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HIV surveillance in Rwanda: readiness assessment to transition from antenatal care-based to prevention of mother-to-child transmission program-based HIV surveillance

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SUMMARY

Background: In 2013, the World Health Organization (WHO) recommended that for efficiency and ethical considerations, transitioning from antenatal clinic-based surveillance to prevention of mother-to-child transmission (PMTCT)-based routine data should be investigated. An assessment of the readiness for this transition was carried out in Rwanda in 2011 and 2013.
Methods: This assessment applied the WHO recommended method. Individual HIV rapid testing at site was compared to antenatal surveillance results at all existing 30 sites, involving 13 292 women. In addition, PMTCT HIV testing quality assurance and PMTCT routine data quality were assessed at 27 out of the 30 sites.
Results: All sentinel sites provided PMTCT services and had a high uptake of HIV testing (more than 90%). At all sites, PMTCT data were recorded in longitudinal and standardized antenatal clinic registers. Twenty-six out of 27 sites had HIV result completeness above 90%. A positive percentage agreement of 97.5% and negative percentage agreement of 99.9% were observed between routine PMTCT and sero-surveillance HIV test results. Of 27 sites, 25 scored more than 80% in all phases of HIV testing quality assurance.
Conclusions: According to WHO standards, Rwanda antenatal care HIV sero-surveillance is ready to transition to PMTCT-based sero-surveillance.

1. Introduction

The last decade has seen remarkable changes in the global HIV epidemic. An estimated 35.3 million people were living with HIV in 2012, an increase from previous years and mainly attributable to people living longer due to successful antiretroviral therapy programs.[1] Simultaneously, the incidence of HIV has been falling, with a 33% decline in the number of new infections from 2001 (3.4 million) to 2012 (2.3 million). The number of AIDS-related deaths also declined from 2.3 million in 2005 to 1.6 million in 2012.[1]

HIV surveillance activities have been crucial to track the progress of the epidemic, understand the burden of HIV disease, and inform HIV control interventions. HIV sentinel surveillance among pregnant women attending antenatal clinic sentinel sites has been the cornerstone of HIV surveillance in countries with generalized epidemics (defined as HIV prevalence greater than 1% in the general population).[2] Historically, antenatal care HIV sero-surveillance (ANC-HSS) has been conducted using the method of unlinked anonymous testing (UAT). Introduced by the World Health Organization (WHO) in 1988, UAT extracts routinely recorded demographic information and collects remnant blood samples from specimens provided for routine antenatal care (ANC) services from antenatal clinic attendees. These data and specimens are then permanently delinked from all personally identifiable information and sent to a regional or central laboratory for HIV testing and

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epidemiological analysis.[2] In 2007, the WHO recommended exploring the feasibility of shifting HIV surveillance to using routinely collected prevention of mother-to-child transmission (PMTCT) program data,[3] for two primary reasons. First, there were ethical concerns about the UAT approach, as women do not give consent to participate or provide blood, nor do they receive the surveillance HIV test results. Second, the use of routinely collected data would demand less resources and be more sustainable than ANC-HSS.[3–8] In 2013, the WHO published guidelines to support country assessments of their readiness to transition from ANC-HSS to PMTCT-based sero-surveillance (PMTCT-SS).[3]

In Rwanda, the prevalence of HIV has stabilized at 3% in the general population.[9] The Rwanda Ministry of Health has used ANC-HSS to track the HIV epidemic since 1998, expanding from six initial sentinel sites to 24 sentinel sites in 2002 and to 30 sites in 2005. Rwanda used the UAT approach for ANC-HSS through 2007, but transitioned to using linked anonymous testing (LAT) with informed consent in 2011 in order to collect data to assess readiness to switch from ANC-HSS to PMTCT-SS. Due to strong integration of ANC and PMTCT services and data quality improvement strategies, interest in the use of routine PMTCT data for ANC-HSS increased. It is against this context that the readiness for routine PMTCT data use was assessed. The assessment examined the five key areas, the five key areas are: (i) uptake of HIV testing in antenatal clinics, (ii) percent bias, (iii) the quality of routinely collected PMTCT program data, (iv) the PMTCT HIV rapid testing quality assurance parameters and (v) the accuracy of PMTCT HIV testing results.

