTRUCTIONS: The second section collects information about PMTCT HIV testing and syphilis testing services provided at this site and off-site. Explain to the interviewee that "at this site" refers to the building or compound of buildings that contains ANC services. "Off-site" refers to locations outside the building or compound of buildings that contains ANC services.	
9. PMTCT HIV testing approach	☐ Opt-in ☐ Opt out
10. Is PMTCT HIV testing done at this site (the building or compound of buildings that contains ANC services) or off-site (locations outside the building or compound of buildings that contains ANC services)?	☐ At this site ⇨ if Yes, skip to **Question 15** ☐ Off-site ⇨ If No, go to next question
11. Where is off-site PMTCT HIV testing done?	☐ Off-site laboratory ☐ Care and treatment centre ☐ VCT site ☐ Other _____
12. If a pregnant woman is referred to an off-site location for PMTCT HIV testing, when does she do her off-site HIV testing?	☐ Always on the same day that she is referred for testing ☐ Sometimes on the same day that she is referred for testing ☐ Rarely on the same day that she is referred for testing
13. How are the results of off-site PMTCT HIV testing physically returned to this facility?	☐ Returned by the testing site (lab, VCT site, etc.) ☐ Returned by the pregnant woman
14. When are off-site PMTCT HIV test results physically returned to this facility?	☐ Always on the same day that a pregnant woman is referred for testing ☐ Sometimes on the same day that a pregnant woman is referred for testing ☐ Rarely on the same day that a pregnant woman is referred for testing } Skip to **Question 17**
15. What is the PMTCT HIV testing algorithm for on-site rapid testing?	**15a.** Screening test:
	15b. Confirmatory test:
	15c. Tie-breaker test:

16. In the past 12 months, was there ever a time when HIV test kits were unavailable due to stock-outs?	☐ No ☐ Yes ⇨ **16a.** If Yes, how many distinct instances of stock-outs were there in the past 12 months? ☐ 1 ☐ 2 ☐ 3 or more
17. In the past 12 months, did pregnant women have to pay for PMTCT HIV testing services?	☐ No ☐ Yes
18. When is syphilis testing part of routine ANC services?	☐ Syphilis testing done routinely all year ☐ Syphilis testing done routinely only during surveillance ☐ Syphilis testing not done routinely
19. Is syphilis testing done at this site (the building or compound of buildings that contains ANC services) or off-site (locations outside the building or compound of buildings that contains ANC services)?	☐ At this site ☐ Off-site

C. Patient data recording in the site registers

INSTRUCTIONS: This section asks about site registers, what variables are routinely recorded in each register and when HIV test results are routinely recorded. This section asks whether each variable is recorded in: a separate ANC register, a separate PMTCT HIV testing register (for all women who attend ANC services, not only those who are HIV-positive), a combined ANC/PMTCT register (ANC and PMTCT HIV testing records both contained in one physical register), a laboratory register, or whether the variable is not recorded. These questions only concern at site registers, not patient files or patient records retained by the pregnant woman. Please ask to see the registers to verify that all the variables are recorded as described.

In what site registers are the following variables recorded? (check all that apply)

Variable	A. Separate ANC register	B. Separate PMTCT HIV testing register (for all women who attend ANC services, not only HIV-positive women)	C. Combined ANC/PMTCT HIV testing register (ANC and PMTCT HIV testing records both contained in one register)	D. Laboratory register	E. Not recorded
20. Age	☐	☐	☐	☐	☐
21. Gravidity	☐	☐	☐	☐	☐
22. Parity	☐	☐	☐	☐	☐
23. Residence	☐	☐	☐	☐	☐
24. Date of visit	☐	☐	☐	☐	☐
25. Educational level	☐	☐	☐	☐	☐
26. Occupation	☐	☐	☐	☐	☐
27. HIV test offered	☐	☐	☐	☐	☐
28. HIV test accepted	☐	☐	☐	☐	☐
29. HIV test result	☐	☐	☐	☐	☐
30. Syphilis test result	☐	☐	☐	☐	☐

