Republic of Namibia

Ministry of Health and Social Services

Report on the Assessment of the Utility of Prevention of Mother to Child Transmission Program Data for Routine HIV Sentinel Surveillance among Pregnant Women Receiving Antenatal Care Services, 2012-2013

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List of Abbreviations

HIV	Human immunodeficiency virus infection
AIDS	Acquired immunodeficiency syndrome
ANC	Antenatal clinic
HSS	HIV sentinel surveillance
WHO	World Health Organization
UAT	Unlinked-anonymous testing
PCT	Prevention, care and treatment
ELISA	Enzyme-linked immune-sorbent assay
PMTCT	Prevention of mother-to-child transmission
MOHSS	Ministry of Health and Social Services
CDC	Centers for Disease Control and Prevention
NHSS	Namibia HIV sentinel survey
RPR	Rapid plasma reagent
NIP	Namibia Institute of Pathology
PITC	Provider-initiated testing and counseling
HCT	HIV counseling and testing
PPA	Positive percent agreement
NPA	Negative percent agreement
IQR	Interquartile range
DQA	Data quality assessment
MSF	Monthly summary form
DHIS	District Health Information System
HAART	Highly active antiretroviral therapy
RT	Rapid test
QA	Quality Assurance

PREFACE

The Ministry of Health and Social Services (MOHSS) of Namibia has been conducting HIV surveillance among pregnant women attending ANC every other year since 1992. However, population-based HIV surveillance for the very first time was attained with the completion of the 2013 National Demographic and Health Survey.

In 2012, the Ministry embarked upon the first evaluation to assess the utility of PMTCT program data as the basis for HIV surveillance among pregnant women. This exercise comprises of an assessment of the quality and completeness of routine PMTCT data; to compare HIV test results and prevalence estimates from ANC HSS and PMTCT data; to assess the quality of PMTCT HIV testing and quality assurance methods.

The results showed high levels of agreement between NHSS and PMTCT HIV test results. However the levels of percent agreement were slightly below what is set as a general standard by WHO/UNAIDS for the use of PMTCT program data alone for HIV Sentinel Surveillance.

The assessment further revealed that Namibia may be approaching readiness to transition to a PMTCT-program-data-based system of HSS. However, Implementing and standardizing the proper measures to address and rectify site-level sources of discrepancies in results would adequately prepare Namibia to phase out the current practice of conducting UAT-based ANC HSS in order to transition to utilizing routinely collected PMTCT program data for HIV surveillance purposes.

The MOHSS is thankful for the political commitment that the Government of Namibia has shown in giving the fight against HIV and AIDS a top priority in all its undertakings. It is this support and commitment that create a favorable environment enabling the Ministry to achieve all its accomplishments in the fight against HIV and AIDS to date. We will be failing in our duty if we don't acknowledge the tremendous contributions made by our partners. The MOHSS appreciates the support of our development and bilateral partners, including the United States Centers for Disease Control and Prevention, the technical assistance of the University of California San Francisco, and the staff and participants who were integral to the success of this evaluation.

PERMANENT SECRETARY
2015-11-03
REPUBLIC OF NAMIBIA
MINISTRY OF HEALTH AND SOCIAL SERVICES

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Mr Andrew Ndishishi

The Permanent Secretary

EXECUTIVE SUMMARY

This evaluation was used to assess the utility of Prevention-of-Mother-to-Child HIV Transmission (PMTCT) program data for HIV surveillance in place of Antenatal Clinic (ANC) based surveillance in Namibia.

ANC-based HIV sentinel surveillance (ANC HSS) is the basis for monitoring national trends in HIV infection in many countries, through HIV testing of blood samples collected during routine ANC visits by pregnant women. With PMTCT programs rapidly expanding, PMTCT data may increasingly be used for surveillance purposes. PMTCT programs target the same population of pregnant women as in ANC-based surveillance and they often collect similar information. At the WHO/AFRO HIV Surveillance meeting in July 2009 it was established that the strengthening of PMTCT programmes for surveillance purposes should be a priority surveillance activity. There is, however, little known about the comparability of ANC-based PMTCT data to ANC based sentinel surveillance data in most countries. It is not known how HIV test results and prevalence would compare between ANC HSS and PMTCT program data. The quality of site PMTCT individual-level data and HIV testing quality assurance methods are often uncertain.

In Namibia, the Ministry of Health and Social Services (MOHSS) conducts ANC HSS every other year, using standardized methodology recommended by the World Health Organization (WHO). Unlinked, anonymous HIV testing is completed on blood samples collected for routine syphilis screening from pregnant women attending ANC clinics. ANC HSS among pregnant women began in Namibia in 1992 at 8 sites. The number of sites continued to increase since 1994 to improve national representativeness. Most recently, the 2014 sentinel survey covered all 35 main sites in the country, including an additional 98 satellite sites.

The objective of this evaluation was to assess the utility of PMTCT program data as the basis for HIV surveillance among pregnant women in Namibia, including: to assess the quality and completeness of routine PMTCT data; to compare HIV test results and prevalence estimates from ANC HSS and PMTCT data; to assess the quality of PMTCT HIV testing and quality assurance methods. The evaluation achieved these objectives by prospectively capturing information about PMTCT HIV testing uptake and results on the ANC HSS form; gathering information on site PMTCT HIV testing, recording and patient flow characteristics; retrospectively examining PMTCT records from before and during the ANC HSS period; and assessing adherence to HIV rapid testing quality assurance measures put in place by the MOHSS and implemented by the National Institute of Pathology (NIP). Data collected contained no personal identifiers.

Results of this assessment highlighted that a transition from UAT-based to PMTCT-based HIV sentinel surveillance is feasible in Namibia. High levels of agreement between NHSS and PMTCT HIV test results, minimum selection bias, excellent HCT availability and uptake through the PMTCT program at HSS sites, and high data quality indicate that Namibia may be approaching readiness to transition to a PMTCT-program-data-based system of HSS. Although national

level NHSS and PMTCT-program-data prevalence estimates are virtually identical, levels of percent agreement are slightly below what would be required for the use of PMTCT program data alone for HSS and trend-analysis which all require accurate sub-national inputs. Potential site-level sources of results disagreement, including quality of PMTCT rapid testing and data, must be identified and corrected and compliance with existing RT-QA standards needs to be strengthened. Implementing and standardizing the proper measures to address and rectify site-level sources of discrepancies in results would adequately prepare Namibia to phase out the current practice of conducting UAT-based ANC HSS in order to transition to utilizing routinely collected PMTCT program data for HIV surveillance purposes.

1. BACKGROUND

Information about trends in the prevalence of human immunodeficiency virus (HIV) infection in the general population is necessary for countries to monitor the course of their epidemics and to measure the effectiveness of, and plan for, evidence-based prevention, care and treatment (PCT) interventions. In most countries of sub-Saharan Africa (SSA) with generalized or mixed epidemics, national HIV estimates and projections are based on annual or biennial antenatal care (ANC)-based HIV sentinel sero-surveillance (ANC-HSS) (1). ANC clinics provide an accessible cross-section of healthy, sexually active women in the general population and data from ANC-HSS are considered to be representative of the underlying population. ANC-HSS are typically conducted through unlinked anonymous testing (UAT) of pregnant women, following UNAIDS/World Health Organization (WHO) guidance on sentinel surveys among pregnant women (1, 2), in which leftover blood from specimens collected for routine syphilis testing are sent to reference laboratories and tested for HIV using third or fourth generation enzyme linked immunosorbent assay (ELISA) tests.

Prevention-of-mother-to-child-transmission (PMTCT) programs have scaled-up rapidly in sub-Saharan Africa during the past decade, with many countries attaining high coverage (3). PMTCT programs are integrated into routine ANC services and therefore access the same sample of women accessed through ANC-HSS (4). Standard PMTCT-program reporting tools include the same data required for routine HIV sentinel surveillance (HSS) among pregnant women receiving antenatal care, including the HIV test result, age, gravidity, clinic location and place of residence of each woman receiving ANC/PMTCT services. Therefore, it may be possible to conduct HIV surveillance among pregnant women by utilizing routinely collected PMTCT program data.

There are several potential advantages to replacing ANC- HSS with a system of PMTCT-based surveillance. The expansion of access to treatment services has highlighted ethical issues inherent in UAT-based ANC-HSS, given that this methodology does not allow pregnant women to consent to HIV testing or to receive their HIV test results, and be referred to available treatment services. PMTCT-based surveillance provides prevention services by ensuring that sampled women are tested for HIV, receive their HIV test results, and are referred to the appropriate treatment services. Other advantages include reducing the substantial workload and financial costs associated with conducting ANC HSS, fostering a programmatic culture of using routine program data for surveillance and improving PMTCT program monitoring and evaluation for improved service delivery (5).

