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# Country adoption of WHO 2019 guidance on HIV testing strategies and algorithms: a policy review across the WHO African region

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**Title:** Country adoption of WHO 2019 guidance on HIV testing strategies and algorithms: a policy review across the WHO African region

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## ABSTRACT

**Introduction:** In 2019, the World Health Organization (WHO) released updated guidelines on HIV testing services (HTS) recommending: use of serial testing, a standard 3-assay testing strategy requiring three consecutive reactive serology test results to make an HIV-positive diagnosis; discontinuation of the use of a tie-breaker to rule-in HIV infection, discontinuation of western blotting (WB) for HIV diagnosis, retesting prior to ART initiation, and dual HIV/syphilis rapid diagnostic tests (RDTs) as the first test in antenatal care (ANC). Here we update previous policy reviews conducted in 2014 and 2018 to assess policy adoption of updated recommendations in the WHO African region.

**Methods:** Between May and December 2021, we undertook a comprehensive desk review of national HTS policies. Adoption of WHO recommendations was assessed based on the number of WHO 2019 HTS recommendations adopted and then compared to 2014 and 2018 baseline information.

**Results:** National policies were reviewed for 96% (n=45/47) of countries in the WHO African region, 40% (n=18) were published before 2019, and 62% (n=28) adopted WHO guidance. Between 2018 and 2021, adoption in the region increased from 28% (n=9/32) to 62% (n=28/45). Using a 2-assay testing strategy was the most common form of non-adoption: 31% (n=14) and 22% (n=10) in low (<5%) and high (≥5%) prevalence countries. Ten policies (22%) recommended the use of WB in their HIV testing algorithm, and 51% (n=23) recommended retesting before ART initiation. Dual HIV/syphilis RDTs were recommended in 47% (n=21/45) of policies.

**Conclusions:** Adoption of WHO-recommended HIV testing strategies has improved in the African region. While WB was only used in a few countries, concerted efforts are needed to phase out this technology in favour of RDTs. Countries should plan to accelerate their transition to WHO recommendations by streamlining efforts to adopt and implement a 3-asssay testing strategy and dual HIV/syphilis RDTs.

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**Keywords:** HIV, diagnosis, rapid test, dual HIV/syphilis, policy, guideline, Africa, algorithm

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Compared to the 2018 global review where six WHO Regions were included, by focusing only on the WHO African region, we were able to include thirteen additional national policy documents in this review (n=45 in 2021 vs n=32 in 2018).

⇒ We employed robust searching methods and a standardized data extraction tool.

⇒ We didn't find out how HTS policies were being implemented in each country. Countries may be executing HIV testing plans that diverge from those specified in official policy papers, resulting in misclassification of adoption status. It's likely that decentralization in some countries has resulted in changes in testing procedures and strategies at the subnational level that this evaluation overlooked even though we did not include subnational policy documents.

⇒ Notably, during our review we also identified countries in the process of adopting WHO recommendations – particularly the use of 3-test strategy and dual HIV/syphilis RDTs for ANC. Thus, our estimates of adoption of WHO testing guidelines may be conservative.

## INTRODUCTION

HIV Testing Services (HTS) is the critical gateway to accessing HIV-related care and treatment for those diagnosed as HIV-positive and as a means to accessing prevention services for those who test HIV-negative.[1, 2] Despite considerable progress, reaching the first UNAIDS 95 HIV target by 2025 will require increased testing uptake, particularly among populations with testing gaps such as key population, youth and men.[3] Further, the global emergency caused by the COVID-19 pandemic in 2020 has disrupted many health services including HIV testing services, and supply chains of key commodities such as rapid diagnostic tests (RDTs) have

been stretched.[4] In 2021, it was estimated that 85% of people living with HIV globally were aware of their serostatus.[5]

In 2019, the World Health Organization (WHO) published consolidated guidelines on HIV testing services (HTS),[6] bringing together existing recommendations specific to testing strategies and algorithms e.g., use of serial testing rather than parallel testing (WHO, 2012),[7] discontinuation of a tiebreaker strategy to rule-in HIV infection (WHO, 2015)[1] and, retesting prior to antiretroviral treatment (ART) initiation, recommended since 2014;[1] and released three new recommendations related to testing strategies namely: (moving toward a universal 3-assay testing strategy using three consecutive HIV-reactive tests to provide and HIV-positive diagnosis, (2) discontinuation of western blot (WB) and line immunoassays (LIA) and, (3) use of dual HIV/Syphilis RDTs as first assay in HTS in antenatal care (ANC) settings. In light of these testing modalities, ensuring that HIV testing is accessible and adheres to the "5 C's" including voluntary consent, confidentiality, counselling, correct results, and linkage to care, is of upmost importance.

National guidelines outlining HIV testing strategies are critical to ensuring a correct and timely HIV diagnosis. Many countries still use the 2015 WHO recommendation of using the national HIV prevalence to determine whether a two-assay (≥5%) or three-assay testing strategy (<5%) should be used.[1] However, as ART coverage expands and HIV positivity declines, WHO now recommends countries to use the national HTS positivity and the treatment-adjusted prevalence, which accounts for both the national HIV prevalence and ART coverage, as an indicator to determine when to transition to a three-assay testing strategy.[8] WHO also recommends that countries planning to update their HIV testing algorithms undertake a

verification study to select appropriate HIV serology products and ensure they don't cross-react in order to minimize the risk of misdiagnosis.[9]

A global review of national HIV testing policies was conducted by WHO in 2018 to assess adoption of its testing recommendations and policies.[10] Of 91 policies reviewed only 24 (25%) adhered to WHO guidance. This policy review seeks to update results of the 2018 review and ascertain adoption of six 2019 WHO recommendations particularly in the WHO African region, which hosts several countries with a high HIV burden that have traditionally used a 2-assay testing strategy. The same policy review across the remaining five WHO regions is underway.

## METHODS

### Search strategy

We carried out a comprehensive desk review of national HIV testing policies in 47 Member States in the WHO African region (online supplementary figure 1) using a policy repository maintained by WHO, scanning government websites, and by contacting government officials or other relevant informants through December 2021. The most current policy documents containing information on the HTS policy were included, but when this was unavailable, we included the most recent HIV testing algorithm, but if that was also unavailable, we opted to include previous national policies. Documents of all languages were included. Other supporting documents related to algorithm validation and PMTCT guidelines were identified, when possible, either through references provided in the national HTS policy or through contact with key informants.

**Data extraction**

Data were extracted from each policy document by one reviewer (EF) into standardised coding forms on policy information, HIV testing strategy/algorithm (>18 months of age), dual HIV/syphilis testing strategy/algorithm, and retesting prior to ART initiation (online supplementary table 1). A second reviewer (CL) carried out crosschecking of the data. Differences between coders were resolved through a third reviewer (CJ). To prevent misclassification, items were marked as 'unclear' during data extraction when lack of information prevented complete understanding.

**Analysis**

We assessed national adoption of WHO HTS guidance using six specific recommendations related to testing strategies and algorithms set forth in the WHO 2019 HIV testing guidelines, namely: (1) use of serial testing, (2) use of a 3-assay testing strategy, (3) discontinuation of a tie-breaker to rule in HIV infection, (4) discontinuation of WB/LIA, (5) retesting prior to ART initiation, and (6) use of dual HIV/syphilis RDT in ANC. Based on the number of recommendations adopted, national policies were categorized as: adopted (6); nearly adopted (5 to 4); somewhat not adopted: (3); and not adopted: (2 or less).

To determine the proportion of countries adopting WHO guidance, country policies categorised as 'fully adopted and 'nearly adopted' were considered adopted and those categorised as 'somewhat not adopted' or 'not adopted' were considered non-adopted. Descriptive analyses disaggregated by subregions (Western, Central, Eastern and Southern Africa; online supplementary figure 1) were also conducted to determine rates of adherence by subregion. All analyses were conducted in Microsoft Excel.

## Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans of this study.

## RESULTS

We identified updated national policies or HIV testing algorithms for 41 countries out of 47 (87%) in 2021. Previous policies for 6 countries (Algeria, Botswana, eSwatini, Cote d'Ivoire, Malawi, and Zimbabwe) identified in the 2018 review were included in this current analysis, with Malawi and Zimbabwe providing updated HIV testing algorithms. São Tomé e Principe was included based on the HIV testing algorithm provided but without a national policy document. In total, we included 96% of countries from the WHO African region (n=45/47). Two countries, Republic of the Congo and Cabo Verde, were not included because we were unable to obtain their national policies (figure 1).

Of the 45 policies providing information on HIV testing strategies, 16 were from Western Africa (36%), 16 from Eastern Africa (36%), 8 from Central Africa (18%), and 5 from Southern Africa (11%). Policies were published in English (n=22), French (n=18), Portuguese (n=4) and Spanish (n=1). Policy publication dates ranged from 2013 to 2021 and 40% of policies (n=18/45) were published before 2019. Based on the most recent national HIV prevalence reported by UNAIDS[1], 34 countries (76%) had a low prevalence (<5%) and 11 countries (24%) had a high prevalence (≥5%) (online supplementary table 2).

**Overall adoption of WHO-recommended HIV testing strategies**

In 2021, 62% of national testing strategies (n=28/45) adopted WHO 2019 recommendations and 38% (n=17/45) were non-adopted (table 1). This represents a 2.4-fold increase in the number of national policies adopting WHO guidance compared to the 2018 review (28 *vs* 9). The subregions with the highest adoption were Southern Africa (80%) and Eastern Africa (75%) whilst Central Africa (63%) and Western Africa (44%) had the lowest adoption rates (table 1; figure 2).

In low-prevalence countries (n=34), 53% of policies (n=18/34) were fully adopted or mostly adopted and 47% (n=16/34) were somewhat not adopted or not adopted. The most common reasons for non-adoption were not using a dual HIV/syphilis RDT in ANC (n=15/34), no retesting prior to ART initiation (n=14/34) and using only two assays to make an HIV-positive diagnosis (n=10/34). In high-prevalence countries (n=11), 91% of policies (n=10/11) were either fully adopted or nearly adopted and 9% were not adopted (1/11). The most common reasons for non-full adoption were the use of only two assays to make an HIV-positive diagnosis (n=10/11), the use of both serial and parallel testing strategies (n=4/11), no use of dual HIV/syphilis RDTs in ANC (n=4/11) and no retesting prior to ART initiation (n=3/11).

When the analysis was restricted to a subset of countries with policies included in the 2018 review that also had an updated policy in the current review (n=28), the proportion adopting WHO guidance in 2018 was 25% (n=7/28) *vs* 71% (n=20/28) in the current review (see online supplementary table 3).