31. At which ANC visit is a woman's PMTCT HIV test result recorded in the separate ANC register?	☐ Always 1st visit ☐ Usually 1st visit	☐ Usually 2nd or 3rd visit ☐ Not recorded in this register
32. At which ANC visit is a woman's PMTCT HIV test result recorded in the separate PMTCT HIV testing register?	☐ Always 1st visit ☐ Usually 1st visit	☐ Usually 2nd or 3rd visit ☐ Not recorded in this register
33. At which ANC visit is a woman's PMTCT HIV test result recorded in the combined ANC/PMTCT HIV testing register?	☐ Always 1st visit ☐ Usually 1st visit	☐ Usually 2nd or 3rd visit ☐ Not recorded in this register
34. At which ANC visit is a woman's PMTCT HIV test result recorded in the laboratory register?	☐ Always 1st visit ☐ Usually 1st visit	☐ Usually 2nd or 3rd visit ☐ Not recorded in this register

D. Register formats		
INSTRUCTIONS: This section asks about the format of site registers. Please ask to see the current registers to confirm the format of the registers in use.		
35. Is the site using the current national standard separate ANC register?	☐ No ☐ Yes	☐ This type of register not in use at the site
36. Is the site using the current national standard separate PMTCT HIV testing register?	☐ No ☐ Yes	☐ This type of register not in use at the site
37. Is the site using the current national standard combined ANC/PMTCT HIV testing register?	☐ No ☐ Yes	☐ This type of register not in use at the site
38. Is the site using the current national standard laboratory testing register?	☐ No ☐ Yes	☐ This type of register not in use at the site
E. Previously known HIV-positive pregnant women		
INSTRUCTIONS: This section collects information about pregnant women who already know that they are HIV-positive upon presenting at their first ANC visit, what kind of PMTCT HIV testing services they receive and how their information is recorded. registers in use.		
39. If a pregnant woman already knows she is HIV-positive upon presenting at her first ANC visit, is she still given an HIV test for PMTCT?	☐ No ⇨ ☐ Yes	39a. If No, what is recorded in the pregnant woman's "HIV test result" field in the relevant register? ☐ "Positive" ☐ "Known positive" ☐ Nothing recorded ☐ Other _____
40. Is any information recorded in site registers to indicate that a pregnant woman already knows she is HIV-positive upon presenting at her first ANC visit?	☐ No ☐ Yes ⇨	40a. If Yes, in which column of the relevant register is this information recorded? ☐ HIV test accepted / HIV test done ☐ HIV test result ☐ Notes/comments ☐ Other _____
F. Women who opt out of PMTCT HIV testing		
41. If a pregnant woman (who does NOT already know she is HIV-positive) opts out of PMTCT HIV testing, where is this opt out recorded?	☐ Opt out recorded in a "HIV test acceptance" or "HIV test done" column ☐ Opt out recorded in the "HIV test results" column ☐ Nothing recorded ☐ Other _____	
G. Patient flow walk-through		
INSTRUCTIONS: The goal of this section is to understand in more depth the flow of a pregnant woman through the clinic and collection of her data. This will be done by physically walking through the entire process while each step is explained and recorded below. You may use information collected in sections A–F to probe or clarify responses. You may also use this section to further describe non-standard practices not adequately captured till now. Each time the interviewee indicates that a piece of information (e.g. age) is recorded in a certain place (e.g. ANC register), ask to see and visually verify that the information is recorded there. Make sure that the walk-through covers each step in the PMTCT HIV testing process and what information is collected (e.g. age, parity, etc.), where it is recorded (e.g. registers, etc.), when it is recorded and how it is recorded.		
42. Please walk me through the entire process by which a pregnant woman moves through the clinic during her first ANC visit, from the time she enters to her departure. At every step of the way, please describe in detail PMTCT HIV testing procedures, when patient information is collected, where it is recorded, and who is responsible for recording it.		
INSTRUCTIONS: The following additional questions should be asked **only** if this information was not described (or not described in sufficient detail) in Question 42 above.		