There are some limitations to using PMTCT data for HIV surveillance: PMTCT HIV testing services may be inaccessible; inconsistent due to stock-outs of HIV test kits; or of poor quality at some or many sites (4). Quality of PMTCT program data may vary by site or over time. Selection bias of PMTCT HIV testing data may arise if testing acceptance varies by

patient sub-groups. Each of these factors could affect the accuracy and representativeness of HIV prevalence estimates and therefore limit the utility of PMTCT program for routine surveillance.

The WHO/AFRO Technical Network on HIV/AIDS and STI Surveillance recommended in 2009 that the strengthening of PMTCT programmes for surveillance purposes should be a priority surveillance activity (6). Currently, no country in sub-Saharan Africa (SSA) has replaced ANC-HSS with PMTCT-based surveillance. Several countries have conducted assessments to explore the potential for transition. Published results from studies conducted in SSA prior to 2010 provide mixed evidence in support of using PMTCT program data for routine surveillance. Studies in Botswana (2005–2007) (4), Cameroon (2003) (7), and Uganda (2001-2003, 2004–2005) (8, 9) reported that PMTCT data could be adequate for surveillance purposes in these countries. However, studies in Kenya (2003, 2005, 2006, 2008, 2010) (10 - 13), Burkina Faso (1996) (14), Zimbabwe (2004) (15), Uganda (2002–2003, 2004) (16), Ethiopia (2005) (12), and Rwanda (2007) (17) suggest that PMTCT program data for routine HIV surveillance in these countries would be biased . Common factors contributing to bias that were reported by these studies include: 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; poor PMTCT data quality; site-level differences in HIV prevalence estimates between ANC HSS and PMTCT data.

Until recently, no standardized methodology for assessing the utility of PMTCT program data for routine surveillance had been available. In July 2013, the WHO/UNAIDS Working Group on Global HIV/AIDS and STI Surveillance collaboratively released, *Guidelines for assessing the utility of data from prevention of mother-to-child transmission (5)*. Briefly, the guidelines advise that countries may consider replacing ANC-HSS with PMTCT-program based-surveillance if the following criteria are met:

1. Agreement between ANC HSS and PMTCT HIV test results is high.
2. The magnitude of selection bias inherent in PMTCT HIV testing data compared to ANC HSS data is limited .
3. The proportion of ANC HSS sites that provide PMTCT HIV testing services is universal.
4. The quality of routinely collected PMTCT program data at ANC HSS sites, including the minimum dataset of variables for surveillance is high.
5. Quality Assurance (QA) practices for PMTCT HIV testing at ANC HSS sites are robust.

This study was a collaborative effort between the Ministry of Health and Social Services (MOHSS) of the Government of the Republic of Namibia (GRN) and the United States Centers for Disease Control and Prevention (CDC), with assistance from the Namibia Institute of Pathology (NIP), which aimed to assess the utility of PMTCT program data for routine HIV surveillance among pregnant women receiving ANC in Namibia (18). This study was implemented in accordance with the methodological guidance from WHO/UNAIDS (5).

2. METHODS

2.1 Overview of ANC-HSS and PMTCT program in Namibia

ANC-HSS in Namibia is conducted biennially according to UNAIDS/World Health Organization (WHO) 2003 guidelines on surveillance among pregnant women and utilizes an UAT approach without informed consent or disclosure of results to participants (2, 19). However, all the ANC patients inclusive of those who participated in the survey are offered the opportunity to know their HIV status through the HIV counseling and testing routine test. In Namibia, ANC-based sentinel surveillance has been conducted biennially since 1992. This survey is called the National HIV Sentinel Survey (NHSS). The survey began with eight sites in 1992 and has since expanded to include main and satellite sites from all 35 health districts in order to generate nationally-representative HIV prevalence estimates among pregnant women.

WHO guidelines for conducting HIV sentinel surveillance among pregnant women recommend an UAT approach for data collection. In this approach individual survey forms (ISF) are used to collect socio-demographic information from eligible women. All required data elements for the survey are extracted from the ANC records (ANC Passport & register) and logged onto the self-carbonizing ISF, which includes the following information; a bar coded sticker with unique identification code, date of ANC visit, district abbreviation and site number, type of facility, woman's age, gravidity, place of residence, whether or not a patient is on ART, and whether or not the patient is counseled for PMTCT. Once routine testing for other purposes (e.g., syphilis) is complete, an aliquot (0.5 to 2.0ml) of leftover sera is obtained and transferred to a sterile plastic tube or cryovial and labeled with the survey code that corresponds to that found on the form with the socio-demographic data. After testing, the left over specimen is unlinked by removal of all personal identifiers. This specimen is then used for HIV testing, the results of which are included in the ANC HSS.

For Namibia's NHSS, blood specimens are collected in ethylenediaminetetraacetic acid (EDTA) anticoagulant tubes for routine syphilis testing via rapid plasma reagent (RPR) and the leftover volume is sent to the NIP reference laboratory in Windhoek for HIV antibody testing using an enzyme-linked immunosorbent assay (ELISA) (19). The Roche Architect HIV ag/ab Combi Assay screening test is an ELISA used to detect HIV antibodies (HIV-1/2) (sensitivity 100% [95% CI: 98.4 – 100%], specificity 99.5% [95% CI: 97.2 - 100%]) (Roche Diagnostics, Manheim, Germany) (20). All NHSS specimens that test positive are confirmed using a second ELISA, the COBAS e601 Analyzer Assay (sensitivity % [95% CI: %], specificity % [95% CI: %]) (21). Discordant results are classified as HIV-negative.

The PMTCT program in Namibia has scaled up rapidly since its introduction in 2002 and it was available in over 90% of health facilities nationwide by 2012 (22). According to routine program data, approximately 90% of pregnant women who delivered at ANC clinics knew their HIV status at time of delivery and the percentage of HIV positive pregnant

women that received ART in ANC or labor and delivery settings reached 95%. PMTCT services are integrated into routine ANC services in Namibia. PMTCT services are currently available at all main and satellites sites that were included in the 2012 NHSS. All women sampled in the NHSS are offered PMTCT services on the same visit when they are sampled for the NHSS. PMTCT services in Namibia include provider-initiated HIV testing and counseling (PITC), which is performed by the ANC nurse or an HIV testing lay counselor during the first ANC visit. PMTCT HIV testing and counseling (HCT) follows the national HIV diagnostic testing algorithm: each woman receives parallel rapid testing with the Determine HIV-1/2 test (Abbott Laboratories, Abbott Park, Illinois, USA: sensitivity 100.0% [CI: 95.5- 100.0%], specificity 99.4% [CI: 96.7-100.0%]) and the Uni-Gold HIV (Trinity Biotech, Dublin, Ireland: sensitivity 100.0% [CI: 95.5-100.0%], specificity 100.0% [CI: 97.9-100.0%]); discordant results are confirmed with a tiebreaker test using the Clearview Complete HIV 1/2 assay (Chembio Diagnostic Systems, Inc., Medford, NY, USA: sensitivity 99.7% [CI: 98.9%-100%], specificity 99.9% [CI: 99.6%-100%]) (20). If initial or tie-breaking test results confirm a negative result before 29 weeks into the pregnancy, women are advised to be re-tested from 36 weeks of gestation.

To ensure quality control, standardized HIV rapid test logbooks are used at all ANC/PMTCT sites. Internal quality assurance is conducted weekly by facility supervisors. External quality assurance through retesting is performed, requiring that all facilities submit 5.0% (i.e."one-in-20") of all blood samples each month to the NIP National Reference Laboratory for retesting. External quality assurance through proficiency testing is performed quarterly at all dual ANC/PMTCT sites where HIV rapid testing services are available. Quarterly site assessments are conducted by regional quality assurance officers from NIP. During site assessments, quality assurance officers review the testing logbooks and systematically review HIV rapid testing procedures and site operations using a standardized checklist.

2.2 Methods of the assessment

The 2012 NHSS individual survey forms (ISF) were modified to collect data about routine HCT received through the PMTCT program - including the PMTCT HIV test results- from each NHSS participant at the time of NHSS sampling. The NHSS was conducted from March to August 2012 at 35 main-sites, representing each of the country's 35 health districts, which were supplemented by 98 satellite sites (totaling 130 sites). At the end of the survey, NHSS ELISA and PMTCT rapid HCT results were compared for each NHSS participant who had both results available.