**Table 1.** Policy adoption of 2019 WHO-recommended HIV testing strategies in the WHO African region from 2014 to 2021

| AFRO subregions (countries) | Policies reviewed | | | Overall adoption | | | Serial testing strategy | | | Discontinuation of tiebreaker* testing strategy | | | Retesting prior to ART initiation | | Universal 3-test strategy | Use of dual HIV/syphilis test** | No use of Western Blot |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year | 2014 | 2018 | 2021 | 2014 | 2018 | 2021 | 2014 | 2018 | 2021 | 2014 | 2018 | 2021 | 2018 | 2021 | 2021 | 2021 | 2021 |
| All (n=47) | 25 (53%) | 32 (68%) | 45 (96%) | 2 (8%) | 9 (28%) | 28 (62%) | 21 (84%) | 26 (81%) | 29 (64%) | 15 (60%) | 26 (81%) | 37 (82%) | 24 (51%) | 23 (51%) | 21 (47%) | 21 (47%) | 35 (78%) |
| Western (n=17) | 6 (35%) | 9 (53%) | 16 (94%) | 0 (0%) | 2 (22%) | 7 (44%) | 5 (83%) | 7 (78%) | 9 (56%) | 4 (67%) | 5 (56%) | 9 (56%) | 11 (69%) | 5 (31%) | 8 (50%) | 7 (44%) | 10 (63%) |
| Central (n=9) | 4 (44%) | 5 (56%) | 8 (89%) | 1 (25%) | 1 (20%) | 5 (63%) | 4 (100%) | 5 (100%) | 7 (88%) | 3 (75%) | 4 (80%) | 7 (88%) | 2 (25%) | 5 (63%) | 3 (38%) | 2 (25%) | 6 (75%) |
| Eastern (n=16) | 11 (69%) | 13 (81%) | 16 (100%) | 1 (9%) | 3 (23%) | 12 (75%) | 10 (91%) | 10 (77%) | 12 (75%) | 5 (45%) | 12 (92%) | 16 (100%) | 9 (69%) | 9 (56%) | 9 (56%) | 9 (56%) | 14 (88%) |
| Southern (n=5) | 4 (80%) | 5 (100%) | 5 (100%) | 0 (0%) | 3 (60%) | 4 (80%) | 2 (40%) | 4 (80%) | 1 (20%) | 3 (75%) | 5 (100%) | 5 (100%) | 5 (100%) | 4 (80%) | 1 (20%) | 3 (60%) | 5 (100%) |

*Use of a third assay to rule-in HIV infection

**Dual HIV/syphilis RDT as first test in ANC

**Adoption of serial testing strategy**

In 2021, 64% of national testing strategies (n=29/45) adopted the use of serial testing and 36% (n=16/45) recommended the mix use of serial and parallel testing (figure 3_1). The subregions with the highest adoption were Central (88%) and Eastern Africa (75%), followed by Western Africa (58%); Southern Africa had the lowest adoption rate (20%) (table 1).

Most policies recommending serial or parallel testing (n=15/16) conducted simultaneous testing of assay 1 (A1) and assay 2 (A2) in case of discrepant test results, and the Namibian policy recommended parallel testing of A2 and A3 after a reactive A1.

Only 44% of policies (n=20/45) provided guidance on the assay order in relation to their sensitivity and specificity. The proportion of HIV testing strategies/algorithms using 2 consecutive HIV-reactive tests to make an HIV-positive diagnosis was 53% (n=24/45) whereas 47% (n=21/45) recommended the use 3 consecutive HIV-reactive tests.

Sixty-four percent of the HIV testing strategies reviewed (n=29/45) included testing algorithms, i.e., contained specific product names and all of them included WHO prequalified products. Determine HIV 1/2 (Abbott Diagnostics Medical Co., Ltd, Japan) was the most common product used as A1 and Bioline HIV 1/2 3.0 (Abbott Diagnostics Korea Inc., Republic of Korea) or Uni-Gold HIV (Trinity Biotech, Ireland) as A2 or A3 (see online supplementary table 4). Only 31% of policies (n=14/45) mentioned the need to locally verify or validate the HIV testing algorithm.

**Discontinuation of a tiebreaker testing strategy**

The discontinuation of a third assay to rule in HIV infection (i.e., tiebreaker) was recommended in 82% of national policies (n=37/45) (figure 3_2). The subregions with the highest adoption were Southern Africa and Eastern Africa (100% each) followed by Central Africa (88%), whereas Western Africa had the lowest adoption (56%) (table 1).

Of the eight policies recommending a tiebreaker testing strategy, seven were from Western Africa and one from Central Africa. Seven policies specified the type of A3 to be used, for example, RDT (n=4), RDT or EIA (n=1), nucleic acid testing (NAT: n=2) and LIA (n=1).

**Adoption of WHO standard 3-assay testing strategy**

The use of three consecutive HIV-reactive tests for the diagnosis of HIV was recommended by 47% of the policies (n=21/45) (figure 3_3). The adoption of this WHO recommendation was highest in Eastern Africa (56%) and Western Africa (50%) and lowest in Southern Africa (20%) (table 1). Most policies recommending a 3-assay testing strategy (n=20/21) were from low HIV-burden countries. Among high HIV-burden countries, only 18% of policies (n=2/11) recommended the use of a 3-assay testing strategy and this corresponded to two countries, Malawi and Zimbabwe, respectively.

Compared to the 2018 review, 10 policies that previously recommended a 2-assay testing strategy transitioned to a 3-assay testing strategy in 2021 (Burkina Faso, Burundi, Chad, Ethiopia, Ghana, Kenya, Lesotho, Malawi, Madagascar, and Zimbabwe, respectively).

Of policies supporting a 3-assay testing strategy, only 53% (n=11/21) also recommended the use of dual HIV/syphilis RDTs among pregnant women.

**Adoption of retesting to verify positive status prior to ART initiation**

In 2021, 51% of national strategies (n=23/45) recommended retesting prior to ART initiation compared to 50% in 2018 (figure 3_4). The regions with the highest policy adoption were Southern Africa (80%) followed by Central Africa (63%) and Eastern Africa (56%) (table 1). Sixty-five percent of the policies (n=15/23) recommending retesting prior to ART initiation, conduct retesting using the same national HIV testing algorithm in a new specimen run by a different operator in a different testing site; 26% (n=6/23) did not specify how retesting was carried out and 9% of policies (n=2/23) utilized retesting strategies that differed from the national HIV testing algorithm, which included parallel testing of A1/A2 in Botswana and Malawi, respectively.

**Discontinuation of Western Blotting**

The proportion of national policies not including WB or LIA as part of the HIV testing algorithm was 78% (n=35/45) (figure 3_5). This proportion was highest in Southern Africa (100%) and Easter Africa (88%) followed by Central Africa (75%) and Western Africa (63%) (table 1). Most countries with a supporting policy in favour of WB or LIA (n=9/10) recommended its use to manage persistent inconclusive/indeterminate test results and one policy used WB as A3 (Mauritius).

**Adoption of dual HIV/syphilis RDT in ANC settings**

Forty-seven percent (n=21/45) of policies supported the use of dual HIV/syphilis RDTs among pregnant women in ANC (figure 3_6). The region was the highest policy uptake was Southern Africa (60%), followed by Eastern Africa (56%) and Western Africa (44%). Central Africa had the lowest policy uptake (25%) (table 1).

The majority of policies (n=20/21) recommended the use of dual HIV/syphilis RDT as A1 among pregnant women and only one policy (Lesotho) recommended its use as a triage test (A0) as an interim algorithm while waiting for the results of a national verification study. The dual HIV/syphilis testing algorithm was not aligned with the national HIV testing algorithm in one country (Zambia): while Determine HIV-1/2 (Abbott Diagnostics Medical Co., Ltd, Japan) and SD Bioline HIV-1/2 3.0 (Abbott Diagnostics Korea Inc, Republic of Korea) products were used as A1 and A2 in the national testing algorithm, Bioline HIV/Syphilis Duo (Abbott Diagnostics Korea Inc, Republic of Korea) and Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China) were used as A1 and A2 in the ANC testing algorithm.

In addition to the use in ANC settings, three countries also recommended testing with dual HIV/syphilis RDTs among other populations such as male partners of pregnant women and key populations. Only 50% of policies (n=11/21) specified the brand name of the dual HIV/syphilis RDT in the testing algorithm, and among the policies mentioning the brand name, Bioline HIV/Syphilis Duo (Abbott Diagnostics Korea Inc, Republic of Korea) was the most employed RDT (100%). Only 57% of policies (n=12/21) mentioned whether syphilis treatment was provided immediately after a reactive syphilis test result.

**Use of nucleic acid testing (NAT) to diagnose HIV infection**

Twenty-two percent of national policies (n=10) recommended the use of NAT as part of the testing algorithm for the diagnosis of HIV infection. Four policies were from Eastern Africa (Malawi, Mauritius, Mozambique and United Republic of Tanzania); three national policies from Southern Africa (Eswatini, Lesotho and Namibia); two policies from Central Africa

(Angola and Sao Tomé et Principe); and one national policy from Western Africa (Guinea Bissau).

Two policies employed NAT as the third assay (A3) of the algorithm while the remaining 8 policies recommended NAT to resolve persistent inconclusive/indeterminate test results (referring either to viral load, PCR or DNA-PCR).

## DISCUSSION

The current review found a significant improvement in the overall policy uptake of the latest WHO-recommended HIV testing strategies with 62% of countries in the African region adopting WHO guidance in 2021 compared to 28% of countries in 2018.[10] This represents a 2.4-fold increase in the number of national policies adopting WHO guidance compared to 2018 (28 *vs* 9). However, because a significant proportion (40%) of national policies were published before 2019, country adoption of latest WHO guidance was less likely. Given the rapid changes in HIV testing landscape, this underscores the need of national programmes to update their national HIV testing policies at more regular intervals to keep up with latest WHO guidance.

The recommendations with highest adoption were the discontinuation of a tiebreaker (82%) and western blotting (78%) as well as the use of serial testing (64%). Half of countries (51%) also recommend retesting prior to ART initiation. One likely explanation for the higher policy adoption is that these WHO´s recommendations were published in 2012, 2014 and 2015, respectively (save for discontinuation of western blotting) providing national HIV programmes ample time to incorporate these recommendations into their national HIV testing guidelines. Although moving away from western blotting was recommended more

recently in 2019,[11] low resource countries in the WHO African region has been at the forefront of implementing HIV RDTs compared to other WHO regions as a way to rapidly expand and increase access to HIV testing services.[12]

Having said that, our review found that a dozen of countries, mostly in Western Africa, still use western blotting as part of the HIV testing algorithms, hindering same-day diagnoses and rapid access to ART and Pre-exposure prophylaxis (PrEP).[11] Despite observing a 1.43 fold increase in the number of countries recommending retesting prior to ART initiation compared to 2018 (23 vs 16), we noted virtually no progress in the proportion of countries with supportive policy, with 51% in 2021 and 50% in 2018.