43. Is PMTCT HIV testing done at this site or off site? (PROBE: If off site, at what point of a pregnant woman's first visit does she go to the off-site location? When and how are HIV test results returned to the clinic to be recorded in the register?)
44. Please describe the clinical flow and how information is recorded for pregnant women who already know that they are HIV-positive upon presenting at their first ANC visit. (PROBE: Is information regarding a pregnant woman who already knows she is HIV-positive recorded anywhere? Are these pregnant women still tested for HIV?)
45. If a pregnant woman opts out of PMTCT HIV testing, what are the procedures? (PROBE: Is opt out recorded? If yes, where is this recorded?)
46. Where are the PMTCT HIV test results recorded? (PROBE: Are HIV test results recorded in one or multiple data tools? Where is this information recorded for the first time?)
INSTRUCTIONS: Thank the interviewee for his or her time and assistance.

Appendix E: Sample quality assurance checklist for PMTCT HIV testing

Region/Provider_____

District _____

Site_____

Date _____ **Assessor name** _____

Assessment instructions: For each question, please write the number 1 if the answer is "Yes" and the number 0 if the answer is "No." As a general standard, a facility score of 80% or higher in each phase category (pre-testing phase, testing phase and post-testing phase) would be considered to be within acceptable quality assurance parameters for HIV rapid testing

Pre-testing phase			
QUESTIONS	YES = 1	NO = 0	COMMENTS
1. Are there routine testing guidelines available which cover all HIV testing in the facility?			
2. Is the testing algorithm used at the facility current and updated according to the national guidelines?			
3. Are there signed records that all HIV testing procedures have been read and understood by HIV rapid testing personnel?			
4. Have all testing personnel received hands-on training in HIV rapid testing?			
5. Are all testing personnel trained in the use of standardized registers/logbooks?			
6. Are all testing personnel trained in safety and waste management procedures?			
7. Are only MOH-approved kits available for use?			
8. Are testing supplies stored in a secure cabinet or room?			
9. Are test kits stored according to the manufacturer's recommendations?			
10. Is the supply inventory updated periodically and expired materials discarded?			
11. When a kit in the algorithm is expired, and there are no kits available, is testing suspended until more kits become available?			
Total number of "Yes" answers ⇨			
Assessment score ⇨ ("Yes" answers divided by total number of questions)			

Testing phase			
QUESTIONS	YES = 1	NO = 0	COMMENTS
1. Is there a designated area for HIV testing at the facility?			
2. Is there clean water available for hand-washing?			
3. Is sufficient lighting available in the designated testing area?			
4. Is a first-aid kit available to testing personnel?			
5. Are safety gloves available to testing personnel?			
6. Are job aids on specimen collection available and posted?			
7. Are job aids on HIV testing procedures available and posted?			
8. Are job aids on testing algorithms available and posted?			
9. Are timers available and used routinely for HIV rapid testing?			
10. Are test kits used within the expiration date (first-to-expire, first-out [FEFO] principle)?			
11. Are test cartridges properly labelled (i.e. client ID) during use?			
12. Is the nationally standardized testing register/logbook in use?			
13. Are the kit names, lot numbers and expiration dates recorded for every test?			
14. Is the name of the person conducting the test recorded for each test?			
15. Are invalid tests recorded in a register/logbook, and then repeated?			
16. Are positive and negative quality control (QC) specimens routinely used (i.e. daily or weekly) according to country guidelines?			
17. Are QC specimen data recorded in a standardized logbook?			
18. Are appropriate steps documented and taken when QC specimens fail?			
Total number of "Yes" answers ⇨			
Assessment score ⇨ ("Yes" answers divided by total number of questions)			