2. Methods

This study included all 30 sites in the 2011 Rwanda ANC-SS round. Except for Kigali City, which is represented by three urban sentinel sites, each of the remaining four provinces were represented by at least two urban and two rural sites. Among the 30 sites, 14 were located in urban areas and 16 in rural areas. The assessment included three distinct data collection activities: (1) the capture of routine PMTCT HIV testing information as part of the 2011 ANC-SS at the 30 sites; (2) a PMTCT HIV testing quality assurance assessment at 27 of the 30 sites; and (3) a retrospective PMTCT data quality assessment at 27 of the 30 sites.

2.1. The capture of routine PMTCT HIV testing information as part of the 2011 ANC-HSS

For the 2011 ANC-HSS, the survey population consisted of pregnant women, aged 15–49 years, making their first antenatal visit (during their current pregnancy) at one of the 30 sentinel sites during the surveillance period. Women were excluded from the study if they were referred by another health facility or if they were attending a follow-up ANC visit. According to standard ANC service delivery, all women were offered routine HIV testing in the context of PMTCT. Women who accepted HIV testing received a venous blood draw and on-site HIV testing according to the national HIV diagnostic algorithm: all blood specimens were screened by Determine HIV-1/2 (Abbott Laboratories, Abbott Park, IL, USA) and positive specimens were confirmed by SD Bioline HIV-1/2 3.0 (Standard Diagnostics Inc., at, Hagal-Dong, Giheng-Ku, Yongin-Si, Kyonggi-do Korea); the Uni-Gold HIV rapid test (Trinity Biotech, Dublin, Ireland) was used as a tie-breaker. The results of rapid HIV testing were provided to women on the same day.

Women who accepted HIV testing were also recruited for the surveillance survey. Women providing informed consent were administered a brief interview capturing basic demographic data and PMTCT HIV testing uptake and results, and a remnant of their routine blood sample provided for syphilis and other tests was sent with the interview form to the National Reference Laboratory (NRL) for HIV testing linked by a unique surveillance code. These samples were tested by ELISA using HIV Vironostika HIV Uni-Form II Ag/Ab (bioMérieux, Marcy l'Etoile, France) fourth-generation as the screening test and Murex HIV Ag/Ab Combination (Abbott/Murex, Wiesbaden, Germany) fourth-generation as the confirmatory test. If there was a discrepancy between the Vironostika and Murex tests, the samples were confirmed by Enzygnost HIV Integral II (Dade Behring, Marburg, Germany). All eligible women were enrolled consecutively in the survey for 6 months from May to November 2011.

Data on routine PMTCT HIV testing uptake and the surveillance ELISA results from the NRL (considered the gold standard) were used to calculate the following measures: (1) the uptake of routine PMTCT HIV testing; (2) the agreement between routine PMTCT HIV testing results and ANC-HSS testing results as measured by positive and negative percentage agreement (PPA and NPA; the PPA was calculated as the proportion of pregnant women found HIV-positive by ANC-HSS who were identified as HIV-positive by rapid diagnostic testing, while the NPA was the percentage of pregnant women found HIV-negative by ANC-HSS who were identified as HIV-negative by rapid diagnostic testing); (3) percentage bias, which was the percentage difference from the HIV prevalence among all women enrolled in the antenatal clinic and the HIV prevalence among women who accepted PMTCT HIV testing.

2.2. PMTCT HIV testing quality assurance assessment

A WHO standardized checklist was used to assess all areas of PMTCT HIV rapid testing quality assurance.[3] Data were collected in April and May 2013. The checklist was administered to all sentinel sites by a surveillance staff member with laboratory training. The checklist recorded the presence of quality assurance elements in PMTCT HIV testing in three phase categories: pre-testing phase, testing phase, and post-testing phase. Every quality assurance element in the checklist that met the defined standard was scored 1 point. The sentinel site was considered to be within acceptable quality assurance parameters if the assessment score was at least 80% in each of the three phase categories. The score was produced by calculating the percentage of possible points that were awarded.

2.3. PMTCT data quality assessment

A data quality assessment of PMTCT routine data was conducted through an adapted WHO standard checklist.[3] The quality of surveillance variables of interest in routine ANC registers was assessed retrospectively for women meeting the eligibility criteria of the 2011 ANC-HSS (pregnant women making their first ANC visit during their current pregnancy) during the period September 2012 to February 2013. Fifteen key variables were assessed: ANC code, PMTCT code, age, visit date, gravidity, parity, marital status, residence, occupation, education, HIV testing date, HIV test result, syphilis screening date, syphilis screening results, and previous HIV testing. The variables were assessed for completeness and validity. A field was considered complete if there was a value present and valid if the recorded value was in the expected range.[3] The proportion of records with complete and valid data was reported for each variable. Site was treated as a clustering variable to allow for intra-site correlations when calculating the confidence intervals around the estimates.