The WHO´s recommendations with a lower country uptake were the use of a standard 3-assay testing strategy (47%) and the use of dual HIV/syphilis RDT among pregnant women (47%), both recommendations released in 2019.[6]

Before 2019, WHO recommended the use of a 2-assay testing strategy in high HIV prevalence settings (≥5%) and the use of a 3-assay testing strategy in low HIV prevalence settings (<5%) to maintain at least a 99% positive predictive value (PPV).[1] However, as HTS and ART have been scaled up substantially and fewer people undergoing HTS are HIV-positive, the national HTS positivity has also declined, even in high HIV burden settings.[13] Given this changes in the epidemic, WHO now recommends that all settings move toward using a 3-assay testing strategy to ensure high-quality testing.[13] Specifically, in high HIV burden settings in southern Africa (5 countries) and eastern Africa (6 countries), WHO recommends countries still using a 2-assay testing strategy to move toward using a 3-assay testing strategy as their

treatment-adjusted prevalence, rather than the national HIV prevalence, and national HTS positivity fall below 5%.[13]

In this review we found that only 18% (n=2/11) of the high-burden countries in the WHO African region has a supportive policy on a 3-assay testing strategy. A likely explanation for this slower policy adoption is that national programmes and donors in high burden countries have focused on implementing high-yielding testing approaches,[14, 15] which may have inadvertently let them thinking that HTS positivity was usually >5%, and therefore moving to a 3-assay testing strategy was considered less of a priority. An additional explanation is that countries may perceive that the addition of a third assay to the national 2-assay testing algorithm can be challenging due to additional training and quality assurance requirements, procurement, inventory management and budget implications to the national programme.[16]. While countries will need to develop a plan and identify the optimal time for the transition, in terms of costs, a modelling study found that the total cost of the 3-assay testing strategy was only 2.5% greater than the 2-assay testing strategy at 5% positivity, reflecting that HTS programme cost is primarily determined by the number of A1 conducted.[17] Also, programmatic experience from Ghana transitioning to a 3-assay testing strategy showed that although there were some logistical hiccups related to kit supply and lack of staff for training, it was found feasible and was considered a significant intervention toward assuring high-quality testing as well as saving costs of unnecessary life-long treatment of false HIV-positive clients.[18]

We found that among low-prevalence countries (n=34), a significant proportion (41%) still use a suboptimal testing strategy with 2 assays to make an HIV positive diagnosis, which will

increase the likelihood of false-positive diagnosis.[19] A retrospective study in Nigeria using household survey data found that the performance of the 2-assay HIV testing algorithm in a low prevalence setting of about 1.4% was poor with a PPV of 94% and a false-positive rate of 5.5%.[16] This PPV is similar to a modelling study assessing the accuracy of the 2015 and 2019 WHO HIV testing algorithms, which was 95.4% using a 2-assay testing strategy.[17]

Considering that the recommendation to use dual HIV/syphilis RDTs in ANC was released only in 2019,[20] its adoption has been rapid with 21 national policies recommending its use. However, the number of countries adopting dual HIV/syphilis RDTs among pregnant women may be in practice higher considering that preliminary NCPI survey data reported that a total of 26 countries in the WHO African region adopted the use of dual HIV/syphilis RDTs in ANC.[21] This inconsistency with our review underscores the difficulties in aggregating accurate policy data in surveys. Some countries may choose not to introduce dual HIV/syphilis RDT. For example, in Malawi where dual HIV/syphilis RDT introduction has been considered but not adopted, the national programme has opted to retain stand-alone HIV and syphilis RDTs in ANC in an effort to prioritize point-of-care test options for HIV and syphilis while maintaining a single HIV testing algorithm in a resource limited context. Dual HIV/syphilis testing is also now recommended for key populations by WHO and this may further increase its use in HIV testing algorithms in national programmes.[22] It is an important option to increase HIV and syphilis detection and treatment and a recent modelling study in Viet Nam shows that it was cost saving or cost-effective.[23]

As countries update their national HIV testing guidelines to incorporate latest WHO guidance and adapt their national HIV testing strategies and algorithms to shift toward using three

consecutive reactive serology tests to diagnose HIV, introduce dual HIV/syphilis RDTs among pregnant women and key populations, move away from western blotting, reinforcing retesting prior to ART initiation as well as design flexible algorithms to address kit shortages, WHO encourages national programmes to conduct a verification study to provide objective evidence, before national scale-up, that a specific combination of products work well together without sharing false-reactivity, thus reducing the risk of misdiagnosis.[6, 9] To assist countries achieve this, WHO has put together a practical toolkit to optimize HIV testing algorithms;[24] this toolkit contains different resources to select and shortlist HIV products, checklist of laboratory consumables and reagents, budget template for conducting a verification study, generic verification protocol, Ghantt chart to plan the study as well as a database to analyze results and a proposed methodology to conduct rapid implementation and evaluation of the newly selected HIV testing algorithms. Some components of this toolkit have already been used by more than a dozen of countries undertaking this verification study with support from WHO including Armenia, Burkina Faso, Cameroon, Chad, Central African Republic, Cote D´Ivoire, Democratic Republic of Congo, eSwatini, Kenya, Lao, Lesotho, Mali, South Sudan and Zambia. Preliminary results of the verification study have been published by Chad and Cameroon.[25]

While countries update their national HIV testing strategies and wait for the results of a verification study, a practical option to rapidly start implementation without compromising the quality testing is to select interim testing algorithms using WHO prequalified tests as implementing a 3-assay testing strategy without a verification study will ensure a PPV >99%) as opposed to implementing only a validated 2-assay testing strategy that will not achieve the WHO-recommended PPV.

## Conclusions

Adoption of WHO-recommended HIV testing strategies has improved in the African region. While WB was only used in a few countries, concerted efforts are needed to phase out this technology in favour of RDTs. Countries should plan to accelerate their transition to WHO recommendations by streamlining efforts to adopt and implement a 3-asssay testing strategy and dual HIV/syphilis RDTs. Conducting verification of testing algorithms, and using appropriate assays can ensure accurate HIV diagnosis in a cost-efficient and time-efficient manner.

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## Contributors

CJ devised and supervised the review. EF updated the study protocol and conducted the screening, data extraction and analysis. CL acted as a second reviewer and CJ as third reviewer. All authors reviewed the draft, provided critical review and read and approved the final version of the manuscript.

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**Map disclaimer**

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**Competing interests**

The authors declare no competing interests. The contents in this article are those of the authors and do not necessarily reflect the view of the World Health Organization.

**Patient consent for publication**

Not required.

**Ethics approval**

This study does not involve human participants and ethical approval was therefore not required.

**Data availability statement**

All data generated in the study are included in the article or uploaded as supplementary information. National policies may be publicly available. Some policies included in this review may be available through the following websites: (1)

https://aidsfree.usaid.gov/resources/guidance-data/hts. (2)

http://www.hivpolicywatch.org/database.htlm. If information on a policy cannot be found through these resources, please contact the authors of this review for additional information.

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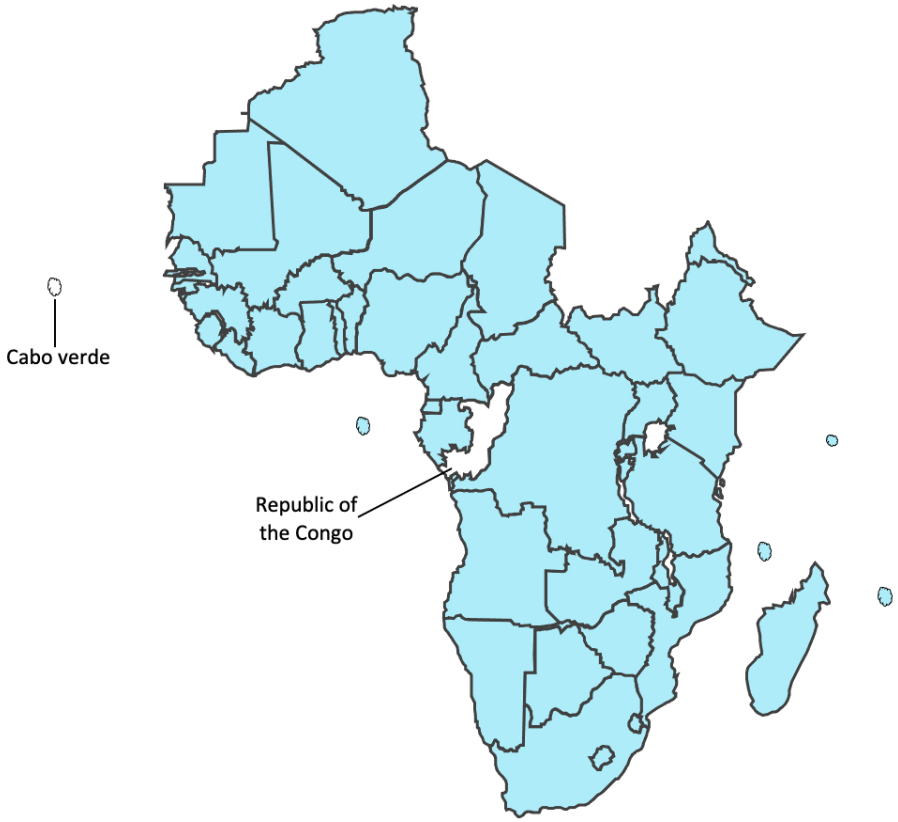
## Figure legends

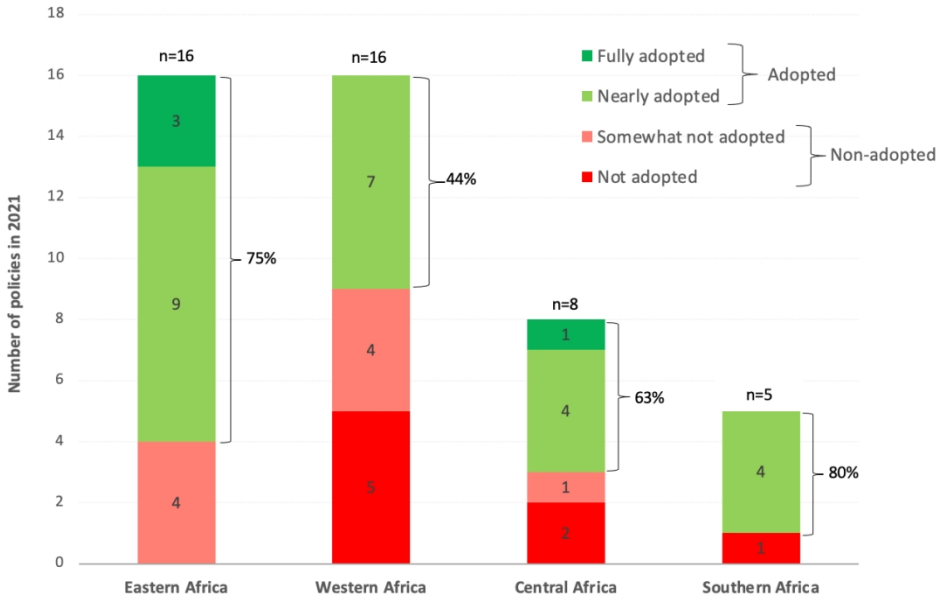
**Figure 1.** Countries from the WHO African Region with HIV testing policies identified (in blue) and included in the analysis (n=45/47). The two countries not included in the review are indicated in the map.