Post-testing phase			
QUESTIONS	YES = 1	NO = 0	COMMENTS
1. Do testing supervisors routinely review testing logbooks/ registers (e.g. to identify high rates of discordant results between test 1 and test 2)?			
2. Are QC records routinely reviewed by a testing supervisor?			
3. Are registers/logbooks kept in a secure location?			
4. Are registers/logbooks properly labelled and archived when full?			
5. Is annual refresher training on HIV rapid testing offered to testing personnel?			
6. Is the testing site enrolled in an external quality assessment (EQA) programme (e.g. proficiency testing, site supervision, dried blood spot [DBS] retesting)? If yes, which one?			
7. Are proficiency samples tested by all personnel involved in HIV testing?			
8. Are testing personnel retrained when they fail an EQA activity?			
9. Is the site and/or testing personnel certified by the national certification system?			
10. Are sharps (e.g. lancets and needles) disposed of into appropriate containers?			
11. Are test cartridges disposed of into appropriate containers?			
12. Are waste containers emptied regularly?			
Total number of "Yes" answers ⇨			
Assessment score ⇨ ("Yes" answers divided by total number of questions)			

Recommendations/Comments:

_____

_____

_____

_____

Number of staff performing HIV tests_____

Name of: **Facility supervisor** _____

Nurse _____

Community counsellor_____

Others (please state)_____

Name of current kits in use	**Expiration dates**
_____	_____
_____	_____
_____	_____
_____	_____

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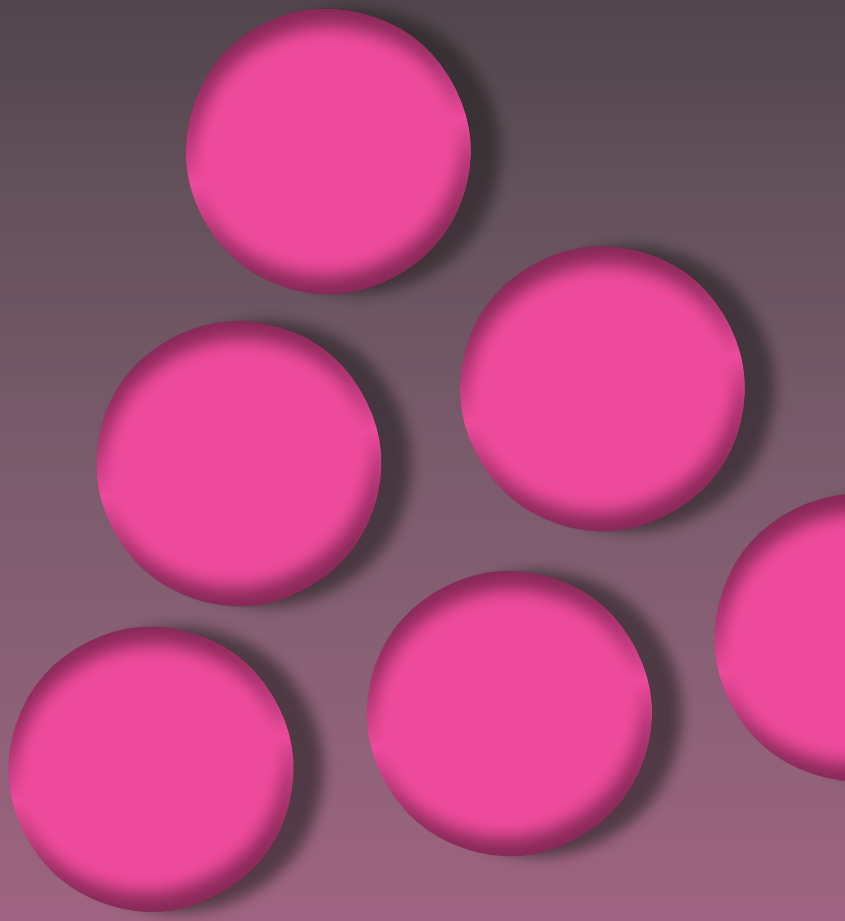
Notes

Notes



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