2.3 Assessment of testing agreement between NHSS and PMTCT program

Individual level data were used to calculate positive percent agreement (PPA) and negative percent agreement (NPA) of NHSS and PMTCT HIV testing in order to measure concurrence between the two testing methods. NHSS and PMTCT HIV prevalence, PPA and NPA between NHSS and PMTCT HCT HIV test results were calculated at the site level. Using the HSS test result as the "Gold Standard," PPA was defined as the percentage of women testing HIV positive by NHSS ELISA who were correctly classified as HIV positive by the PMTCT rapid test, while NPA was defined as the percentage of women testing HIV negative by HSS who were correctly classified as HIV negative by the PMTCT rapid test.

2.4 Assessment of selection bias in PMTCT program

PMTCT HCT access and PMTCT HCT uptake were measured to ensure that all sites participating in the assessment were offered HCT services and to assess the level to which pregnant women were accessing HCT services. The magnitude of selection bias inherent in PMTCT HIV testing data compared to ANC HSS data was also measured to deduce potential associations between acceptance of PMTCT HIV testing and likelihood of being HIV-positive or of known HIV-positive status. Selection bias is defined as the percent relative change from the total NHSS HIV prevalence among participants who do and do not receive PMTCT HCT, to the NHSS HIV prevalence among HSS participants who do receive PMTCT HCT. The formula for calculating selection bias is as follows:

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

2.5 ANC facility site assessment

The site assessment was conducted by a study staff member to collect quantitative and qualitative data on basic features and procedures of the co-located ANC HSS and PMTCT site. The aim of this questionnaire was to identify programmatic or service-delivery gaps that could pose challenges to a PMTCT-based system of HIV surveillance in Namibia (e.g. variations in registers used for data collection, accuracy of programmatic and data collection procedures, frequency of rapid testing kit stock outs, etc.). The questionnaire inquired about services offered and data collection procedures at each facility during that were in place from March to September of 2013, approximately one year after the implementation of the 2012 NHSS.

Increasingly, HIV positive women who know their positive status are having repeated pregnancies. Because women who are already known to be HIV positives would be included in an ANC HSSPMTCT data would falsely underestimate HIV prevalence if HIV information on these women is not collected in PMTCT records. The site assessment examined whether known HIV positive women are tested and how and where the status of known HIV positive women is recorded.

2.6 PMTCT program data quality assessment (DQA)

A retrospective, PMTCT program data quality assessment (DQA) was performed. Demographic and clinical data of pregnant women that were recorded during routine ANC/PMTCT first-visits were assessed from facility based PMTCT registers. The following variables in the registers were assessed for completeness and validity:

- age;
- gravidity;
- trimester;
- receipt of HIV pre-test counseling, HIV test, and HIV post-test counseling;
- HIV test result, and;
- receipt of ARV prophylaxis for PMTCT and CD4 test among HIV positive women only.

Any non-missing or legal value of a variable recorded in the register was classified as complete and/or valid, respectively. The predetermined evaluation standard for both completeness and validity were set by a national level technical working group at 90%, which is consistent with the "Guidelines for On-Site Data Verification and Rapid Services Quality Assessment used by The Global Fund to Fight AIDS, Tuberculosis and Malaria" *(23)*. The DQA were performed from March to May 2012 and again from March to May 2013 to assess whether data quality varied between NHSS and non-NHSS years.

2.7 PMTCT HIV rapid testing QA assessment

The WHO/UNAIDS guidance advises that assessments of the utility PMTCT program data for ANC-HSS include the administration of an HIV rapid testing quality assurance (QA)"checklist" to assess PMTCT HIV rapid testing QA procedure in place at each ANC-HSS site (5). However, because Namibia has a fully functioning HIV rapid testing QA system, the WHO/UNAIDS recommended checklist was not used. NIP oversees HIV rapid testing QA at public health facilities in Namibia and administers two QA tests on a regular basis to all sites that provide HIV rapid testing. The 5% or "one-in-20"

retest requires all sites to send a blood sample for every 20th client who receives a rapid testing to an NIP laboratory for confirmatory testing each month. Proficiency panel tests are blind panels that are sent to all sites on a quarterly basis for testing and the sites must test the samples and return their results to NIP. NIP staff also visit rapid test sites to perform supervisory visits and qualitatively evaluate the sites' adherence to rapid testing conditions and protocols using a standardized questionnaire, which is based on the HIV rapid testing standard operating procedures specified in the MOHSS National Guidelines on HIV Counseling and Testing (24). Data collected from each element of this HIV rapid testing QA system is stored in a national-level NIP HIV rapid testing QA database.

2.8 Data analysis

All analyses were performed using Stata/SE 12.1 software (*StataCorp. 2011. Stata Statistical Software: Release 12.1 College Station, TX: StataCorp LP.*).

2.8.1 HIV prevalence estimates

Pooled and site level HIV prevalence estimates by NHSS and PMTCT were calculated. Tests for site level differences between NHSS and PMTCT HIV prevalence estimates were performed using the Chi-square two-sample test of proportions, with P values ≤ 0.05 considered statistically significant. All statistical tests were two-sided.

2.8.2 Testing agreement and selection bias

PPA and NPA were calculated at the site level. The calculations for PPA and NPA are identical to those of sensitivity and specificity, respectively **(Table 1)**. However, because the NHSS HIV testing algorithm has imperfect performance characteristics (i.e. < 100% sensitivity and specificity) it should not be considered a reference standard; hence the terms positive percent agreement and negative percent agreement were used. These measures are used in this context because they provide the most accurate picture of the interface between the two testing algorithms and where disagreement may be occurring. NPA and PPA calculations were performed including and excluding known positives, in order to assess the effect of this sub-group on overall testing agreement. Logistic regression was used to estimate the participant level odds for negative disagreement (i.e. PMTCT result positive and NHSS result negative) and positive disagreement (i.e. PMTCT result negative and NHSS result positive) at the individual participant level, adjusted for age, gravida, urban/rural clinic location, and site sample size. Stata's *"svyset"* command was used to declare a survey design for the dataset with the NHSS site indicated as the primary sampling unit and the *"svy"* prefix was used during the logistic regression analysis so that each NHSS site was treated as a separate cluster and each woman was given equal statistical weight in all analyses.

Table 1: Calculation of positive percent agreement and negative percent agreement of ANC SS and PMTCT HIV testing

	ANC SS 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
* Non-reference standard			

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

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

Selection bias was also calculated at the site-level. Pooled percentages, as well as the median and interquartile range (IQR), of the site-level percentages, were calculated at the national-level. General assessment standards set by the WHO for using PMTCT data for surveillance are as follows: pooled PPA > 97.9, pooled NPA > 99.7, pooled PMTCT HCT uptake ≥ 90%, and pooled selection-bias ≤ +/- 10%.

2.8.3 ANC facility site assessment

The total number and percentage of facilities complying with different programmatic and data collection procedures between March to September of 2013 (22) were calculated using the site assessment questionnaire.

2.8.4 PMTCT DQA

Median percent completeness and validity of select variables and interquartile ranges (IQRs) were assessed for each site, as well as pooled for all sites participating in the 2012 NHSS.

2.8.5 HIV rapid testing quality assurance

Data from the NIP RT QA database were abstracted and the total number and percentage of NHSS sites meeting the following criteria was tallied:

1. Submitted at least one "one-in-20" retest sample during NHSS;
2. Submitted the required number of "one-in-20" retest samples during NHSS
3. Received a passing score (based on nationally set standards) on all "one-in-20" retest samples submitted during the NHSS;

4. Submitted at least one proficiency panel test during the NHSS;
5. Submitted the required number of proficiency panel tests during survey period (i.e. one proficiency panel every 3 months of the NHSS implementation);
6. Received a passing score on all proficiency panel samples submitted during NHSS.

Passing scores are evaluated according to pre-determined standards set by NIP in accordance with standard operating procedures specified in the MOHSS National Guidelines on HIV Counseling and Testing (24).

2.9 Human subjects consideration

The 2012 NHSS protocol, which included the protocol for the assessment of routine PMTCT program data for ANC-HSS, was approved by the Research Committee of the MOHSS and the Associate Director of Science of the Centers for Global Health of the US CDC. Informed consent was not collected from women from whom data was collected and analyzed as this was a retrospective study using routine program data and personally de-identified data from the 2012 NHSS.