2.4. Ethical considerations

For the comparison of PMTCT HIV results and the 2011 ANC-HSS results, a linked confidential testing procedure with informed consent approach was used. Participants gave informed consent to

Table 1
Agreement between antenatal care surveillance-based ELISA test results and PMTCT-based routine rapid test results, Rwanda 2011

	ELISA-positive		ELISA-negative		ELISA HIV prevalence estimate	PMTCT HIV prevalence estimate	PPA[a]	NPA[b]
	PMTCT-positive (*n*)	PMTCT-negative (*n*)	PMTCT-positive (*n*)	PMTCT-negative (*n*)				
Overall (*n* = 13 279)	432	10	10	12827	3.3 (2.6–4.0)	3.3 (3.0–3.6)	97.51 (95.65–99.38)	99.85 (99.74–99.96)
Rural (*n* = 6626)	118	1	5	6502	1.8 (1.4–2.2)	1.8 (1.5–2.2)	98.32 (96.26–100.00)	99.82 (99.62–100.00)
Urban (*n* = 6653)	314	9	5	6325	4.8 (4.1–5.6)	4.9 (4.3–5.3)	97.21 (94.54–99.88)	99.89 (99.77–100.00)

PMTCT, prevention of mother-to-child transmission.
[a] The positive percentage agreement (PPA) was calculated as the proportion of pregnant women tested HIV-positive by ELISA who were identified as HIV-positive by rapid testing
[b] The negative percentage agreement (NPA) was calculated as the percentage of pregnant women tested HIV-negative by ELISA who were identified as HIV-negative by rapid testing.

be part of the surveillance. Thus they benefited from pre-test and post-test counseling of routine PMTCT HIV testing. Blood specimens were coded with a survey code and linked to the ANC code that was considered as a personal identifier. Using this link, surveillance laboratory results were returned to sites and provided to patients. Interview-based data collection was only performed with eligible participants who provided informed consent. Participant confidentiality was ensured during the surveillance activity. Participant names were not collected. All paper data were maintained in lock-protected storage locations. Electronic data were maintained on a single password-protected database. Once all the surveillance laboratory results had been returned to sites/patients, the ANC code was delinked from the surveillance database before analysis.

Table 2
Agreement between ANC HIV surveillance (ELISA) and PMTCT HIV testing (rapid diagnostic test) results by site

Name of site	Number	PPA	NPA
Bungwe	542	100 (80.5–100)	100 (99.3–100)
Busasamana	486	100 (63.1–100)	100 (99.2–100)
Byumba	492	100 (81.5–100)	100 (99.2–100)
CMS Bilyogo	447	100 (89.1–100)	100 (99.1–100)
CMS Gikondo	434	100 (90.0–100)	100 (99.1–100)
Gisenyi[a]	416	90.9 (76.2–99.9)	99.7 (98.2–99.9)
Gitarama	476	96.0 (79.7–99.9)	100 (99.2–100)
Gitare	456	100 (47.8–100)	100 (99.2–100)
Kabuga	508	100 (87.2–100.0)	100 (99.2–100)
Kigembe	383	100 (29.2–100)	100 (99.0–100)
Kirehe	411	100 (54.1–100)	100 (99.1–100)
Mashesha	510	100 (54.1–100)	100 (99.3–100)
Mugina	370	100 (54.1–100)	99.5 (98.0–99.9)
Mukungu	383	100 (54.1–100)	100 (54.7–100)
Murunda	383	100 (69.2–100)	99.7 (98.5–100)
Musebeya	387	100 (29.2–100)	100 (99.0–100)
Nyagatare[a]	482	83.33 (58.6–96.4)	99.6 (98.5–99.9)
Nyamagabe	416	100 (78.2–100)	99.8 (98.6–100)
Nyanza	458	100 (81.5–100)	100 (99.7–100)
Rubengera	562	100 (87.2–100)	100 (99.3–100)
Ruhango[a]	577	91.7 (73.0–99.0)	100 (99.3–100)
Ruhengeri	565	100 (86.8–100)	100 (99.3–100)
Ruhuha	340	100 (63.1–100)	99.7 (98.3–100)
Rukara	419	100 (59.0–100)	100 (99.1–100)
Rukomo	311	100 (59.0–100)	100 (98.8–100)
Ruli	388	100 (63.1–100)	100 (99.0–100)
Runyombyi	402	100 (39.8–100)	100 (99.1–100)
Rusizi	401	100 (84.6–100)	99.7 (98.5–100)
Rwamagana	426	100 (75.3–100)	99.8 (98.7–100)
Simbi[a]	461	93.33 (68.1–99.8)	99.9 (98.8–100)

ANC, antenatal care; PMTCT, prevention of mother-to-child transmission; PPA, positive percentage agreement; NPA, negative percentage agreement.
[a] Poor performing site: a site were PPA or NPA is <95%.