**Figure 2.** Overall adoption of 2019 WHO HIV testing strategies in Africa by subregion in 2021.

**Figure 3.** Policy adoption in 2021 of six specific WHO HIV testing recommendations in the WHO African Region.




187x162mm (144 x 144 DPI)

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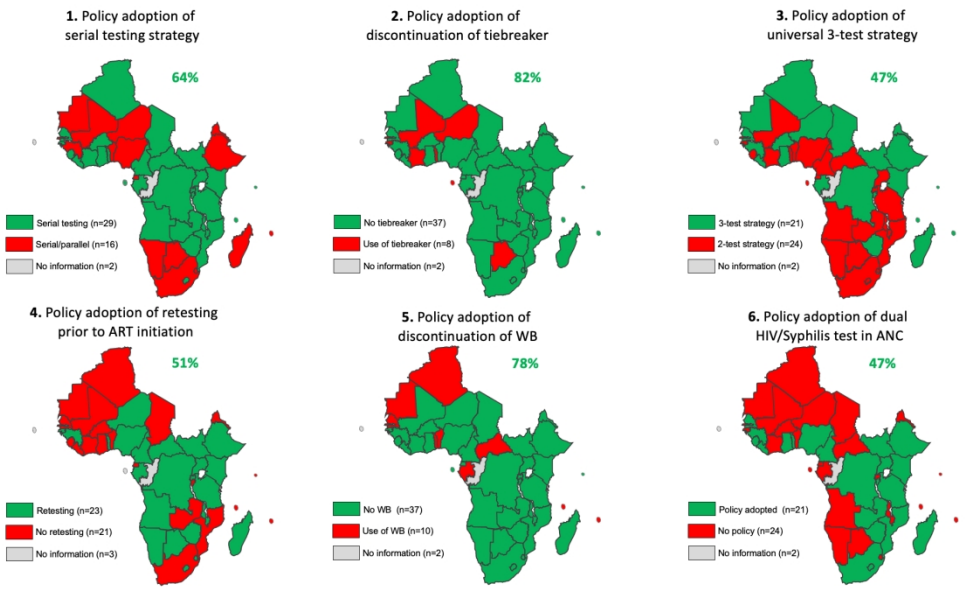


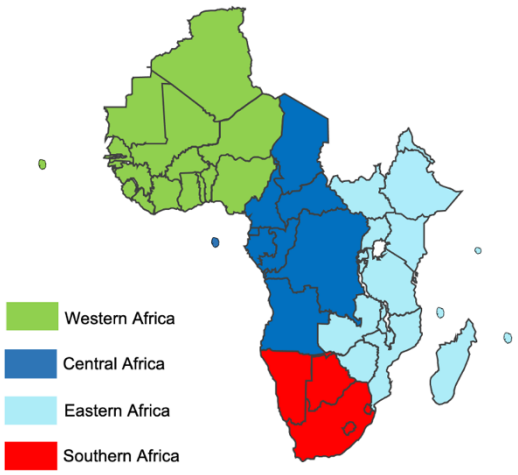

350x207mm (144 x 144 DPI)

**Supplementary Appendix**

Country adoption of WHO 2019 guidance on HIV testing strategies and algorithms: a policy review across the WHO African region

Emmanuel Fajardo,[1] Céline Lastrucci,[1] Nayé Bah,[2] Casimir Manzengo Mingiedi,[3] Ndoungou Salla Ba,[4] Fausta Shakiwa Mosha,[5] Frank John Lule,[6] Margaret Alia Sampson Paul,[6] Lago Hughes,[6] Magdalena Barr-DiChiara,[1] Muhammad Shahid Jamil,[1] Anita Sands,[7] Rachel Baggeley,[1] Cheryl Johnson[1]

**Supplementary Figure 1.** Countries in the WHO African Region and grouping by subregion




| WHO African Region (n=47) | | | |
|---|---|---|---|
| Western Africa (n=17) | Central Africa (n=9) | Eastern Africa (n=16) | Southern Africa (n=5) |
| Algeria | Angola | Burundi | Botswana |
| Cabo Verde | Cameroon | Comoros | eSwatini |
| Burkina Faso | CAR | Eritrea | Lesotho |
| Benin | Chad | Ethiopia | Namibia |
| Ghana | DRC | Kenya | South Africa |
| Guinea | Equotorial Guinea | Madagascar | |
| Guinea-Bissau | Gabon | Malawi | |
| Ivory Coast | Republic of the Congo | Mauritius | |
| Liberia | Sao Tome and Principe | Mozambique | |
| Mauritania | | Rwanda | |
| Mali | | Seychelles | |
| Niger | | South Sudan | |
| Nigeria | | Tanzania | |
| Senegal | | Uganda | |
| Sierra Leone | | Zambia | |
| The Gambia | | Zimbabwe | |
| Togo | | | |

**Supplementary Table 1.** Categories for data extraction

| | |
|---|---|
| **1. Policy Information** | |
| ▪ Country<br>▪ WHO region<br>▪ HIV testing policy identified? | ▪ Year of policy publication<br>▪ Type of policy document<br>▪ National HIV prevalence |
| **2. HIV testing algorithm (after 18 months of age)** | |
| ▪ HIV testing algorithm provided?<br>▪ Image or text format?<br>▪ Type of scenario in which algorithm is used<br>▪ Number of assays used in algorithm<br>▪ Serial or parallel strategy<br>▪ Use of tiebreaker?<br>▪ Use of Western Blot or LIA?<br>▪ Mention of test order relating to sens/spec?<br>▪ High or low prevalence strategy used?<br>▪ Type of tests mentioned?<br>▪ Brand of tests mentioned?<br>▪ Are assays pre-qualified by WHO?<br>▪ A1 test name<br>▪ A1 type of assay | ▪ A1 sens-/spec<br>▪ A2 test name<br>▪ A2 type of assay<br>▪ A2 sens-/spec<br>▪ A3 test name<br>▪ A3 type of assay<br>▪ A3 sens-/spec<br>▪ Source of assay sens/spec<br>▪ Mention of in-country assay validation<br>▪ Alignment with WHO policy?<br>▪ Primary reason(s) algorithm fails to meet WHO recommendations<br>▪ Other notes about testing strategy |
| **3. HIV testing algorithm among pregnant women using dual HIV/Syphilis RDTs** | |
| ▪ HIV testing algorithm provided?<br>▪ Image or text format?<br>▪ Type of scenario in which algorithm is used<br>▪ Type of scenario in which algorithm should not be used (women on ART, already diagnosed/treated for syphilis, retesting for HIV)<br>▪ What is there syphilis testing strategy for women with HIV?<br>▪ Is dual test used as A1 or A0?<br>▪ Is the dual test algorithm aligned with the national HIV testing algorithm?<br>▪ Is the dual test algorithm aligned with the national syphilis testing algorithm?<br>▪ Brand of dual test mentioned? | ▪ Is dual test prequalified by WHO?<br>▪ Dual test name<br>▪ Mention of penicillin treatment for reactive TP?<br>▪ Mention of further testing for reactive TP?<br>▪ Mention of in-country assay validation<br>▪ Alignment with WHO policy?<br>▪ Primary reason(s) algorithm fails to meet WHO recommendations<br>▪ Other notes about testing strategy |
| **4. Retesting prior to ART initiation** | |
| ▪ Retest required before starting ART?<br>▪ Retest strategy same as national algorithm?<br>▪ Notes about retesting strategy | |

**Supplementary Table 2.** List of national policies on HIV testing services in the WHO African Region collected in 2018 and 2021 by subregion

| Subregion | Count | Country | Policy reviewed in 2018? | New policy or algorithm identified? | Publication year | Type of document | Language | Algorithm provided? | National HIV prevalence |
|---|---|---|---|---|---|---|---|---|---|
| Central Africa | 1 | Angola | Yes, 2015 | Yes | 2020 | HTS | Portuguese | Yes | Low |
| | 2 | Cameroon | Yes, 2015 | Yes | 2019 | ART | French | Yes | Low |
| | 3 | CAR | Yes, 2010 | Yes | 2018 | ART | French | Yes | Low |
| | 4 | Chad | Yes, 2011 | Yes | 2017 | HTS | French | Yes | Low |
| | 5 | DRC | Yes, 2017 | Yes | 2020 | ART | French | Yes | Low |
| | 6 | Equatorial Guinea | No | Yes | 2018 | ART | Spanish | Yes | Low |
| | 7 | Gabon | No | Yes | 2017 | HTS | French | Yes | Low |
| | 8 | Republic of the Congo | No | **No** | – | – | | – | – |
| | 9 | São Tomé e Principe | No | Yes | 2018 | Algorithm | Portuguese | Yes | Low |
| Eastern Africa | 10 | Burundi | Yes, 2016 | Yes | 2020 | HTS | French | Yes | Low |
| | 11 | Comoros | Yes, 2007 | Yes | 2016 | HTS | French | Yes | Low |
| | 12 | Eritrea | No | Yes | 2019 | HTS | English | Yes | Low |
| | 13 | Ethiopia | Yes, 2017 | Yes | 2018 | ART | English | Yes | Low |
| | 14 | Kenya | Yes, 2017 | Yes | 2021 | HTS | English | Yes | Low |
| | 15 | Madagascar | Yes, 2011 | Yes | 2018 | HTS | French | Yes | Low |
| | 16 | Malawi* | Yes, 2016 | Yes* | 2016 | HTS | English | Yes | High |
| | 17 | Mauritius | No | Yes | 2020 | HTS | English | Yes | Low |
| | 18 | Mozambique | Yes, 2016 | Yes | 2020 | PMTCT | Portuguese | Yes | High |
| | 19 | Rwanda | Yes, 2016 | Yes | 2018 | HTS | English | Yes | Low |
| | 20 | Seychelles | No | Yes | 2019 | HTS | English | Yes | Low |
| | 21 | South Sudan | Yes, 2017 | Yes | 2020 | ART | English | Yes | Low |
| | 22 | Tanzania | Yes, 2017 | Yes | 2021 | HTS | English | Yes | High |
| | 23 | Uganda | Yes, 2016 | Yes | 2020 | ART | English | Yes | High |
| | 24 | Zambia | Yes, 2018 | Yes | 2020 | HTS | English | Yes | High |
| | 25 | Zimbabwe* | Yes, 2016 | Yes* | 2016 | Other | English | Yes | High |
| Southern Africa | 26 | Botswana** | Yes, 2016 | **No** | 2016 | ART | English | Yes | High |
| | 27 | eSwatini** | Yes, 2018 | **No** | 2018 | ART | English | Yes | High |
| | 28 | Lesotho | Yes, 2016 | Yes | 2021 | PMTCT | English | Yes | High |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 29 | Namibia | Yes, 2016 | Yes | 2018 | HTS | English | Yes | High |
| | 30 | South Africa | Yes, 2016 | Yes | 2020 | ART | English | Yes | High |
| Western Africa | 31 | Algeria** | Yes, 2013 | **No** | 2013 | HTS | French | Yes | Low |
| | 32 | Benin | No | Yes | 2017 | HTS | French | Yes | Low |
| | 33 | Burkina Faso | Yes, 2008 | Yes | 2021 | ART | French | Yes | Low |
| | 34 | Cabo Verde | No | **No** | – | – | – | – | – |
| | 35 | Ghana | Yes, 2014 | Yes | 2019 | ART | English | Yes | Low |
| | 36 | Guinea | No | Yes | 2019 | HTS | French | Yes | Low |
| | 37 | Guinea-Bissau | No | Yes | 2021 | ART | Portuguese | Yes | Low |
| | 38 | Ivory Coast** | Yes, 2016 | **No** | 2016 | HTS | French | Yes | Low |
| | 39 | Liberia | Yes, 2015 | Yes | 2020 | HTS | English | Yes | Low |
| | 40 | Mauritania | No | Yes | 2020 | HTS | French | Yes | Low |
| | 41 | Mali | No | Yes | 2017 | HTS | French | Yes | Low |
| | 42 | Niger | No | Yes | 2020 | HTS | French | Yes | Low |
| | 43 | Nigeria | Yes, 2016 | Yes | 2020 | ART | English | Yes | Low |
| | 44 | Senegal | Yes, 2017 | Yes | 2018 | HTS | French | Yes | Low |
| | 45 | Sierra Leone | Yes, 2017 | Yes | 2020 | ART | English | Yes | Low |
| | 46 | The Gambia | Yes, 2014 | Yes | 2019 | ART | English | Yes | Low |
| | 47 | Togo | No | Yes | 2019 | HTS | French | Yes | Low |