3. RESULTS

3.1 HIV testing agreement and selection bias

A total of 7,996 pregnant women participated in the 2012 NHSS, 68.2% and 50.3% of which were prima-gravida and sampled from rural clinics, respectively **(Table 2).** Median participant age was 25 years. Overall, 18.2% of women tested HIV positive through NHSS. Women with previous known positive (KP) status (n= 860) composed 10.8% of the total sample and 59.2% of the 1,452 women that tested HIV **positive (data not shown).**

Table 2. Sample characteristics of women included in the 2012 NHSS

Variable	Result
Total women sampled, #	7,966
Age, *median (IQR) years*	25 (21 - 31)
Age 15-24, *% (CI)*	47.0 (45.2 - 48.7)
Prima-gravida, *% (CI)*	68.2 (66.2 - 70.2)
Sampled at rural site, % (CI)	50.3 (37.0 - 63.6)
Sampled at site with < 200 participants, *% (CI)*	81.2 (67.0 - 95.4)
Tested positive through NHSS, *% (CI)*	18.2 (15.7 - 20.7)

A total of 99.0% of women who participated in the 2012 NHSS received HCT services through the PMTCT program at the time of sampling and the site level median (IQR) of receipt of PMTCT HCT was 100% (98.5-100%)**(Table 3).** Pooled prevalence estimated by PMTCT HIV rapid testing was 18.2% and site level comparisons between PMTCT and NHSS prevalence estimates showed no significant differences between NHSS and PMTCT prevalence estimates. Pooled selection bias was 0.25% and the site level median (IQR) was 0.00% (0.00 – 0.38%). Pooled PPA and NPA were 95.3% and 99.1% respectively. Site level median (IQR) for PPA and NPA was 96.9% (93.1 – 98.2%) and 99.1% (98.7 – 100%) respectively. Assessment criteria for PMTCT HCT uptake, selection bias, PPA, and NPA, respectively, were met at 100%, 100%, 37.1% and 37.1% of the 35 main sites and at 96.9%, 96.2%, 88.5%, and 95.4% of the 130 satellite sites, respectively **(Table 4)**. PMTCT HCT was available at all sites.

Being sampled at a "large" site (i.e. $\geq$ 200 participants) was associated with increased odds for positive results disagreement [AOR: 2.16 (95% CI: 0.99 - 4.71), *P*=0.05], while previously known positive HIV status was associated with increased odds for negative results disagreement [AOR: 9.62 (95% CI: 4.96 - 18.66), *P* <.001] **(Table 5)**.

Table 3. HIV prevalence estimates, receipt of HIV counseling and testing, selection bias and percent agreement, overall and by site.

	PMTCT HIV prevalence (95% CI)	NHSS HIV prevalence (95% CI)	*P*-val.	PMTCT HIV testing uptake (95% CI)	Percent bias	PPA (95% CI)	NPA (95% CI)
Overall (pooled)	18.0 (- -)	18.2 (- -)	(--)	99.0 (--)	0.25	95.3 (- -)	99.1 (- -)
By site							
Andara	19.2 (14.2 - 24.1)	19.1 (14.3 - 23.9)	0.97	100 (- -)	0.0	93.9 (87.1 - 100)	99.5 (98.5 - 100)
Aranos	11.2 (5.6 - 16.8)	11.2 (5.6 - 16.8)	1	96.9 (93.9 - 99.9)	-4.1	100 (- -)	99.1 (97.2 - 100)
Eenhana	14 (9.7 - 18.3)	15 (10.6 - 19.4)	0.75	98.8 (97.5 - 100)	1.2	84.2 (72.4 - 96.0)	98.6 (97.0 - 100)
Engela	20.6 (15.9 - 25.2)	19.3 (14.7 - 23.9)	0.7	100 (- -)	0.0	98.2 (94.6 - 100)	98.3 (96.6 - 99.9)
Gobabis	10.4 (6.3 - 14.6)	9.9 (6 - 13.8)	0.86	95 (92.2 - 97.9)	5.2	100 (- -)	100 (- -)
Grootfontein	15.4 (10.6 - 20.3)	15.9 (11 - 20.8)	0.89	100 (- -)	0.0	91.2 (81.4 -100)	98.9 (97.3 - 100)
Karasburg	14.6 (9.8 - 19.3)	14.9 (10.2 - 19.6)	0.93	97.3 95.2 - 99.4)	-0.3	96.9 (90.7 - 100)	100 (- -)
Katima Mulilo	38 (33 - 43)	38 (33 - 43)	0.95	98.4 (97.1 - 99.7)	0.2	98.6 (96.5 - 100)	99.1 (97.9 - 100)
Katutura	16.4 (12.1 - 20.6)	14.4 (10.4 - 18.4)	0.5	99.3 (98.4 - 100)	0.7	95.2 (88.7 - 100)	97.2 (95.1 - 99.3)
Keetmanshoop	11.2 (6.6 - 15.9)	10.6 (6.1 - 15.1)	0.85	100 (- -)	0.0	94.4 (83.5 - 100)	98.1 (96.0 - 100)
Khorixas	10.2 (5.9 - 14.4)	12.4 (7.8 - 17.1)	0.48	100 (- -)	0.0	79.2 (62.5 - 100)	99.4 (98.2 - 100)
Luderitz	21.7 (16.5 - 26.9)	22 (16.8 - 27.2)	0.93	99.6 (98.8 - 100)	0.4	98.1 (94.5 - 100)	100 (- -)
Mariental	14.6 (9.7 - 19.6)	13.5 (8.8 - 18.2)	0.74	98 (96.1 - 99.9)	2.0	100 (- -)	98.8 (97.2 - 100)
Nankudu	13.6 (8.4 - 18.8)	13.1 (8.4 - 17.8)	0.88	95 (91.9 - 98.0)	5.3	100 (- -)	100 (- -)
Nyangana	22.6 (16.4 - 28.8)	22.0 (16.1 - 27.9)	0.89	100 (- -)	0.0	92.7 (84.6 - 100)	99.3 (97.8 - 100)
Okahandja	16.3 (11.8 - 20.8)	16.3 (11.9 - 20.8)	0.98	100 (- -)	0.0	97.7 (93.1 - 100)	99.5 (98.7 - 100)
Okahao	18.5 (13 - 24.1)	19.3 (13.6 - 24.9)	0.85	100 (- -)	0.0	97.2 (91.7 - 100)	100 (- -)
Okakarara	7.7 (2.8 - 12.5)	9.9 (4.6 - 15.3)	0.55	96.7 (93.5 - 99.9)	-5.2	81.8 (57.7 - 100)	100 (- -)
Okongo	20.9 (15.8 - 25.9)	20.8 (15.8 - 25.8)	0.98	99.2 (98.1 - 100)	-1.1	98.0 (94.2 - 100)	99.0 (97.6 - 100)
Omaruru	11.8 (7.1 - 16.4)	11.8 (7.1 - 16.4)	1	100 (- -)	0.0	100 (- -)	100 (- -)
Onandjokwe	25.7 (20.7 - 30.6)	25.9 (20.8 - 31)	0.95	95.3 (92.9 - 97.7)	0.8	97.3 (93.6 - 100)	99.1 (97.8 - 100)
Opuwo	9.1 (4.4 - 13.8)	9.8 (4.9 - 14.7)	0.83	100 (- -)	0.0	92.9 (78.7 - 100)	100 (- -)
Oshakati	22 (17.4 - 26.6)	22.3 (17.7 – 27.0)	0.92	100 (- -)	0.0	94.2 (88.6 - 100)	98.8 (97.3 - 100)
Oshikuku	24 (19.1 - 29)	24.7 (19.7 - 29.6)	0.86	99.7 (99.0 - 100)	0.4	97.2 (93.3 - 100)	100 (- -)
Otjiwarongo	16.5 (11.8 - 21.3)	16.9 (12.2 - 21.7)	0.9	100 (- -)	0.0	92.5 (84.2 - 100)	99.0 (97.6 - 100)
Outapi	18.7 (13.7 - 23.6)	17.6 (12.9 - 22.3)	0.76	100 (- -)	0.0	77.8 (65.4 - 100)	99.5 (98.4 - 100)
Outjo	12.8 (8.3 - 17.3)	12.8 (8.3 - 17.3)	1	100 (- -)	0.0	96.3 (89.0 - 100)	96.9 (94.5 - 99.4)
Rehoboth	9.8 (3.3 - 16.2)	9.8 (3.3 - 16.2)	1	100 (- -)	0.0	87.5 (62.6 - 100)	98.6 (96.0 - 100)
Rundu	24.5 (19.6 - 29.4)	25.2 (20.2 - 30.1)	0.85	100 (- -)	0.0	97.2 (93.4 - 100)	98.2 (96.4 - 99.9)
Swakopmund	14.8 (10.3 - 19.2)	14.5 (10 - 18.9)	0.93	100 (- -)	0.0	94.3 (86.4 - 100)	98.6 (96.9 - 100)
Tsandi	23.5 (18.8 - 28.3)	23.5 (18.8 - 28.3)	0.96	99.4 (98.5 - 100.3)	0.7	95.8 (91.0 - 100)	98.7 (97.2 - 100)
Tsumeb	18.2 (13.9 - 22.6)	19.2 (14.7 - 23.7)	0.75	99.7 (99.06 - 100.3)	-1.4	96.4 (91.5 - 100)	99.6 (98.8 - 100)
Usakos	12.7 (7.7 - 17.7)	12.2 (7.4 - 17)	0.89	95.6 (92.6 - 98.6)	-0.1	100 (- -)	100 (- -)
Walvis Bay	18.4 (13.7 - 23.1)	17.2 (12.6 - 21.8)	0.72	99.6 (98.9 - 100.4)	0.4	97.8 (93.4 - 100)	98.1 (96.3 - 99.9)
Windhoek Central	17.2 (12.6 - 21.8)	9.6 (4.8 - 14.4)	0.99	100 (- -)	0.0	100 (- -)	100 (- -)
Site level median (IQR)	16.3 (12.0 - 20.8)	15.9 (12.3 - 20.4)	(- -)	100 (98.5 – 100)	0.00 (0.00 – 0.38)	96.9 (93.1 - 98.2)	99.1 (98.7 - 100)