3. Results

3.1. Capture of routine PMTCT HIV testing information as part of the 2011 ANC-HSS

With regard to the uptake of HIV testing in antenatal clinics and potential biases, of the 30 ANC-SS sites that took part in the PMTCT HIV testing assessment conducted from May to November 2011, 100% had provided PMTCT services since 2005. All of the 13 292 eligible women consented to participate in the 2011 ANC-HSS, and 100% of these women, including those known to be HIV-positive (*n* = 297), consented to routine PMTCT HIV testing.

With regard to the comparison of PMTCT HIV testing and ANC-HSS results, out of 13 292 women, 13 279 had both PMTCT HIV rapid diagnostic test (RDT) and ANC-HSS ELISA test results. Of the 13 292, 442 (3.3%) tested positive by RDT. The overall HIV prevalence according to both PMTCT using RDT and ANC-HSS using ELISA testing was 3.3% (95% confidence interval (CI) 3.0–3.7%) (Table 1).

Individual-level comparison of PMTCT and surveillance HIV test results revealed a PPA of 97.5% (95% CI 95.7–99.4%) and an NPA of 99.9% (95% CI 99.7–100.0%) (Table 1). The PPA and NPA were found to be similar among urban and rural sites. Of the 30 sentinel sites, 19 (63.3%) had a PPA of 100% and an NPA of 100%. Four sites showed a PPA of <95% and two had an NPA ≥99.7% (Table 2).

3.2. PMTCT HIV testing quality assurance assessment

The results of the assessment of PMTCT HIV rapid testing quality assurance showed that laboratory registers were available and accessible at all sites and were securely stored when not in use. At all sites, routine HIV testing guidelines were available and the national standardized algorithm with approved test kits was being used. Although there is no printed laboratory register, all sentinel sites had developed standardized handwritten laboratory HIV rapid testing registers, which contained all the NRL recommended information items. A checklist on PMTCT HIV rapid testing quality assurance was used to collect information on the three defined phases of HIV testing quality assurance. The following HIV testing quality assurance elements were most often missed and were similar across the majority of sites: (1) pre-test phase: signed records of all HIV rapid testing procedures (18.5%); (2) testing phase: labeling test kits with date received, date opened, and initials (29.6%); recording the kit names, lot numbers, and expiration dates (29.6%). Findings indicated that 25 out of the 27 sentinel sites had a pass score (≥80%) in all three testing phases (Table 3).

Table 3
HIV rapid testing quality assurance score at 27 antenatal sentinel surveillance sites in Rwanda, 2012–2013

Sentinel sites	Pre-test phase (n = 11 quality elements)	Testing phase (n = 15 quality elements)	Post-test phase (n = 10 quality elements)
Bilyogo	90.9	86.7	90.0
Bungwe	81.8	86.7	90.0
Busasamana	90.9	86.7	90.0
Byumba	81.8	86.7	90.0
Gikondo	90.9	93.3	90.0
Gisenyi	72.7	66.7	80.0
Gitarama	81.8	86.7	90.0
Gitare	81.8	93.3	90.0
Kabuga	81.8	86.7	90.0
Kigembe	90.9	93.3	80.0
Kirehe	81.8	86.7	90.0
Mashesha	81.8	86.7	90.0
Mugina	81.8	80.0	80.0
Murunda	81.8	80.0	80.0
Musebeya	81.8	93.3	80.0
Nyagatare	81.8	73.3	80.0
Nyamagabe	81.8	93.3	80.0
Nyanza	90.9	93.3	100.0
Rubengera	81.8	80.0	80.0
Ruhango	81.8	80.0	90.0
Ruhengeri	81.8	86.7	80.0
Ruhuha	90.9	93.3	90.0
Rukara	100	93.3	90.0
Rukomo	81.8	80.0	90.0
Rusizi	81.8	80.0	80.0
Rwamagana	81.8	86.7	90.0
Simbi	81.8	80.0	90.0