*These countries provided an updated HIV testing algorithm despite having an old HIV testing guideline

** These countries did not provide an update HIV testing guideline but were included in the analysis

**Supplementary Table 3.** Progress on policy adoption in the WHO African Region from 2018 to 2021

| Subregion | Count | Country | Policy reviewed in 2018? | Adherence in 2018 | Policy reviewed in 2021 | Adherence in 2021 |
|---|---|---|---|---|---|---|
| Central Africa | 1 | Angola | Yes, 2015 | Not adopted | 2020 | Mostly adopted |
| | 2 | Cameroon | Yes, 2015 | Not adopted | 2019 | Mostly adopted |
| | 3 | CAR | Yes, 2010 | Not adopted | 2018 | Not adopted |
| | 4 | Chad | Yes, 2011 | Not adopted | 2017 | Mostly adopted |
| | 5 | DRC | Yes, 2017 | Adopted | 2020 | Adopted |
| | 6 | Equatorial Guinea | No | – | 2018 | Not adopted |
| | 7 | Gabon | No | – | 2017 | Mostly adopted |
| | 8 | Republic of the Congo | No | – | – | – |
| | 9 | São Tomé e Principe | No | – | 2018 | Not adopted |
| Eastern Africa | 10 | Burundi | Yes, 2016 | Not adopted | 2020 | Mostly adopted |
| | 11 | Comoros | Yes, 2007 | No information | 2016 | Not adopted |
| | 12 | Eritrea | No | – | 2019 | Not adopted |
| | 13 | Ethiopia | Yes, 2017 | No information | 2018 | Mostly adopted |
| | 14 | Kenya | Yes, 2017 | Mostly adopted | 2021 | Adopted |
| | 15 | Madagascar | Yes, 2011 | No information | 2018 | Mostly adopted |
| | 16 | Malawi | Yes, 2016 | Not adopted | 2016 | Mostly adopted |
| | 17 | Mauritius | No | – | 2020 | Not adopted |
| | 18 | Mozambique | Yes, 2016 | Not adopted | 2020 | Mostly adopted |
| | 19 | Rwanda | Yes, 2016 | Not adopted | 2018 | Mostly adopted |
| | 20 | Seychelles | No | – | 2019 | Not adopted |
| | 21 | South Sudan | Yes, 2017 | Not adopted | 2020 | Adopted |
| | 22 | Tanzania | Yes, 2017 | Not adopted | 2021 | Mostly adopted |
| | 23 | Uganda | Yes, 2016 | Mostly adopted | 2020 | Mostly adopted |
| | 24 | Zambia | Yes, 2018 | Not adopted | 2020 | Not adopted |
| | 25 | Zimbabwe | Yes, 2016 | Adopted | 2016 | Adopted |
| Southern Africa | 26 | Botswana | Yes, 2016 | Mostly adopted | 2016 | Not adopted |
| | 27 | eSwatini | Yes, 2018 | Not adopted | 2018 | Not adopted |
| | 28 | Lesotho | Yes, 2016 | Adopted | 2021 | Mostly adopted |
| | 29 | Namibia | Yes, 2016 | No information | 2018 | Not adopted |
| | 30 | South Africa | Yes, 2016 | Mostly adopted | 2020 | Not adopted |
| Western Africa | 31 | Algeria | Yes, 2013 | Adopted | 2013 | Not adopted |
| | 32 | Benin | No | – | 2017 | Not adopted |
| | 33 | Burkina Faso | Yes, 2008 | Not adopted | 2021 | Mostly adopted |
| | 34 | Cabo Verde | No | – | – | – |
| | 35 | Ghana | Yes, 2014 | Not adopted | 2019 | Mostly adopted |
| | 36 | Guinea | No | – | 2019 | Mostly adopted |
| | 37 | Guinea-Bissau | No | – | 2021 | Not adopted |
| | 38 | Ivory Coast | Yes, 2016 | Not adopted | 2016 | Not adopted |
| | 39 | Liberia | Yes, 2015 | Not adopted | 2020 | Mostly adopted |
| | 40 | Mauritania | No | – | 2020 | Not adopted |
| | 41 | Mali | No | – | 2017 | Not adopted |
| | 42 | Niger | No | – | 2020 | Not adopted |
| | 43 | Nigeria | Yes, 2016 | Not adopted | 2020 | Mostly adopted |
| | 44 | Senegal | Yes, 2017 | Mostly adopted | 2018 | Not adopted |
| | 45 | Sierra Leone | Yes, 2017 | Not adopted | 2020 | Not adopted |
| | 46 | The Gambia | Yes, 2014 | Not adopted | 2019 | Not adopted |
| | 47 | Togo | No | – | 2019 | Not adherent |

Those highlighted in red are policies reviewed in 2018 that were updated (n=28). Number of policies deemed adopted in 2018 (n=7) and number deemed adopted in 2021 (n=20)

**Supplementary Table 4.** Short name of products used as part of the 2-assay or 3-assay HIV testing algorithm in 28 HIV national testing policy documents reviewed in 2021

| Strategy | Count | Country | Assay 1 | Assay 2 | Assay 3 |
|---|---|---|---|---|---|
| 2-assay | 1 | Angola | Determine | Uni-Gold | – |
| | 2 | Cameroon | Determine or Uni-Gold | OraQuick or Shanghai | – |
| | 3 | CAR | Determine | Uni-Gold | – |
| | 4 | Cote D'Ivoire | Determine | SD Bioline or GenieFast | StatPak or EIA (as tiebreaker) |
| | 5 | Equatorial Guinea | Determine | Hexagon | Uni-Gold (for discordants) |
| | 6 | eSwatini | Determine | Uni-Gold | – |
| | 7 | Gambia | Determine | SD Bioline or First Response | – |
| | 8 | Guinea Bissau | Determine | First Response | PCR (as tiebreaker) |
| | 9 | Mali | Alere Combo | SD Bioline | First Response (as tiebreaker) |
| | 10 | Mozambique | Determine | Uni-Gold | – |
| | 11 | Rwanda | Alere Combo | StatPak | – |
| | 12 | São Tomé e Principe | Determine | SD Bioline | PCR (as tiebreaker) |
| | 13 | Sierra Leone | Determine | SD Bioline | Uni-Gold (as tiebreaker) |
| | 14 | Uganda | Determine | StatPak | SD Bioline (for discordants) |
| | 15 | Nigeria | Determine<br>Uni-Gold<br>Stat-Pak<br>Double Check Gold<br>Sure Check<br>HIV Quick Check | Determine<br>Uni-Gold<br>Stat-Pak<br>Double Check Gold<br>Sure Check<br>HIV Quick Check | Determine<br>Uni-Gold<br>Stat-Pak<br>Double Check Gold<br>Sure Check<br>HIV Quick Check<br>(as tiebreaker) |
| | 16 | Togo | Murex HIV Ag/Ab<br>Apdia HIV Ag/Ab<br>Determine<br>Alere Combo<br>Vikia HIV 1/2<br>Wanta Rapid Test<br>ABON HIV 1/2/0<br>Standard Q<br>Hexagon<br>Genie Fast<br>SD Bioline<br>First Response<br>SD Bioline HIV/Syphilis<br>OraQuick HIV Self-Test | ABON HIV 1/2/0<br>Standard Q<br>SD Bioline<br>First Response<br>HIV Tri-Dot | INNOLIA or Genius (as tiebreaker) |
| 3-assay | 17 | Burundi | Alere Combo or Determine | SD Bioline or Uni-Gold | Wondfo One Step |
| | 18 | Gabon | Alere Combo | Determine | SD Bioline |
| | 19 | Ghana | First Response | OraQuick | SD Bioline |
| | 20 | Guinea | Determine | SD Bioline | Multisure |
| | 21 | Kenya | INSTI | Uni-Gold | SD Bioline |
| | 22 | Liberia | Determine | SD Bioline | Uni-Gold |
| | 23 | Madagascar | Determine | Uni-Gold | SD Bioline |
| | 24 | Mauritius | GenScreen Ultra Ag/Ab | Alere Combo | Western Blot |
| | 25 | Malawi | INSTI | Uni-Gold | SD Bioline |

| | | | | | |
|---|---|---|---|---|---|
| | 26 | Niger | Alere Combo | Wondfo One Step | SD Bioline |
| | 27 | Senegal | Determine | SD Bioline | Multisure |
| | 28 | Zimbabwe | Determine | Chembio | INSTI |
| | 29 | Burkina Faso | 3rd generation:<br>Determine<br>Double check Gold Ultra<br>Onsite HIV1+2 Plus Combo<br>VIKIA HIV 1/2<br>4th generation:<br>Alere Ag/Ab Combo<br>OnSite HIV Ab/Ag (CTK) | HIV TriDot<br>ImmunoFlow<br>OnSite HIV 1/2 Ab Plus (CTK)<br>SD Bioline | Any of those not selected as A1 or A2 |

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# Country adoption of WHO 2019 guidance on HIV testing strategies and algorithms: a policy review across the WHO African region

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**Title:** Country adoption of WHO 2019 guidance on HIV testing strategies and algorithms: a policy review across the WHO African region

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## ABSTRACT

**Objectives:** In 2019, the World Health Organization (WHO) released guidelines on HIV testing services (HTS). We aim to understand adoption of these recommendations.

**Design:** Policy review

**Setting:** 47 countries within the WHO African region.

**Participants:** National HTS policies from the WHO African region as of December 2021.

Primary and secondary outcome measures: Uptake of WHO recommendations across national HTS policies including the standard 3-test strategy; discontinuation of a tie-breaker test to rule in HIV infection; discontinuation of western blotting (WB) for HIV diagnosis; use of retesting prior to ART initiation; and the use of dual HIV/syphilis rapid diagnostic tests (RDTs) in antenatal care (ANC). Country policy adoption was assessed on a continuum, based on varying levels of complete adoption.

**Results:** National policies were reviewed for 96% (n=45/47) of countries in the WHO African region, 40% (n=18) were published before 2019, and 62% (n=28) adopted WHO guidance. As of 2021, adoption in the region was 62% (n=28/45). Among countries that had not fully adopted WHO guidance, using a 2-test strategy was the most common reason for misalignment; 31% (n=14) and 22% (n=10) in low (<5%) and high (≥5%) prevalence countries, had not yet adopted the 3-test strategy. Ten policies (22%) recommended the use of WB in their HIV testing algorithm, and 51% (n=23) recommended retesting before ART initiation. Dual HIV/syphilis RDTs were recommended in 47% (n=21/45) of policies.

**Conclusions:** Many countries in the African region have adopted WHO-recommended HIV testing strategies. While WB was only used in a few countries, concerted efforts are needed to phase out this technology in favour of RDTs. Countries should accelerate their transition to

WHO recommendations by streamlining efforts to adopt and implement a 3-test strategy and dual HIV/syphilis RDTs.