Table 4. Main and satellite sites that satisfied the assessment standards for receipt of PMTCT HIV testing, percent bias and percent agreement.

Variable	Main sites (N=35) that satisfied assessment standard, % [a]	Main and sentinel sites (N=130) that satisfied assessment standard, %
Women received PMTCT HCT (i.e. PMTCT testing "uptake")	100	96.9
Percent bias	100	96.2
Negative percent agreement	37.1	88.5
Positive percent agreement	37.1	95.4

a. Assessment standards are as follows: NPA > 99.7, PPA > 97.9, pooled PMTCT HCT uptake ≥ 90%, and pooled selection-bias ≤ +/- 10%.

Table 5. Adjusted odds ratios for PMTCT and NHSS HIV test results disagreement among participants enrolled in the NHSS 2012

Independent variable	AOR (95% CI) for negative disagreement [a]	*P* val.	AOR (95% CI) for positive disagreement [b]	*P* val.
Age 15-24 years [c]	1.20 (0.65 - 2.24)	0.55	1.00 (0.44 - 2.24)	0.99
Prima-gravida [d]	0.99 (0.55 - 1.78)	0.97	0.81 (0.35 - 1.84)	0.61
Previously known positive HIV status [e]	NA	NA	9.62 (4.96 - 18.66)	<.001
Urban site location [f]	0.94 (0.44 - 1.99)	0.34	1.32 (0.68 - 2.57)	0.42
Site sample ≥200 [g]	2.16 (0.99 - 4.71)	0.05	1.36 (0.66 - 2.82)	0.42

a. Participant's PMTCT result = positive and HSS result = negative, b. Participant's PMTCT result = negative and HSS result = positive, c. Ref. group: age 25-49 years, d. Ref. group: multi-gravida, Ref. group: not previously KP. KP variable not included in model to predict negative disagreement because ref. group perfectly predicts failure, Ref. group: rural site location, Ref. group: site with sample <200

3.3 ANC facility site assessment

Of the 130 ANC facilities that participated in the 2012 ANC HSS, 127 had individuals available to respond to the facility assessment questionnaire **(Table 6)**. Results of the questionnaire indicate that the majority of facilities were using the most current version of the ANC/PMTCT register and the Monthly Summary Form (MSF) (86% and 78%, respectively), while 96% offer HIV rapid testing services. Of the facilities offering HIV RT services, 100% were using the correct HIV RT algorithm. In the 12 months preceding the survey, approximately 28% of facilities were unable to provide HIV RT at least once due to HIV RT kit stock outs, while approximately 14% were unable to provide HIV RT because the certified tester was sick or on leave. Approximately 93% of facilities correctly defined someone who is "known positive" (KP) HIV status and 95% of facilities knew to provide HIV test to women who claim they are KP but have no documentation of their status. Almost all (99%) facilities provide syphilis testing as part of routine ANC services and the majority reported using the telephone or community tracing as a means to return syphilis test results to patients.

Table 6. Results of the dual ANC HSS and PMTCT facility site assessment results, 2013 [a]

Variable	Number of sites (N=127)	Percentage of sites
HIV rapid testing is routinely available at site	122	96.0
Correct HIV RT algorithm used at site	127	100
One or more community counselors perform HIV RT at site	125	98.4
≤ 30 minutes average waiting time for clients to receive HIV RT results at site	94	74.2
No instances of HIV RT stock outs during past 12 months at site	91	71.7
No instances of certified rapid tester staff during past 12 months at site	109	85.8
Current version of ANC/PMTCT register in use at site [a]	109	86.1
Current version of ANC/PMTCT monthly summary form in use at site [a]	100	78.5
Correctly entering HIV test result into the ANC register [b]	124	97.5
Staff correctly defined "previously known HIV positive" women at site	118	92.6
HIV rapid testing is offered to women who self-report at previously known positive without documentation at site	121	95.0
Syphilis testing is routinely available during ANC first visit at site	126	99.2
Syphilis test results returned from lab in less than one week at site	77	60.5
Use community tracing to return syphilis test results to clients at site	100	79.0

a. Most current versions of ANC/PMTCT register and MSF were distributed November, 2011, b. HIV rapid tester enters result into ANC passport, woman gives passport to nurse when she returns to the consultation room and nurse enters result into ANC register

3.2 PMTCT DQA

The median site-level percentage of PMTCT program data completeness and validity exceeded 90.0% during both review periods for the following variables: age, gravidity, trimester, receipt of HIV pre-test counseling, receipt of HIV test; HIV test result; receipt of HIV post-test counseling **(Table 7).** The receipt of CD4 and ARV for PMTCT variables were less than 90.0% complete or valid during both review periods.

Table 7. Data quality assessment of completeness and validity of variables in facility-based PMTCT registers.

Variable	Mar - May 2012 Site median % (IQR) Complete	Valid	Mar - May 2013 Site median % (IQR) Complete	Valid
Age	100 (100 - 100)	100 (100 - 100)	100 (100 - 100)	100 (100 - 100)
Gravidity	100 (100 - 100)	100 (100 - 100)	100 (100 - 100)	100 (100 - 100)
Trimester	94.9 (98.6 - 86.3)	95.0 (98.6 - 86.3)	94.0 (97.9 - 84.8)	94.8 (98.2 - 85.8)
HIV pre-test counseling	99.4 (100 - 94.8)	98.4 (100 - 94.4)	97.7 (100 - 91.8)	97.1 (100 - 91.6)
Tested for HIV	97.4 (100 - 93.5)	97.3 (100 - 93.5)	95.9 (100 - 88.1)	94.7 (100 - 88.1)
HIV result	100 (100 - 98.1)	100 (100 - 97.1)	99.5 (100 - 94.9)	99.0 (100 - 92.4)
HIV post-test counseling	93.2 (98.9 - 82.9)	93.0 (98.9 - 82.9)	91.9 (96.2 - 81.8)	90.3 (95.0 - 82.5)
Received ARV for PMTCT	83.3 (100 - 42.9)	83.3 (100 - 42.9)	87.5 (100 - 64.5)	86.7 (100 - 50.0)
Received CD4 test	41.0 (68.6 - 41.0)	31.8 (66.7 - 0)	38.1 (77.8 - 0)	38.1 (77.8 - 0)

3.3 Rapid testing QA

Of the 130 facilities included in the NHSS, 92 (71.0%) submitted at least one "one-in-20" retest samples and 105 (81.0%) sites submitted at least one proficiency panel test during the survey period. Of these sites, 23.0% and 79.0% submitted the required number of "one-in-twenty" retest and proficiency panel test samples, respectively. Among facilities that submitted retest and proficiency panel samples, the pass rate was 99.0% for retests and 99.0% for proficiency panels. Among the 92 sites with "one-in-20" re-test data available, 21 (22.9%) submitted $\geq$4% of their samples for re-testing and 29 (31.3%) submitted $\geq$3% of their samples for re-testing.