Table 4
Completeness and validity of HIV surveillance variables at 27 antenatal care sentinel sites in Rwanda, 2012–2013[a]

Variable of interest	Proportion of completeness (95% CI)	Proportion of validity (95% CI)
	N = 19 389	
ANC or PMTCT code	100	100
Date of visit	100	100.0 (99.9–100.0)
Age	99.0 (98.9–99.1)	100
Gravidity	94.0 (92.4–95.6)	100
Parity	96.0 (94.2–97.8)	99.6 (98.8–100.0)
Marital status	98.0 (97.2–98.8)	100 (99.9–100.0)
Residence	99.0 (98.5–99.5)	100 (99.9–100.0)
Education[b]	-	-
Occupation[b]	-	-
HIV test date	100	100
HIV test result	100	100
Syphilis test offered date	50.0 (43.2–56.8)	100 (99.9–100.0)
Syphilis test result	49.0 (42.3–55.7)	100 (99.9–100.0)
Previously known HIV status	92.0 (84.0–100.0	94.6 (86.0–103.1)
Partner visited ANC services	99.0 (98.8–99.2)	100
Partner HIV test result	98.0 (97.6–98.4)	100
Partner shared HIV test results	97.0 (96.7–97.3)	100

CI, confidence interval; ANC, antenatal care; PMTCT, prevention of mother-to-child transmission.

[a] Site was treated as a clustering variable to allow for intra-site correlations when calculating the confidence intervals.

[b] Education and occupation are among the World Health Organization variables of interest for the assessment of readiness of PMTCT routine data for HIV sero-surveillance; however these data were not routinely recorded in the ANC register in Rwanda.

3.3. PMTCT data quality assessment

Records of 19 389 eligible women attending ANC services at 27 sites during September 2012 to February 2013 were assessed. Results showed that the routine recording of 13 variables (ANC number, PMTCT code, date of visit, age, parity, gravidity, marital status, residence, HIV and syphilis testing date, HIV and syphilis results, and previously known HIV status) was standardized in the ANC/PMTCT register in a standardized fashion at the first ANC visit. Education and occupation were not routinely captured. In addition, routine recording of six variables (ANC code, age of client, date of HIV and syphilis test, and corresponding results) were done in the handwritten laboratory registers (Table 4).

Key variables of interest assessed showed levels of completeness and validity above 90% in the ANC/PMTCT register. For the 19 389 women recorded in ANC/PMTCT registers, the ANC code, visit date, HIV testing date, and HIV testing results were complete and valid for 100%. Ninety-nine percent of women recorded had age and residence complete and valid. Syphilis screening date and testing results were only complete for respectively 50% and 49% of records (Table 4).

4. Discussion

As international guidelines recommend a shift from ANC-HSS to using routine PMTCT-SS, it was found that Rwanda is ready to make this transition. The assessment was comprehensive, following WHO recommendations, and assessed several elements of the PMTCT program and routine data. The findings show a very high uptake of routine HIV testing among ANC attendees at sentinel sites. The core surveillance variables of interest from the PMTCT data quality assessment were routinely recorded in an ANC/PMCT standardized register, with a high degree of completeness and validity. There were robust quality assurance measures for routine PMTCT HIV testing, and a high level of agreement between routine PMTCT HIV rapid testing and surveillance ELISA HIV testing. Several countries have completed similar exercises to determine their readiness, but results have varied for HIV testing uptake, data quality, or concordance between test results.[4,6–8,10–18]

The readiness to transition to PMTCT-based surveillance is due to several marked successes of the Rwandan HIV program, first and notably the integration and universal coverage of ANC/PMTCT services. The Government has rapidly scaled up PMTCT programs over the years, with coverage doubling between 2005 and 2011. Among the sentinel sites, the high uptake of HIV testing at ANC/PMTCT services is due to the strong response to the HIV epidemic in Rwanda and the greater awareness of the importance of PMTCT services fully integrated within ANC services.[19] These data corroborate other findings from the Rwandan National HIV Program, which have indicated that the uptake of HIV testing among ANC attendees nationally increased from 34.4% in 2005 to 100% in 2007 and 98.4% in 2012.[6] Similar increases have been observed in Kenya, where the coverage of PMTCT services increased from 15% in 2003 to 100% in 2005, and the uptake of HIV testing from 56% in 2003 to 99% in 2010.[10,20] From these data, it seems that earlier identified barriers to the uptake of testing in the ANC programs of other countries (including perception of higher risk of infection, unwillingness to test without a partner's consent, educational level, age, parity, gravidity, employment, marital status, partner's occupation, and residence)[5,21,22] did not affect the uptake of HIV testing in Rwanda. This universal acceptance of routine PMTCT HIV testing among study participants in Rwanda removed the non-consent bias inherent in PMTCT program data. Additionally, to minimize a potential systematic source of selection bias, pregnant women who already knew their HIV status to be positive at first ANC visit were also solicited and accepted to PMTCT HIV testing.