**Keywords:** HIV, diagnosis, rapid test, dual HIV/syphilis, policy, guideline, Africa, algorithm

**Strengths and limitations of this study**

- This study provided a comprehensive review of existing national HTS policies in the African region and was able to identify current policies for 45 countries. While this represents nearly all countries in the region, we were unable to identify policies for two countries.
- Data was collected and analyses using a robust search and global repository developed by WHO, as well as a standardised extraction tool to synthesise national policy information. Translation of policies was conducted by the review team.
- The review focused only on published policies and did not assess country implementation at the national, subnational, or site level. Thus, it is possible that some practices in country differ than policies reviewed, and level of adoption reported may vary.
- The review focused on WHO recommendations related to HIV testing strategies for individuals ≥18 months of age. HIV testing strategy recommendations, such as early infant diagnosis, was not included.
- The review also identified countries which reported that they were in the process of adopting WHO recommendations – particularly the use of 3-test strategy and dual HIV/syphilis RDTs. Thus, our estimates may be conservative an under-estimate policy adoption in the African region.

## INTRODUCTION

HIV Testing Services (HTS) is the critical gateway to accessing HIV-related care and treatment for those diagnosed as HIV-positive and as a means to accessing prevention services for those who test HIV-negative.[1, 2] Despite considerable progress, reaching the UNAIDS 95-95-95 targets by 2025 will require increased testing uptake, particularly among populations with testing gaps such as key population, youth and men.[3] Further, the global emergency caused by the COVID-19 pandemic in 2020 has disrupted many health services including HIV testing services, and supply chains of key commodities such as rapid diagnostic tests (RDTs) have been stretched.[4] In 2021, it was estimated that 85% of people living with HIV globally were aware of their serostatus.[5]

In 2019, the World Health Organization (WHO) published consolidated guidelines on HIV testing services (HTS),[6] bringing together existing recommendations specific to testing strategies and algorithms e.g., use of serial testing rather than parallel testing (WHO, 2012),[7] discontinuation of a tiebreaker strategy to rule-in HIV infection (WHO, 2015)[1] and, retesting prior to antiretroviral treatment (ART) initiation, recommended since 2014;[1] and released three new recommendations related to testing strategies namely: (1) moving toward a universal 3-assay testing strategy using three consecutive HIV-reactive tests to provide and HIV-positive diagnosis, (2) discontinuation of western blot (WB) and line immunoassays (LIA) and, (3) use of dual HIV/syphilis RDTs as first assay in HTS in antenatal care (ANC) settings. In light of these testing modalities, ensuring that HIV testing is accessible and adheres to the "5 C's" including voluntary consent, confidentiality, counselling, correct results, and linkage to care, is of upmost importance.

These recommendations have been prioritised because they are essential to achieving global 95-95-95 goals by making testing accurate, affordable and high impact. [3,6] By moving away from testing services with WB, programmes will no longer have long turnaround times which delay the ability to offer same day ART or PrEP initiation. [6] Adoption of innovative tools such as the dual HIV/syphilis RDTs will enable more people to be tested and treated for syphilis, which is essential for achieving triple elimination goals. [6] Additionally, many countries still use the 2015 WHO recommendation of using the national HIV prevalence to determine whether a two-assay (≥5%) or three-assay testing strategy (<5%) should be used.[1] However, as ART coverage has expanded HIV positivity and the proportion of people with HIV who are undiagnosed and not in care will continue to decline. As a result, the positive predictive value of previous testing strategies will also decline and lead to an increase in false positive diagnoses. In relation to the guideline development process, WHO now recommends all countries use a standard 3-test strategy.[8] WHO also recommends that countries planning to update their HIV testing algorithms undertake a verification study to select appropriate HIV serology products and ensure they don't cross-react in order to minimize the risk of misdiagnosis.[9]

**Box 1. WHO recommendations for HIV testing strategies for individuals ≥18 months of age, 2019**

- Western blotting and line immunoassays should not be used in national HIV testing strategies and algorithms.
- Dual HIV/syphilis RDTs can be the first test in HIV testing strategies and algorithms in ANC settings.

- In response to changes in the HIV epidemic, WHO recommends countries use three consecutive reactive tests to provide an HIV-positive diagnosis.
- Testing strategies should use tests serially, not in parallel, and should not use a tiebreaker to rule-in HIV infection. Instead, those with discrepant test results should be ruled inconclusive and referred for further testing in 14 days to rule-in or rule-out seroconversion.
- WHO recommends that all HIV testing algorithms use a combination of RDTs and/or EIAs to achieve at least 99% positive predictive value and use a combination of tests with ≥99% sensitivity and ≥98% specificity. WHO does not recommend the use of NAT techniques within HIV testing algorithms for individuals ≥18 months of age.
- The first test in an HIV testing strategy and algorithm should have the highest sensitivity, followed by a second and third test of the highest specificity. Algorithms should be validated and verified to ensure high quality and accurate testing services.
- All people newly diagnosed with HIV should be retested to verify their HIV status prior to starting ART, using the same testing strategy and algorithm as the initial test. To minimize the risk of misdiagnosis, this approach should be maintained in settings in which rapid ART initiation is being implemented.

*Source: WHO 2019, [6]*

To support the implementation of the 2019 guidelines, WHO launched and disseminated the guidance at the Africa Society of Laboratory Medicine and the International Conference on AIDS and STIs in Africa. Following the initial release, WHO also provided detailed country support to adopt the guidelines along with developing an application to access the guidelines

more easily. In addition to dissemination and country support, [10] it is critical to monitor and track the implementation of WHO policy uptake to understand policy priorities and challenges overtime. Such tracking not only provides valuable insights but can help guide revisions to future guidance and can help target country policy support [11—12].

A global review of national HIV testing policies was conducted by WHO in 2018 to assess adoption of its testing recommendations and policies.[13] Of 91 policies reviewed only 24 (25%) adhered to WHO guidance. This policy review follows on from the previous review and seeks to assess country uptake of six 2019 WHO recommendations related to HIV testing strategies. Here we focus on the WHO African region, which hosts several countries with a high HIV burden and with large HIV testing programmes. The same policy review across the remaining five WHO regions is underway as part of the update to the 2023 WHO HTS guidelines.

## METHODS

### Search strategy

We carried out a comprehensive desk review of national HIV testing policies in 47 Member States in the WHO African region (online supplementary figure 1) using a policy repository maintained by WHO, scanning government websites, and by contacting government officials or other relevant informants through December 2021. The most current policy documents containing information on the HTS policy were included, but when this was unavailable, we included the most recent HIV testing algorithm, but if that was also unavailable, we opted to include previous national policies. Documents of all languages were included. Other supporting documents related to algorithm validation and PMTCT guidelines were identified,

when possible, either through references provided in the national HTS policy or through contact with key informants. The full protocol for the review was previously developed and published in 2018. [13]

**Data extraction**

Data were extracted from each policy document by one reviewer (EF) into standardised coding forms on policy information, HIV testing strategy/algorithm (>18 months of age), dual HIV/syphilis testing strategy/algorithm, and retesting prior to ART initiation (online supplementary table 1). When reported the order, type of test kits and name brand of diagnostics used within the HIV testing algorithm was summarised descriptively, as well as information on whether the algorithm was verified or validated.

A second reviewer (CL) carried out crosschecking of the data. Differences between coders were resolved through a third reviewer (CJ). To prevent misclassification, items were marked as 'unclear' during data extraction when lack of information prevented complete understanding. Reviewers than worked to contact key informant to provide further detail and clarity wherever possible.

**Analysis**

We assessed national adoption of WHO HTS guidance using six specific recommendations related to testing strategies and algorithms for those ≥18 months of age set forth in the WHO 2019 HIV testing guidelines, namely: (1) use of serial testing, (2) use of a 3-test strategy, (3) discontinuation of a tie-breaker to rule in HIV infection, (4) discontinuation of WB/LIA, (5) retesting prior to ART initiation, and (6) use of dual HIV/syphilis RDT in ANC. Additional

qualitative details about the national testing algorithm, such as the order of and name brand of test kits used in testing algorithms, were also reviewed when reported and assessed according to WHO recommendations (see Box 1).

Based on the number of recommendations adopted, national policies were categorized as: adopted (6); nearly adopted (5 to 4); somewhat not adopted: (3); and not adopted: (2 or less). We then provide simplified reporting (adopted, partially adopted and not adopted) for national policies which reviewed in 2018 and 2021 to assess changes overtime. Notably, these categories were initially developed as part of the 2018 policy review and maintained to assist with future updates and policy tracking.

Descriptive analyses were then stratified by subregions (Western, Central, Eastern and Southern Africa; online supplementary figure 1) were also conducted to determine rates of adherence by subregion. All analyses were conducted in Microsoft Excel. Countries which had policies reviewed in 2018 and 2021 were also compared to assess changes in alignment with WHO recommendations over time.

**Patient and public involvement**

Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans of this study.

**RESULTS**

In total, we were able to identify policy documents from 96% of countries from the WHO African region (n=45/47); 71% of countries had a policy reviewed in both 2018 and 2021

(n=32/45). Two countries, Republic of the Congo and Cabo Verde, were not included because we were unable to obtain their national policies and sufficient information (figure 1). Out of all these policies, 91% (41/45) had updated their national policies as of December 2021. Policy publication dates ranged from 2013 to 2021. Out of the six country policies that had not been fully updated since 2018 (Algeria, Botswana, eSwatini, Cote d'Ivoire, Malawi, and Zimbabwe), two (Malawi and Zimbabwe) provided new HIV testing algorithms that were included in the review.

Of the 45 policies providing information on HIV testing strategies, 16 were from Western Africa (36%), 16 were from Eastern Africa (36%), 8 were from Central Africa (18%), and 5 were from Southern Africa (11%). Policies were published in English (n=22), French (n=18), Portuguese (n=4) and Spanish (n=1). Based on the most recent national HIV prevalence reported by UNAIDS [1], 34 countries (76%) had a low HIV prevalence (<5%) and 11 countries (24%) had a high HIV prevalence (≥5%) (online supplementary table 2).

**Overall adoption of WHO-recommended HIV testing strategies**

In 2021, 62% of national testing strategies (n=28/45) were either fully or partially aligned with WHO 2019 HTS recommendations and 38% (n=17/45) had not adopted the recommendations (table 1). When the analysis was restricted to a subset of countries with policies in both the 2018 and 2021 review (n=32), the proportion adopting WHO guidance in 2018 was 28% (n=9/32) *vs* 62% (n=20/32) in the current (2021) review (see online supplementary table 3; supplementary figure 2). Across the sub-regions, Southern (80%) and Eastern (75%) Africa had the greatest level of alignment, whilst Central Africa (63%) and Western Africa (44%) had the lowest adoption rates (table 1; figure 2).

In low-prevalence countries (n=34), 53% of policies (n=18/34) had fully or mostly adopted the guidance and 47% (n=16/34) had generally not adopted guidance. The most common reasons for non-adoption were not using a dual HIV/syphilis RDT in ANC (n=15/34), no retesting prior to ART initiation (n=14/34) and using only two assays to make an HIV-positive diagnosis (n=10/34). In high-prevalence countries (n=11), 91% of policies (n=10/11) had fully or nearly adopted WHO guidance and 9% had not adopted WHO guidance (1/11). The most common reasons for not fully adopting WHO guidance was: continuing to use a 2-test strategy to make an HIV-positive diagnosis (n=10/11), employing both serial and parallel testing strategies (n=4/11), not adopting dual HIV/syphilis RDTs in ANC (n=4/11) and not implementing retesting prior to ART initiation (n=3/11). Overall, only two out of eleven high HIV-burden countries, Malawi and Zimbabwe, recommended the use of a 3-assay testing strategy (18%).