Table 9. Summary of rapid testing quality assurance procedures implemented at NHSS sites

Variable (N)	Number (%)
Submitted at least one "one-in-20" retest sample during NHSS (N=130)	92 (71.0)
Submitted required number of "one-in-20" retest samples during NHSS [a] (N=130)	21 (23.0)
Received a passing score on all "one-in-20" retest samples submitted during NHSS [b] (N=92)	91 (99.0)
Submitted at least one proficiency panel test during survey period (N=130)	105 (81.0)
Submitted required number of proficiency panel tests during survey period [c] (N=130)	79 (75.0)
Received a passing score on all proficiency panel samples submitted during NHSS [d] (N=105)	78 (99.0)

a. required number according to NHSS sample size, e.g. if 200 women were sampled at site during NHSS, 10 retest samples should be submitted for that site, b. denominator of percent calculation only includes sites that submitted "one-in-20" retest samples, c. required number according to number of quarters of implementation of NHSS (2 quarters), i.e. all sites should have submitted at leost 2 proficiency panel samples, d. denominator of percent calculation only includes sites that submitted proficiency panel samples

4. DISCUSSION

This study is the first to report results produced by methods recommended by the WHO/UNAIDS for assessing the utility of PMTCT program data for routine HIV surveillance among pregnant women receiving ANC in Namibia. According to our results, there is strong evidence in support of using PMTCT data for routine HSS in Namibia.

The WHO/UNAIDS guidance stipulates that PPA or NPA between PMTCT and ANC-HSS results in countries with ANC-HSS prevalence of ≥17.0% should generally be 97.6% and 99.5%, respectively, in order to favor a transition to PMTCT-based HSS *(5)*. Agreement below those thresholds exceeds what would be expected due to statistical variability and is likely due to performance characteristics between the HSS or PMTCT HIV testing algorithms *(5)*. In this study, the estimated PPA (95.3%) and NPA (99.1%) were both lower than what is generally recommended by WHO/UNAIDS. PPA was higher than estimates produced in similar settings *(26)*, but NPA was less robust. These results suggest that Namibia is approaching but has not entirely arrived at readiness to transition to a PMTCT program data-based system of routine HSS. Our results suggest that additional analyses designed to elucidate factors contributing to results disagreement, additional data quality activities and strengthening of the existing RT QA program may be required prior to a full transition.

Exploratory analysis of site-level PPA and NPA suggest that excluding known positives from PPA/NPA calculations improves PPA but reduces NPA. The effect of KP on NPA could be an indication that HSS participants may be incorrectly recorded as known positive, and/or that PPA may be less than originally estimated. Further investigation is needed to determine the underlying effect of KPs on PPA and NPA calculations, to discern whether HSS is giving false positive results or whether PMTCT HIV RT is giving false negative results. Low NPA also has important programmatic implications, suggesting that approximately one in 100 HIV-negative women receive a false positive RT result at first ANC. Given the high volume of negatives, this could mean a small but substantial proportion of women may be receiving ARV for PMTCT under false pretext. However, analysis at the site level found RT positive results disagreement to be concentrated in few sites. Therefore, identification and correction of factors affecting agreement at these sites could result in improved overall NPA and could be in place for PMTCT surveillance data collection activities.

The association between patient factors and results disagreement that was explored through logistic regression showed that; 1) women sampled at large sample sites were more likely to produce negative results disagreement, and; 2) women classified as previously KP were more likely to produce positive results disagreement. The first result suggests that client volume at an ANC clinic may adversely affect testing quality. It is plausible that nurses performing RT in high-volume sites may rush to complete a client's RT in order to attend to all of the clients awaiting services during an ANC-

first visit clinic, subsequently leading to human errors in reporting test results. Previous studies have reported that with a high volume of testing, even a small error can result in a large number of misdiagnosed cases (27).

The second result suggests that KP positive women may be incorrectly classified or recorded as such during the ANC first visit. Namibia ANC/PMTCT guidelines stipulate that women without official documentation of KP status be offered an HIV test *(22)*. However, our results suggest that this guidance may not be uniformly implemented, or that women self-identifying as KP but without documentation may be refusing an HIV test but are, nevertheless, documented as KP by the nurse responsible for entering data in the PMTCT register. If known HIV-positive women are not systematically included in PMTCT programme data, surveillance estimates based on PMTCT data would falsely underestimate HIV prevalence *(5)*. This interpretation is partially supported by further analysis indicates that excluding known HIV positive women from PPA and NPA calculations improves PPA from 95.3% to 99.6%, and decreases NPA from 99.1% to 88.8%. The extent to which self-report and documentation of previously known positive HIV status effects percent agreement needs to be further explored.

HCT access and uptake through the PMTCT program in Namibia was excellent, and the introduction of bias due to exclusion of women who do not receive PMTCT HCT was minimal. These results strongly support transition to PMTCT program-based HIV surveillance and compare favorably to findings in other countries in SSA: Studies in Zimbabwe (2004), Cameroon (2003), and Botswana (2005-2007) all listed low HCT uptake as an obstacle to using PMTCT program data for HIV surveillance. Other studies have identified factors which may lead to the introduction of selection bias into PMTCT-based prevalence estimates *(28 - 34)*. 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 underestimation 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, underscoring the need to consider the unique status of these women when conducting an assessment *(5)*.

The facility assessment results highlighted strengths of introducing a PMTCT program-based HSS in Namibia. Overall, facilities appear to comply with all proper procedures for PMTCT program services as outlined in the MOHSS PMTCT Guidelines *(22)*. The high number of facilities providing on-site HIV rapid testing services and complying with programmatic procedures to confirm the status of known HIV-positive women are both conducive to a PMTCT-based system of HIV surveillance. However, the frequency of HIV RT kit stock-outs has the potential to undermine a PMTCT-based system of HIV surveillance, thus steps need to be put in place to ensure that RT kits are procured in a timely manner. Additionally, changes in routine data collection tools, such as the ANC/PMTCT register and Monthly Summary

reporting Form, could pose challenges to data collection processes if facilities do not transition to the appropriate tools in a timely manner. Finally, although facilities may be abiding by the correct procedures to confirm a woman's KP status, women with no proof of their HIV-positive status may still refuse an HIV test, thus underestimating HIV prevalence in that facility.

The DQA results also support transition to PMTCT program-based HSS in Namibia. Completeness and validity of data elements essential to surveillance in the ANC/PMTCT registers was excellent and only data elements not essential to surveillance reporting were of low quality. These DQA results are considerably higher than results produced in similar settings. A study conducted in South Africa (2009) revealed that data collected and reported across high HIV-prevalence districts was neither complete nor accurate enough to track process performance or outcomes for PMTCT care *(35)*, while another study in Kenya (2003) cited variances in PMTCT logbook formats and low levels of accurately reported data as challenges to a PMTCT-based HIV surveillance system *(10)*.

Nevertheless, the accuracy of data in Namibia varied between different levels of the PMTCT program data reporting chain, with the point of 'breakdown' in the chain occurring during data abstraction and entry from paper-based monthly summary forms to the electronic DHIS. Values observed in monthly summary forms were minimally divergent from values of "raw" data observed in the site-level PMTCT registers, whereas values observed in DHIS reports were greatly divergent from values observed in the registers. This finding has important implications for the practical application of a PMTCT program-based system of ANC-HSS in Namibia; namely, if HIV prevalence estimates are to be produced from data abstracted from routine PMTCT-program reporting tools, data cannot be abstracted from the national level DHIS data base until sources of data inaccuracy are identified and corrected. At present, only data abstracted directly from the facility based registers (at an individual level) or monthly summary forms (at an aggregate level) would be acceptable for producing PMTCT-based surveillance estimates.

Namibia has established robust standards for implementing RT QA procedures at health facilities where RT is performed. Namibia's standards are aligned with international standards *(24, 36)*. However, our results show that these standards are not uniformly implemented at all sites. According to data in the NIP RT-QA database, few sites were fully compliant with standardized QA protocols. The explanatory potential of PMTCT-based HIV prevalence estimates would be limited without assurance that all sites were implementing RT-QA in compliance with standardized guidelines. Therefore, proposals to transition to a PMTCT program-based system of ANC-HSS in Namibia would need to be accompanied by a fortification of the RT-QA system to ensure that all sites are routinely compliant with standardized protocols.