The high completeness and validity of surveillance variables in routine PMTCT registers may be attributed to the recent activities to improve site data quality, such as site supervision and mentorship visits, integrated training, and experience of staff. The quality was markedly better than the results from a

2006 Kenyan study with varying PMTCT data quality and surveillance variables spread across several logbooks.[10] However, the present assessment found that syphilis screening and syphilis screening results – one of the main ANC-HSS variables of interest[23] – had low levels of completeness, possibly due to the frequent lack of available rapid plasma reagin (RPR) reagents. This low syphilis completeness may have implications for the WHO recommendations to combine HIV, syphilis, and viral hepatitis screening in pregnant women attending ANC, because inconsistent syphilis testing constitutes an obstacle to the effective integrated ANC services.[24–26] WHO recommendations would be achievable if testing services resources were integrated and reagents appropriately supplied.

A high level of positive and negative percentage agreement between PMTCT RDT and surveillance HIV ELISA test results was found. These results were corroborated by the robust PMTCT HIV rapid testing quality assurance practices at most ANC sentinel sites and may be attributable to the quality improvement strategies, including services decentralization, integrated supervision, training and mentorship, and performance-based financing. Despite this, there were a few sites like Gisenyi, Nyagatare, Ruhango, and Simbi that demonstrated lower performance, possibly due to trained personnel turnover, overly high staff workloads, or inadequate laboratory practices. These factors should be studied in the future.

Very few studies have examined individual-level agreement between PMTCT and surveillance HIV test results, notably a study from Mozambique that found a PPA of only 88.5%.[21] Most published studies have been limited to comparing PMTCT and ANC surveillance HIV test results through prevalence. Studies conducted in Sub-Saharan Africa found similar prevalence when ANC surveillance and PMTCT data were compared across participating clinics.[8,10,14,27] However, in a 2005 Uganda study, a higher HIV prevalence was observed among women who accepted voluntary counseling and testing as compared to those who tested anonymously.[28] In Kenya the UAT and PMTCT data were compared at the same clinics and for the same time period. The HIV testing uptake for PMTCT was defined as the number of ANC attendees tested for HIV out of those who had their first ANC visit during the ANC surveillance period. It showed that there was considerable inter-clinic variability of HIV prevalence estimates at the same clinics and for the same time period.[10]

Although the NPA is quite high, in a country with a low prevalence like Rwanda, where most women are negative, even this high NPA, when applied to the large number of negative women, will translate into an insignificant number of HIV-negative women receiving false-positive HIV testing results. This scenario could lead to treating uninfected persons for HIV. Sub-100% PPA and NPA reinforce the need for quality assurance of HIV testing and counseling.[29]

There are several limitations to this study that should be considered. First, the comparison of individual HIV RDT and ELISA results may be affected by differences in staff performance and technology capacity. This is likely minor because there have been no changes to the national HIV testing algorithm. Three sites out of 30 were not assessed because the assessment was conducted during the rainy season and the sites were not accessible. However, researchers believe that the general findings would apply to these three sites because every site in Rwanda applies the same standards. Finally, it is important to note that these findings apply directly to the Rwanda program and should not be generalized to other countries. While each country will have to assess their own readiness to transition to PMTCT-based sero-surveillance, this study is useful outside of Rwanda as it demonstrates how to apply the WHO guidelines appropriately for this assessment.

In conclusion, Rwanda is ready to switch from ANC to PMTCT sero-surveillance; the country meets the WHO standards regarding universal acceptance of HIV testing, accuracy of diagnostic testing, high data quality, and high coverage of HIV testing at the health facility level. Additional efforts should be made to ensure the sustainability of high quality data and to avoid running out of consumables, as occurred in the case of syphilis reagents.

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Ethical approval: The survey was approved by the Rwanda National Ethics Committee (RNEC; Ref. RNEC 011/RNEC/2012) and the US CDC Associate Director for Science at the Center for Global Health, CDC, Atlanta, GA, USA.

Conflict of interest: The authors declare that they have no competing interests.

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