**Table 1.** Policy adoption of 2019 WHO-recommended HIV testing strategies in the WHO African region, 2021

| AFRO subregions (countries) | Policies reviewed | Serial testing strategy | Discontinuation of tiebreaker* testing strategy | Retesting prior to ART initiation | Recommended 3-test strategy | Use of dual HIV/syphilis test** | No use of Western Blot |
|---|---|---|---|---|---|---|---|
| **All (n=47)** | 45 (96%) | 29 (64%) | 37 (82%) | 23 (51%) | 21 (47%) | 21 (47%) | 35 (78%) |
| **Western (n=17)** | 16 (94%) | 9 (56%) | 9 (56%) | 5 (31%) | 8 (50%) | 7 (44%) | 10 (63%) |
| **Central (n=9)** | 8 (89%) | 7 (88%) | 7 (88%) | 5 (63%) | 3 (38%) | 2 (25%) | 6 (75%) |
| **Eastern (n=16)** | 16 (100%) | 12 (75%) | 16 (100%) | 9 (56%) | 9 (56%) | 9 (56%) | 14 (88%) |
| **Southern (n=5)** | 5 (100%) | 1 (20%) | 5 (100%) | 4 (80%) | 1 (20%) | 3 (60%) | 5 (100%) |

*Use of a third assay to rule-in HIV infection

**Dual HIV/syphilis RDT as first test in ANC

**Adoption of serial testing strategy**

In 2021, 64% of national testing strategies (n=29/45) adopted the use of serial testing and 36% (n=16/45) recommended the mix use of serial and parallel testing (figure 3_1). The subregions with the highest adoption were Central (88%) and Eastern Africa (75%), followed by Western Africa (58%); Southern Africa had the lowest adoption rate (20%) (table 1). However, fewer countries in southern Africa recommended serial testing in 2021 (n=1) than in 2018 (n=4) (supplementary table 4). Most policies recommending serial or parallel testing (n=15/16) conducted simultaneous testing of assay 1 (A1) and assay 2 (A2) in case of discrepant test results, and the Namibian policy recommended parallel testing of A2 and A3 after a reactive A1.

Only 44% of policies (n=20/45) provided guidance on the assay order in relation to their sensitivity and specificity. The proportion of HIV testing strategies/algorithms using two consecutive HIV-reactive tests to make an HIV-positive diagnosis was 53% (n=24/45) whereas 47% (n=21/45) recommended the use 3 consecutive HIV-reactive tests.

Sixty-four percent of the HIV testing strategies reviewed (n=29/45) included information on the testing algorithms, i.e., contained specific product names and all of them included WHO prequalified products. Determine HIV 1/2 (Abbott Diagnostics Medical Co., Ltd, Japan) was the most common product used as A1 and Bioline HIV 1/2 3.0 (Abbott Diagnostics Korea Inc., Republic of Korea) or Uni-Gold HIV (Trinity Biotech, Ireland) as A2 or A3 (see online supplementary table 5). Only 31% of policies (n=14/45) mentioned the need to locally verify or validate the HIV testing algorithm.

**Discontinuation of a tiebreaker testing strategy**

The discontinuation of a third assay to rule in HIV infection (i.e., tiebreaker) was recommended in 82% of national policies (n=37/45) (figure 3_2). The subregions with the highest adoption were in Southern Africa and Eastern Africa (100%, each) followed by Central Africa (88%), whereas Western Africa had the lowest adoption (56%) (table 1).

Of the eight policies recommending a tiebreaker testing strategy, seven were from Western Africa and one from Central Africa. Seven policies specified the type of A3 to be used, for example, RDT (n=4), RDT or EIA (n=1), nucleic acid testing (NAT: n=2) and LIA (n=1).

**Adoption of WHO standard 3-assay testing strategy**

The use of three consecutive HIV-reactive tests for the diagnosis of HIV was recommended by 47% of the policies (n=21/45) (figure 3_3). The adoption of this WHO recommendation was highest in Eastern Africa (56%) and Western Africa (50%) and lowest in Southern Africa (20%) (table 1). Most policies recommending a 3-test strategy (n=20/21) were from low HIV-burden countries. Among high HIV-burden countries, only 18% of policies (n=2/11) recommended the use of a 3-test strategy and this corresponded to two countries, Malawi and Zimbabwe, respectively.

Overall, across countries which had policies reviewed in both 2018 and 2021, 10 policies that previously recommended a 2-assay testing strategy transitioned to a 3-test strategy as of 2021 (Burkina Faso, Burundi, Chad, Ethiopia, Ghana, Kenya, Lesotho, Malawi, Madagascar, and Zimbabwe, respectively).

**Adoption of retesting to verify positive status prior to ART initiation**

In 2021, 51% of national strategies (n=23/45) recommended retesting prior to ART initiation (figure 3_4). The regions with the highest level of policy adoption were in Southern Africa (80%) followed by Central (63%) and Eastern Africa (56%) (table 1). However, fewer countries in southern Africa recommended retesting before ART initiation in 2021 (n=4) than in 2018 (n=5) (supplementary table 5). Sixty-five percent of the retesting policies (n=15/23) recommended retesting using the same national HIV testing algorithm in a new specimen run by a different operator in a different testing site; 26% (n=6/23) did not specify how retesting was carried out and 9% of policies (n=2/23) utilized retesting strategies that differed from the national HIV testing algorithm, which included parallel testing of A1/A2 in Botswana and Malawi.

**Discontinuation of Western Blotting**

The proportion of national policies not including WB or LIA as part of the HIV testing algorithm was 78% (n=35/45) (figure 3_5). This proportion was highest in Southern Africa (100%) and Eastern Africa (88%) followed by Central Africa (75%) and Western Africa (63%) (table 1). Most countries with a supporting policy in favour of WB or LIA (n=9/10) recommended its use to manage persistent inconclusive/indeterminate test results and one policy used WB as A3 (Mauritius).

**Adoption of dual HIV/syphilis RDT in ANC settings**

Forty-seven percent (n=21/45) of policies supported the use of dual HIV/syphilis RDTs among pregnant women in ANC (figure 3_6). The region was the highest policy uptake was Southern Africa (60%), followed by Eastern (56%), Western (44%) and Central Africa (25%) (table 1).

And of policies supporting a 3-test strategy, only 53% (n=11/21) also recommended the use of dual HIV/syphilis RDTs among pregnant women. The majority of policies (n=20/21) recommended the use of dual HIV/syphilis RDT as A1 among pregnant women and only one policy (Lesotho) recommended its use as a triage test (A0) as an interim algorithm while waiting for the results of a national verification study.

The dual HIV/syphilis testing algorithm was not aligned with the national HIV testing algorithm in one country (Zambia): while Determine HIV-1/2 (Abbott Diagnostics Medical Co., Ltd, Japan) and SD Bioline HIV-1/2 3.0 (Abbott Diagnostics Korea Inc, Republic of Korea) products were used as A1 and A2 in the national testing algorithm, Bioline HIV/Syphilis Duo (Abbott Diagnostics Korea Inc, Republic of Korea) and Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China) were used as A1 and A2 in the ANC testing algorithm.

In addition to the use in ANC settings, three countries also recommended testing with dual HIV/syphilis RDTs among other populations such as male partners of pregnant women and key populations (Liberia, Madagascar and Uganda). Only 50% of policies (n=11/21) specified the brand name of the dual HIV/syphilis RDT in the testing algorithm, and among the policies mentioning the brand name, Bioline HIV/Syphilis Duo (Abbott Diagnostics Korea Inc, Republic of Korea) was the most employed RDT (100%). Only 57% of policies (n=12/21) mentioned whether syphilis treatment was provided immediately after a reactive syphilis test result.

**Use of nucleic acid testing (NAT) to diagnose HIV infection in individuals ≥18 months of age**

Twenty-two percent of national policies (n=10) recommended the use of NAT as part of the testing algorithm for the diagnosis of HIV infection in individuals ≥18 months of age. Four policies were from Eastern Africa (Malawi, Mauritius, Mozambique and United Republic of Tanzania); three national policies from Southern Africa (Eswatini, Lesotho and Namibia); two policies from Central Africa (Angola and Sao Tomé et Principe); and one national policy from Western Africa (Guinea Bissau). Two policies employed NAT as the third assay (A3) of the algorithm while the remaining 8 policies recommended NAT to resolve persistent inconclusive/indeterminate test results (referring either to viral load, PCR or DNA-PCR).

## DISCUSSION

The current review found a significant improvement in the overall policy uptake of the latest WHO-recommended HIV testing strategies with 62% of countries in the African region adopting WHO guidance in 2021. When directly comparing 32 countries with policies reviewed in 2018 and 2021, [13] policy adoption increased more than 2-fold (20 vs 9). As of the 2021 review, 40% of policies were published before 2019 which underscores the need to update national testing policies at more regular intervals.

Given the rapid changes in HIV testing landscape, this underscores the need of national programmes to update their national HIV testing policies at more regular intervals to keep up with latest WHO guidance. This is particularly critical now as WHO is now updating HTS guidance in 2023 and it will be essential for WHO to continue policy tracking, [10] to allocate sufficient resources, to conduct implementation science research to understand bottlenecks

hinder policy change and to support country-led technical working groups to drive policy change [11—12].

The recommendations with highest adoption were the discontinuation of a tiebreaker (82%) and western blotting (78%) as well as the use of serial testing (64%). Half of countries (51%) also recommend retesting prior to ART initiation. One likely explanation for the higher policy adoption is that these WHO´s recommendations were first published in 2012, 2014 and 2015, respectively (save for discontinuation of western blotting) providing national HIV programmes ample time to incorporate these recommendations into their national HIV testing guidelines. Although moving away from western blotting was recommended more recently in 2019,[14] low resource countries in the WHO African region have been at the forefront of implementing HIV RDTs compared to other WHO regions as a way to rapidly expand and increase access to HIV testing services.[15]

Having said that, our review found that a dozen of countries, mostly in Western Africa, still use western blotting as part of the HIV testing algorithms, hindering same-day diagnoses and rapid access to ART and pre-exposure prophylaxis (PrEP). Additionally, between 2018 and 2021, countries in southern Africa appeared to be the one sub-region which shifted away from serial testing to parallel testing strategies. This shift has likely increased testing costs as it requires more test kits per individual tested. Further follow-up with countries is needed to understand their policies and should continue to promote serial testing.

Despite observing that many countries recommended retesting prior to ART initiation in 2021, we noted that progress in policy adoption was minimal and that in southern Africa one less

country was implementing when compared to 2018. Retesting prior to ART initiation remains an important quality assurance strategy, however if countries are struggling to adopt this recommendation it may be important for WHO to provide alternative approaches and address implementation challenges.