A limitation of this study is that the quantitative (i.e. optical density ELISA values) of the NHSS results were not available for analysis. The raw surveillance laboratory testing data could elucidate the origin of discrepancies in the RT/ELISA

comparison. In particular, RT false negatives may be associated with ELISA optical density (OD) values that are above the threshold but low, suggesting possible ELISA false positive *(5)*. Namibia may consider further testing of such specimens by Western blot or polymerase chain reaction (PCR) to confirm or rule out HIV infection. A second limitation of this study is that it was not powered to assess correlations between compliance with RT-QA protocols and PPA/NPA between PMTCT and ANC-HSS results. Finally, methods included in the WHO guidelines focus on assessing PMTCT and ANC-HSS results agreement using the HSS result as the reference standard. Since HSS is done in a controlled laboratory environment with QA procedures in place, we presume these results are likely to be accurate and reliable; however we were not able to further investigate them to exclude HHS errors as the cause of discrepancies.

5. CONCLUSION AND RECOMMENDATIONS

This activity highlighted the potential strengths and challenges for a PMTCT-based HSS in Namibia. High levels of agreement between NHSS and PMTCT HIV test results, minimum selection bias, excellent HCT availability and uptake through the PMTCT program at HSS sites, and high data quality indicate that Namibia is approaching readiness to transition to a PMTCT-program-data-based system of HIV surveillance. Although national level NHSS and PMTCT-program-data prevalence estimates are virtually identical, levels of percent agreement are slightly below what is set as a general standard by WHO/UNAIDS for the use of PMTCT program data alone for HSS, trend-analysis, and estimates, which all require accurate sub-national inputs. By prioritizing measures to address and rectify site-level sources of discrepancies, the MOHSS should be able to phase out the current practice of conducting UAT-based ANC HSS and transition to utilizing routinely collected PMTCT program data for HIV surveillance purposes in the near future. With this in mind the MOHSS and its partners should consider the following recommendations:

- Identify and correct site-level sources of results disagreement - including quality of PMTCT rapid testing and data and proper recording of KP pregnant women - through additional exploratory analyses, in-service trainings and supervisory support that focus on correct data entry and reporting procedures.
- Ensure compliance with existing RT-QA standards at all levels of PMTCT program implementation, and strengthen the ability of the NIP QA Unit to conduct routine QA site visits at all sites where HIV RT is available.
- Conduct routine DQA assessments to ensure that PMTCT program data sustains the high level of quality that was observed by this study.
- Strengthen HIS at all levels to facilitate access, quality and use of PMTCT program data.
- Prioritize the development of methodology for a PMTCT program data system of routine HSS.

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9. APPENDICES

Appendix A: 2012 Individual Survey Form for collection of demographic variables

Ministry of Health and Social Services

HIV ANC Sentinel Surveillance Survey

Individual survey form

Form Serial # 0 0 0 1

AFFIX BAR CODE STICKER HERE

1	Date of interview	D D / M M / Y Y Y Y
2	District abbreviation	
3	Site Number	
4	Type of facility *1=hospital 2=health centre 3=clinic*	
	Extract information below directly from the Ante Natal Care Passport and the ANC Register	
5	Patient age (in years)	
6	Place of current residence (town name/farm/village and not locations)	
7	Gravidity	
8	Patient on HAART? *1=yes 2=no*	
9	Did patient receive HIV pre-test counseling? *1=Yes 2 =No*	
10	Was patient tested for HIV? *1= Yes 2= No*	
11	HIV test Result *1=Positive, 2 =Negative 3 =Undetermined 4 =Not tested 5 =known positive (not tested) 6=results missing*	
12	Nurse's initials *(Surname followed by initial or given name)*	

Appendix B: Assessment of the Utility of PMTCT Program Data for Routine HIV Sentinel Surveillance in Namibia

COMPLETENESS-VALIDITY ASSESSMENT FORM							
Facility Name _____ *NHSS Site Code* _____ *(XXX-#)*							
Variable		**Month**					
		Mar-12	Apr-12	May-12	Mar-13	Apr-13	May-13
Age	# complete						
	# valid						
Gravida	# complete						
	# valid						
Trimester	# complete						
	# valid						
PRE TEST COUN	# complete						
	# valid						
TESTED	# complete						
	# valid						
HIV RESULT	# complete						
	# valid						
POST TEST COUN	# complete						
	# valid						
ARV GIVEN	# complete						
	# valid						
CD4 COUNT RESULT	# complete						
	# valid						

Appendix C: HSS/PMTCT Comparison FACILITY ASSESSMENT INTERVIEW QUESTIONAIRE

1. NHSSS site code (XXX -##)

→ *Notes: refer to Appendix E of the SOP manual to confirm the facility's NHSS site code.*

☐☐☐-☐☐

2. Site Name

---

3. Name and Job Title *(e.g. Enrolled Nurse, Registered Nurse, Community Counselor)* of Respondent (s)

---

4. Today's date (dd/mm/yyyy)

☐☐-☐☐ -☐☐☐☐

5. Interviewer's *(Field Team Leader)* name

---

6. PMTCT program at site since date (mm/yyyy)

☐☐ -☐☐☐☐

7. Is ANC/PMTCT HIV testing performed by rapid test at this facility?

☐ a. Yes

☐ b. No

7b. If "yes", since what date (mm/yyyy)

☐☐ -☐☐☐☐

8. Is the ANC/PMTCT HIV testing approach "opt-in" or "opt-out"

☐ a. opt-in

☐ b. opt-out

9. Versions of ANC/PMTCT Register in use

→ *Notes: field team should ask to see the ANC/PMTCT and HCT register for each indicated time point*

9a. Which version of the ANC/PMTCT register is in use currently?

_____

9b. Which version of the ANC/PMTCT register was in use from Mar. 2012 - May 2012

_____

10. Versions of HCT Register in use

10a. Which version of the HCT Register is in use currently?

_____

10b. Which version of the HCT Register was in use from Mar. 2012 - May 2012

_____

→ If RAPID TESTING IS NOT PERFORMED AT THIS SITE, SKIP TO QUESTION 20

11. What is the PMTCT HIV testing algorithm for on-site rapid testing, including the screening assay, confirmatory assay, and tie breaker assay?

11a. screening assays?

☐ a. Determine and Unigold

☐ b. Determine and Clearview

☐ c. Unigold and Clearview

☐ d. other

11b. tie-breaker/ confirmation assay ?

☐ a. Determine

☐ b. Unigold

☐ c. Clearview

☐ d. other

12a. Who is currently responsible for performing HIV rapid testing for ANC clients

☐ a. always a registered nurse

☐ b. always an enrolled nurse

☐ c. always a community counselor

☐ d. either an RN or an EN, depending on who is available

☐ e. either an RN, an EN, or a community counselor depending on who is available

☐ f. others

12b. if "other", please specify _____

13. How many community counselors are currently performing rapid testing for ANC clients at this facility?

☐ a. none

☐ b. one

☐ c. two

☐ d. three or more

14a. Who was responsible for performing HIV rapid testing for ANC clients during the 2012 HIV sentinel survey period (March 2012 – May 2012)?

☐ a. always a registered nurse

☐ b. always an enrolled nurse

☐ c. always a community counselor

☐ d. either an RN or an EN, depending on who is available

☐ e. either an RN, an EN, or a community counselor depending on who is available

☐ f. other

14b. if "other", please specify _____

15. How many community counselors were performing rapid testing at this facility during the 2012 NHSS survey period (March 2012 – May 2012)?

☐ a. none

☐ b. one

☐ c. two

☐ d. three or more

16. If rapid testing is performed on site, where in the facility is the rapid testing performed?

☐ a. in the ANC consultation room

☐ b. in a separate HIV counseling and testing or "rapid testing" room

☐ c. Not applicable

17. If rapid testing is performed in a separate room within the facility, where is this room in relation to the ANC consultation room?

☐ a. in the same building as the ANC consultation within the same facility

☐ b. in a different building from the ANC consultation within the same facility

☐ c. Not applicable

18. If rapid testing is performed in a separate room, when is the woman tested during the ANC visit?

☐ a. before the medical examination

☐ b. after the medical examination

☐ c. Not applicable

19. If rapid testing is performed in a separate room within the facility, on average, how long must a woman usually wait in queue to be tested?

☐ a. Usually no waiting in a queue, women tested immediately

☐ b. < 10 minutes

☐ c. 10-15 minutes

☐ d. 15-20 minutes

☐ e. >15 minutes

☐ f. Not applicable

20. If rapid testing is performed in a separate room within the facility, on average, how long must a woman usually wait in queue to return to the ANC consultation room after she finished rapid testing.

☐ a. Usually no waiting in a queue, women tested immediately

☐ b. < 10 minutes

☐ c. 10-15 minutes

☐ d. 15-20 minutes

☐ e. >15 minutes

☐ f. Not applicable

21a. Who records the results of the HIV test in the HCT Register?

