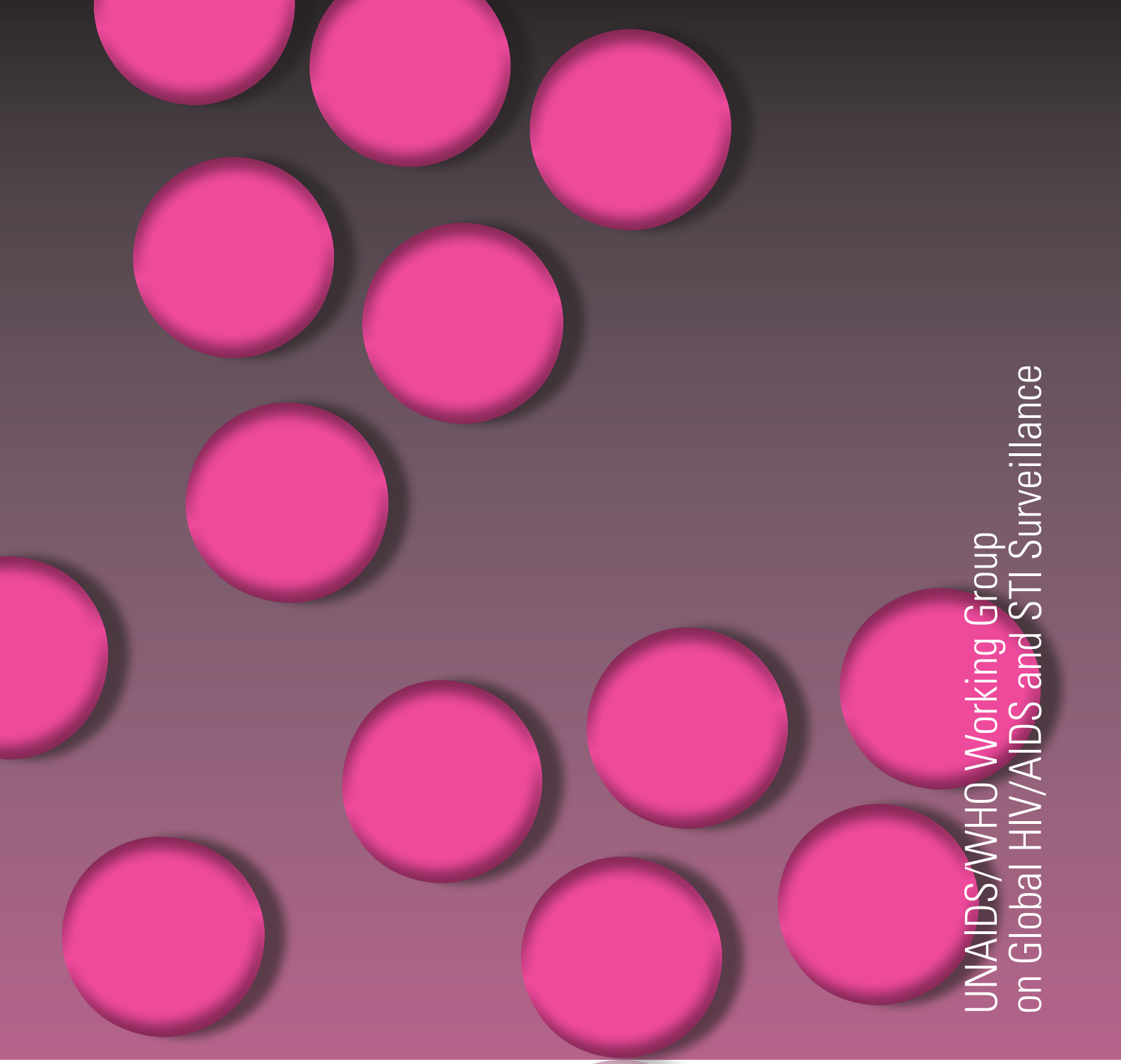

UNAIDS/WHO Working Group
on Global HIV/AIDS and STI Surveillance

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)*

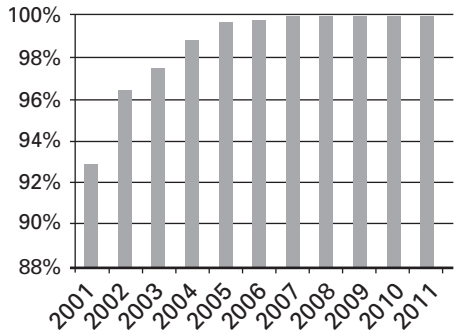
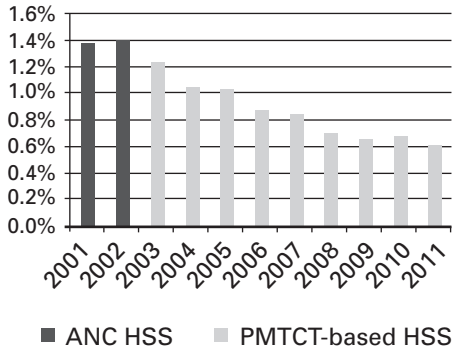


Figure 2. HIV prevalence from ANC HSS and PMTCT-based HSS, Thailand, 2001–2011*(21)*



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

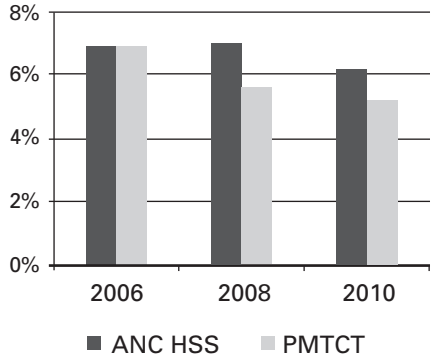
Kenya started biennial ANC HSS in 1990 and rolled out PMTCT services in 1999. Kenya has conducted multiple studies to assess the utility of PMTCT data for HSS, including studies comparing ANC HSS and PMTCT HIV test results among pregnant women sampled by ANC HSS in 2006, 2008 and 2010.*(26,27)* These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