☐ a. always a registered nurse

☐ b. always an enrolled nurse

☐ c. always a community counselor

☐ d. either an RN or an EN, depending on who is available

☐ e. either an RN, an EN, or a community counselor depending on who is available

☐ f. other

21b. if "other", please specify _____

22a. Who is responsible for recording the results of the HIV test in the ANC/PMTCT Register?

☐ a. registered nurse

☐ b. enrolled nurse

☐ c. community counselor

☐ d. either an RN or an EN, depending on who is available

☐ e. either an RN, an EN, or a community counselor depending on who is available

☐ f. other

22b. if "other", please specify _____

23a. If rapid testing is performed in a separate room, how is the result of the HIV test entered into the ANC register?

☐ a. the rapid tester enters the HIV result into the ANC passport, then the ANC nurse enters the HIV result from the ANC passport into the ANC register when the woman returns to the ANC consultation room *(during the same visits)*

☐ b. the rapid tester enters the HIV result into a hand-written note and gives the note to the client. When the client returns to the ANC consultation room, the ANC nurse enters the result from the note into the woman's ANC passport and the ANC register.

☐ c. the rapid tester enters the HIV result into the ANC passport, and then the rapid tester enters all of the day's HIV results from the HCT register into the ANC register at the end of the day

☐ d. the rapid tester enters the HIV result into the ANC passport, and then the ANC nurse enters all of the day's HIV results from the HCT register into the ANC register at the end of the day

☐ e. other

23b. If "other", please specify

_____

_____

_____

_____

_____

24a. In the facility's HCT Register, are ANC clients and general population clients included in the same register?

☐ a. ANC clients and general population clients are entered in the same HCT register

☐ b. there are two separate HCT registers: one for ANC clients and one for general population clients

24b. if "a. same register", does the facility use any code to identify ANC clients in the HCT register ? ***(confirm by checking the register)***

☐ a. Yes

☐ b. No

24c. If "yes", please describe the code by the facility _____

25a. During the last 12 months, was there ever a time when HIV rapid test kits were unavailable due to stock outs?

☐ a. Yes

☐ b. No

25b. If "yes" how many distinct instances of stock out were there in the last 12 months?

☐ a. one

☐ b. two

☐ c. 3 or more

25c. If "yes", how did women receive their HIV test during the stock-out?

☐ a. specimens were collected for ELISA

☐ b. women were asked to return at a later date when rapid test kits were expected to return in stock

☐ c. women were not tested and were not instructed to return for a test at a later date.

26a. In your own words, please describe the term "known positive" and when it is appropriate to record "KP" in the ANC/PMTCT register

☐ a. when the woman is tested during the *current* ANC visit, receives a positive test result and therefore knows that she is HIV positive

☐ b. when the women has been tested for HIV and received a positive result *before* presenting to the first ANC visit of the current and therefore knows that she is HIV positive. This can include a positive test result that was received during a previous pregnancy

☐ c. Other

26b. If "other", please specify _____

27a. If a pregnant woman already knows she is HIV-positive upon presenting at her first ANC visit, *and she has documentation of her status (i.e. the ANC passport)* is she still given an HIV test for PMTCT?

☐ a. Yes

☐ b. No

27b. If No, what is recorded in the pregnant woman's "HIV test result" field in the ANC Register

☐ a. "1" or "P"

☐ b. "5" or "KP"

☐ c. Nothing recorded

☐ d. Other _____

27c. If "other", please specify _____

28. If a pregnant woman already knows she is HIV-positive upon presenting at her first ANC visit, *and she does not have documentation of her status* (i.e. the ANC passport) is she still given an HIV test for PMTCT?

☐ a. Yes

☐ b. No

29. If specimens are collected and sent to the lab for ELISA HIV testing, how are results returned to your facility?

☐ a. Returned by the lab to the ANC clinic of the health facility

☐ b. Returned by the testing site (lab, VCT site, etc.) to a department of the health facility other than ANC

☐ c. Returned by the pregnant woman via the ANC passport

30. When are the results of the laboratory ELISA HIV test results physically returned to this facility?

☐ a. same day as testing

☐ b. <= 1 week after testing

☐ c. 1-2 weeks after testing

☐ d. > 2 weeks after testing

31a. When the results of the laboratory ELISA HIV test are returned to the facility, who is responsible for entering the results in the ANC register?

☐ a. registered nurse

☐ b. enrolled nurse

☐ c. community counselor

☐ d. other

31b. if "other", please specify _____

32a. During the last 12 months, did pregnant women have to pay for any part of ANC or PMTCT HIV testing services?

☐ a. Yes

☐ b. No

32b. If "yes" cost incurred for what? Specify _____

30a. Is syphilis testing always part of routine ANC services the entire year?

☐ a. Yes

☐ b. No

30b. If yes, where are specimens collected for syphilis testing at this facility?

☐ a. in the ANC consultation room

☐ b. in a separate room within this facility

30c ☐ If in a separate room, please specify _____

31. How are the results of the syphilis test returned from the lab to the ANC clinic?

☐ a. Returned by the lab to the ANC clinic of the health facility

☐ b. Returned by the testing site (lab, VCT site, etc.) to ANC clinic of the health facility

☐ c. Returned by the pregnant woman via the ANC passport

32. When are the results of the syphilis test returned to the ANC clinic?

☐ a. same day as testing

☐ b. <= 1 week after testing

☐ c. 1-2 weeks after testing

☐ d. > 2 weeks after testing

33a. Who is responsible for entering the syphilis test results in the ANC register?

☐ a. registered nurse

☐ b. enrolled nurse

☐ c. community counselor

☐ d. other

33b. if other, please specify _____

34a. When are the results of the syphilis test given to the woman?

☐ a. when the woman returns for a follow-up visit

☐ b. when the woman returns for delivery

☐ c. other

35b. if other, please specify _____

35a. If the woman does not return for a follow-up visit, how are the results of the syphilis test returned to her?

☐ a. staff attempt to contact the woman by telephone

☐ b. staff attempt to contact the woman by community based outreach

☐ c. the results are not returned to the woman unless she returns for a follow-up visit.

☐ d. other

35b. if other, please specify _____

36. Who is currently responsible for completing the ANC/PMTCT monthly summary forms?

☐ a. always a registered nurse

☐ b. always an enrolled nurse

☐ c. always a community counselor

☐ d. either an RN or an EN, depending on who is available

☐ e. either an RN, an EN, or a community counselor depending on who is available

☐ f. other

37. Who was responsible for completing the ANC/PMTCT monthly summary forms during the 2012 NHSS study period (Mar 2012 – May 2012?

☐ a. always a registered nurse

☐ b. always an enrolled nurse

☐ c. always a community counselor

☐ d. either an RN or an EN, depending on who is available

☐ e. either an RN, an EN, or a community counselor depending on who is available

☐ f. other

Appendix D: Summary Reporting Assessment Form (Monthly Summary)

SUMMARY REPORTING ASSESSMENT (Monthly Summary Form) FORM							
Facility Name _____ *NHSS Site Code* _____ *(XXX-#)*							
Indicator		**Month**					
		12-Mar	12-Apr	12-May	13-Mar	13-Apr	13-May
Women starting ANC	ANC 01						
ANC clients pre-test counseled	ANC 02						
ANC clients KNOWN HIV POSITIVE	ANC 02.1						
ANC clients tested for HIV	ANC 02.2						
ANC clients (tested) HIV positive	ANC 03						
ANC clients (tested) HIV negative	ANC 04						
ANC clients positive but not yet 14 weeks	ANC 09						
ANC clients given ARV (prophylaxis)	ANC 10+11						
ANC clients started on HAART in ANC	ANC 12						
ANC clients already on HAART	ANC 13						

Appendix E: Summary Reporting Assessment (Register) Form

SUMMARY REPORTING ASSESSMENT (REGISTER) FORM						
Facility Name _____ *NHSS Site Code* _____ *(XXX-#)*						
Indicator	**Month**					
	12-Mar	12-Apr	12-May	13-Mar	13-Apr	13-May
Women starting ANC						
ANC clients pre-test counseled						
ANC clients KNOWN HIV POSITIVE						
ANC clients tested for HIV						
ANC clients (tested) HIV positive						
ANC clients (tested) HIV negative						
ANC clients positive but not yet 14 weeks						
ANC clients given ARV (prophylaxis)						
ANC clients started on HAART in ANC						
ANC clients already on HAART						

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