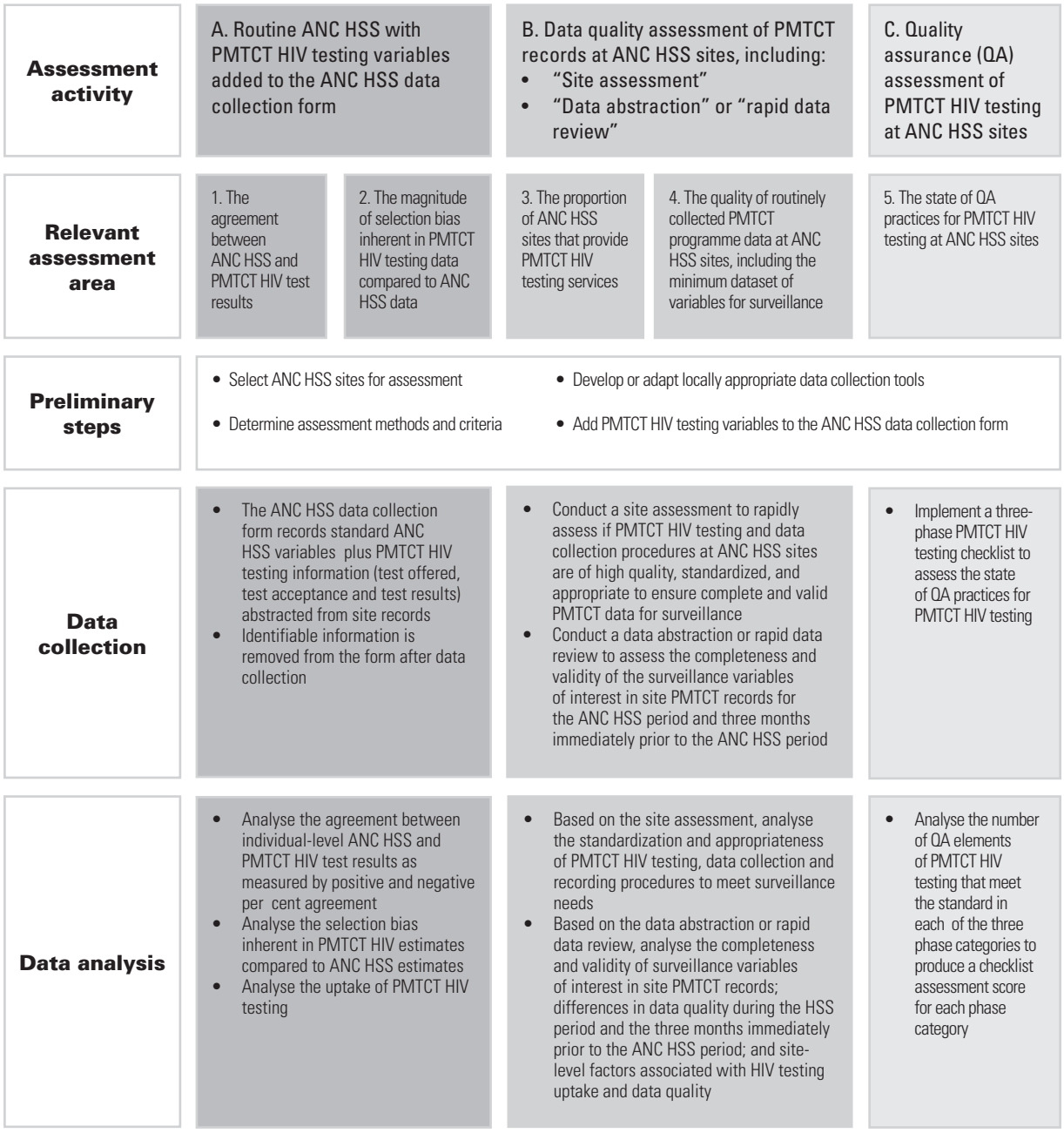
Figure 4 outlines the process flow for conducting a PMTCT surveillance assessment. The three principal assessment activities are as follows:

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

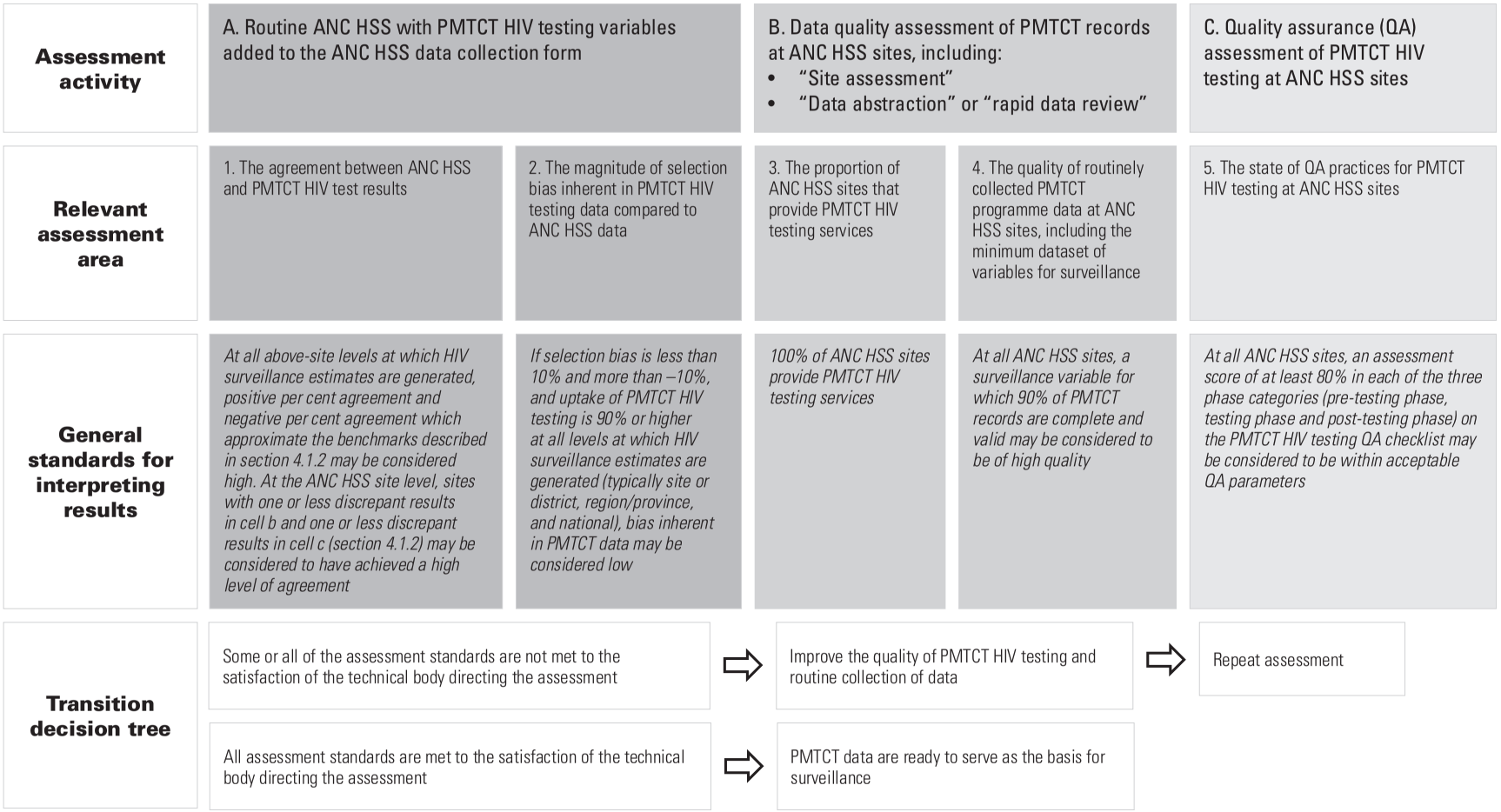
It is necessary that PMTCT HIV testing and programme data meet high standards to be considered ready to serve as the basis for HSS. These standards should reflect the consensus of the technical body charged with directing the PMTCT surveillance assessment, including government public health actors, partners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

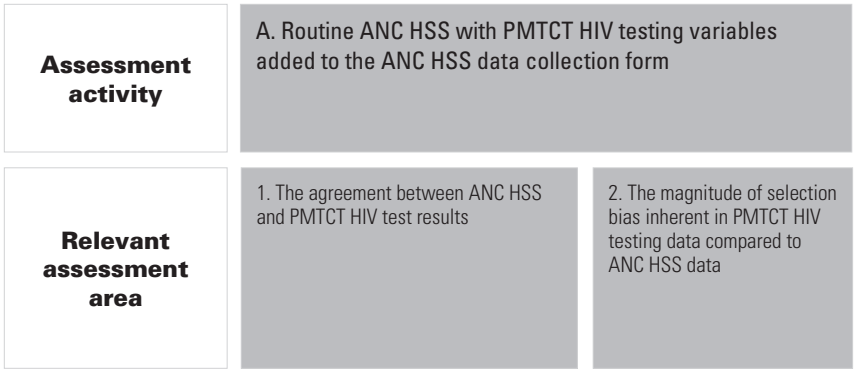
Figure 5. PMTCT surveillance assessment activities, assessment areas, general standards for interpreting results and transition decision tree



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.