The WHO´s recommendations with a lower country uptake were the use of a standard 3-test strategy (47%) and the use of dual HIV/syphilis RDT among pregnant women (47%), both recommendations released in 2019.[6] Before 2019, WHO recommended the use of a 2-test strategy in high HIV prevalence settings (≥5%) and the use of a 3-test strategy in low HIV prevalence settings (<5%) to maintain at least a 99% positive predictive value.[1] However, as HTS and ART have been scaled up substantially and fewer people undergoing HTS are HIV-positive, the national HTS positivity has also declined, even in high HIV burden settings.[16] Given these changes in the epidemic, WHO now recommends that all settings move toward using a 3-assay testing strategy to ensure high-quality testing.[16] Specifically, in high HIV burden settings in southern Africa (5 countries) and eastern Africa (6 countries), WHO recommends countries still using a 2-test strategy to prioritize moving toward using a 3-test strategy.[16]

In this review we found that only 18% (n=2/11) of the high-burden countries in the WHO African region has a supportive policy on a 3-assay testing strategy. A likely explanation for this slower policy adoption is programmes needing to prioritise limited resources and efforts to address the COVID-19 pandemic. Many programmes, including those focused on HIV testing, were affected by disruptions during COVID-19 and updates and changes to national policies were delayed. [4] Changing a testing algorithm also takes time and planning to

implement, including provider training, quality assurance, procurement, inventory management and budget implications to the national programme.[6,16] Many countries indicated they were in the process of transitioning to a 3-test strategy but needed to complete verification studies, conduct tendering process for products, and garner consensus and support among partners. Some countries have yet to prioritise adopting the 3-test strategy because they were focused on higher yield testing approaches alone. [17—18] Lastly, some countries had delayed the transition due to costs concerns. While countries will need to develop a plan and identify the optimal time for the transition, in terms of costs, a modelling study found that the total cost of the 3-test strategy would have a very limited impact on costs.[19] Further, in Ghana after transitioning to a 3-test strategy they found that while there were lessons learned about logistics and training, the new strategy was found to be feasible, improved testing quality and reduced costs due to preventing misdiagnosis.[20]

We found that among low-prevalence countries (n=34), a significant proportion (41%) still use a suboptimal testing strategy with 2 assays to make an HIV positive diagnosis, which will increase the likelihood of false-positive diagnosis.[19--21] A retrospective study in Nigeria using household survey data found that the performance of the 2-test strategy in a low prevalence setting of about 1.4% was poor with a PPV of 94% and a false-positive rate of 5.5%.[22] This positive predictive value is similar to a modelling study assessing the accuracy of the 2015 and 2019 WHO HIV testing algorithms, which was 95.4% using a 2-assay testing strategy.[19]

Considering that the recommendation to use dual HIV/syphilis RDTs in ANC was released only in 2019,[6, 23] its adoption has been rapid with 21 national policies recommending its use.

However, the number of countries adopting dual HIV/syphilis RDTs among pregnant women may be in practice higher considering that preliminary National Commitments and Policy Instrument (NCPI) survey data reported that a total of 26 countries in the WHO African region adopted the use of dual HIV/syphilis RDTs in ANC. [24] The differences likely reflect differences in methodologies (policy reviews versus policy survey). Often annual global policy surveys, like NCPI, may reflect a mixture of policies and anecdotal practices, including unofficial policies not yet within official guidelines. Although the findings of this review likely provide a conservative estimate of policy adoption, they do highlight the need to ensure official national policies are updated accordingly.

Some countries may choose not to introduce dual HIV/syphilis RDT. For example, in Malawi where dual HIV/syphilis RDT introduction has been considered but not adopted, the national programme has opted to retain stand-alone HIV and syphilis RDTs in ANC to prioritize point-of-care test options for HIV and syphilis while maintaining a single HIV testing algorithm in a resource limited context. Dual HIV/syphilis testing is also now recommended for key populations by WHO and this may further increase its use in HIV testing algorithms in national programmes. [25] It is an important option to increase HIV and syphilis detection and treatment and a recent modelling study in Viet Nam shows that it was cost saving or cost-effective.[26]

As countries update their national HIV testing guidelines to incorporate latest WHO guidance and adapt their national HIV testing strategies and algorithms to shift toward using three consecutive reactive serology tests to diagnose HIV, introduce dual HIV/syphilis RDTs among pregnant women and key populations, move away from western blotting, reinforcing

retesting prior to ART initiation as well as design flexible algorithms to address kit shortages, WHO encourages national programmes to conduct a verification study to provide objective evidence, before national scale-up, that a specific combination of products work well together without sharing false-reactivity, thus reducing the risk of misdiagnosis.[6, 9] To assist countries achieve this, WHO has put together a practical toolkit to accelerate policy adoption.[27] To date, the following countries are working directly with WHO to update their testing algorithm: Armenia, Burkina Faso, Cameroon, Chad, Central African Republic, Cote D´Ivoire, Democratic Republic of Congo, eSwatini, Kenya, Lao, Lesotho, Mali, South Sudan and Zambia.

This policy review has strengths as well as weaknesses. Firstly, this review provides a comprehensive review of existing national HTS policies in the African region and was able to identify current policies for 45 countries. While this represents nearly all countries in the region, we were unable to identify policies for two countries. Secondly, unlike other policy surveys this study reviewed official policies for each country that were collected through a robust global search and triangulated data with additional information provided by country-level key informants. Despite this, the review was unable to assess unpublished policies and those in development at the time of the analysis. During the review some countries indicated that they were in the process of updating their guidance, particularly around adoption of a 3-test strategy. We were unable to include this information in the review, and thus our reported level of adoption of WHO recommendations may be an underestimate. Thirdly, this review did not assess policy implementation at the national, subnational, or site level. Thus, it is possible that some practices in country differ than policies reviewed, and level of adoption reported may vary. Lastly, we focused on HIV testing strategies for individuals ≥18 months of

age. As a result, we were unable to report on the adoption of HIV testing strategy recommendations for children, such as early infant diagnosis.

**Conclusions**

Adoption of WHO-recommended HIV testing strategies has improved in the African region. While WB was only used in a few countries, concerted efforts are needed to phase out this technology in favour of RDTs. Countries should plan to accelerate their transition to WHO recommendations by streamlining efforts to adopt and implement a 3-asssay testing strategy and dual HIV/syphilis RDTs. Conducting verification of testing algorithms and using appropriate assays can ensure accurate HIV diagnosis in a cost-efficient and time-efficient manner. Greater efforts are needed now to ensure countries implement high-quality testing services as they are essential for the global goal to achieve and maintain low HIV incidence.

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## Contributors

CJ and AS devised and CJ and RB supervised the review. EF led the study protocol developments, conducted the screening, data extraction and analysis. NB, CM, NSB, FSM, FJL, MASP, LH assisted with acquisition of policies, data collection and results interpretation. CL acted as a second reviewer and CJ as third reviewer. AS, MSJ, MBD and RB assisted with assessing policies and interpreting results. EF led manuscript writing along with CJ, with support from all authors. CL, NB, CM, NSB, FSM, FJL, MASP, LH, MBD, MSJ, AS, RB all reviewed the first draft, provided critical review and input and approved the final version of the manuscript.

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## Map disclaimer

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## Competing interests

The authors declare no competing interests. The contents in this article are those of the authors and do not necessarily reflect the view of the World Health Organization.

## Patient consent for publication

Not required.

## Ethics approval

This study does not involve human participants and ethical approval was therefore not required.

## Data availability statement

All data generated in the study are included in the article or uploaded as supplementary information. National policies may be publicly available. Some policies included in this review may be available through the following websites: (1) https://aidsfree.usaid.gov/resources/guidance-data/hts. (2) http://www.hivpolicywatch.org/database.html. If information on a policy cannot be found through these resources, please contact the authors of this review for additional information.

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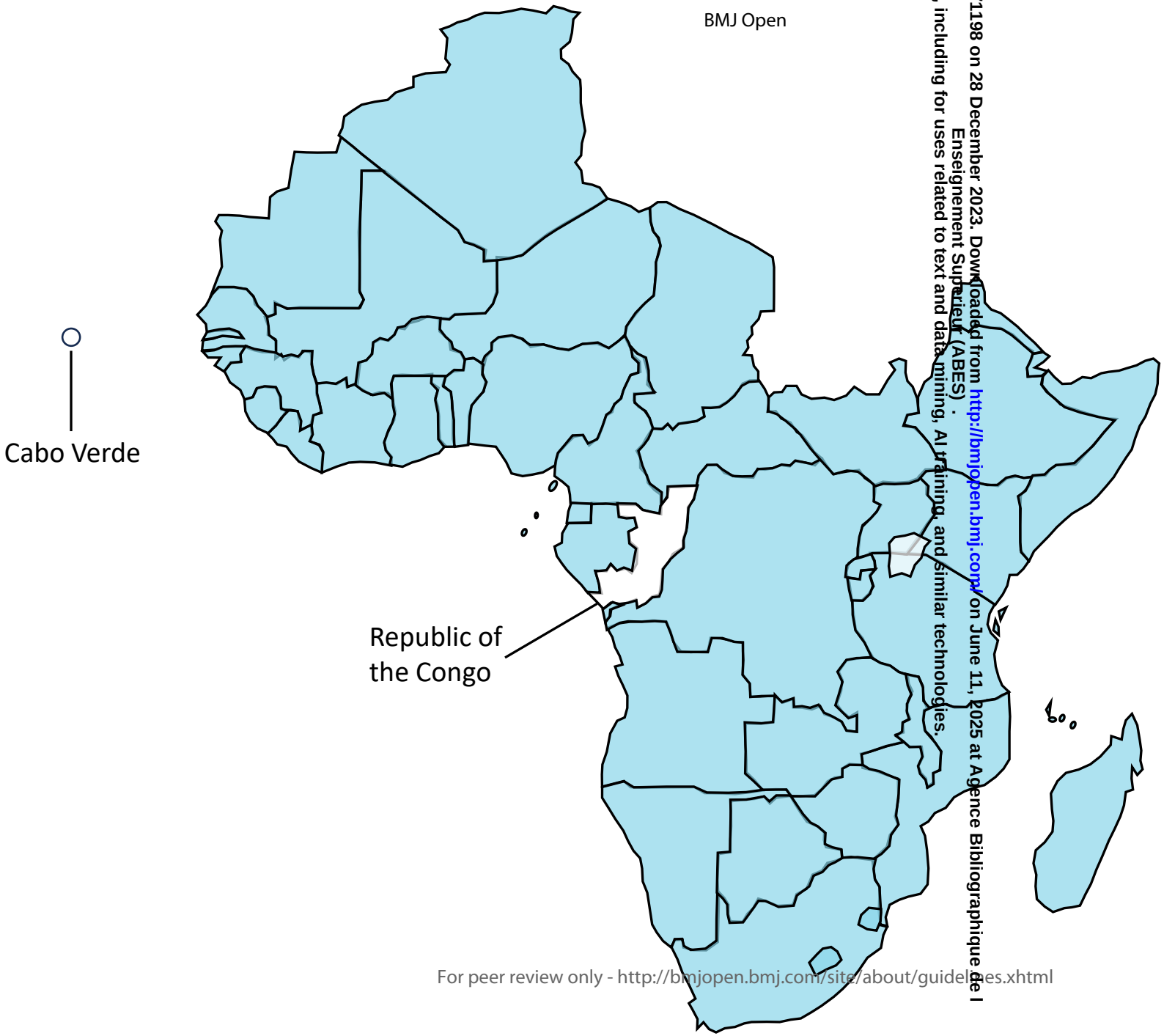
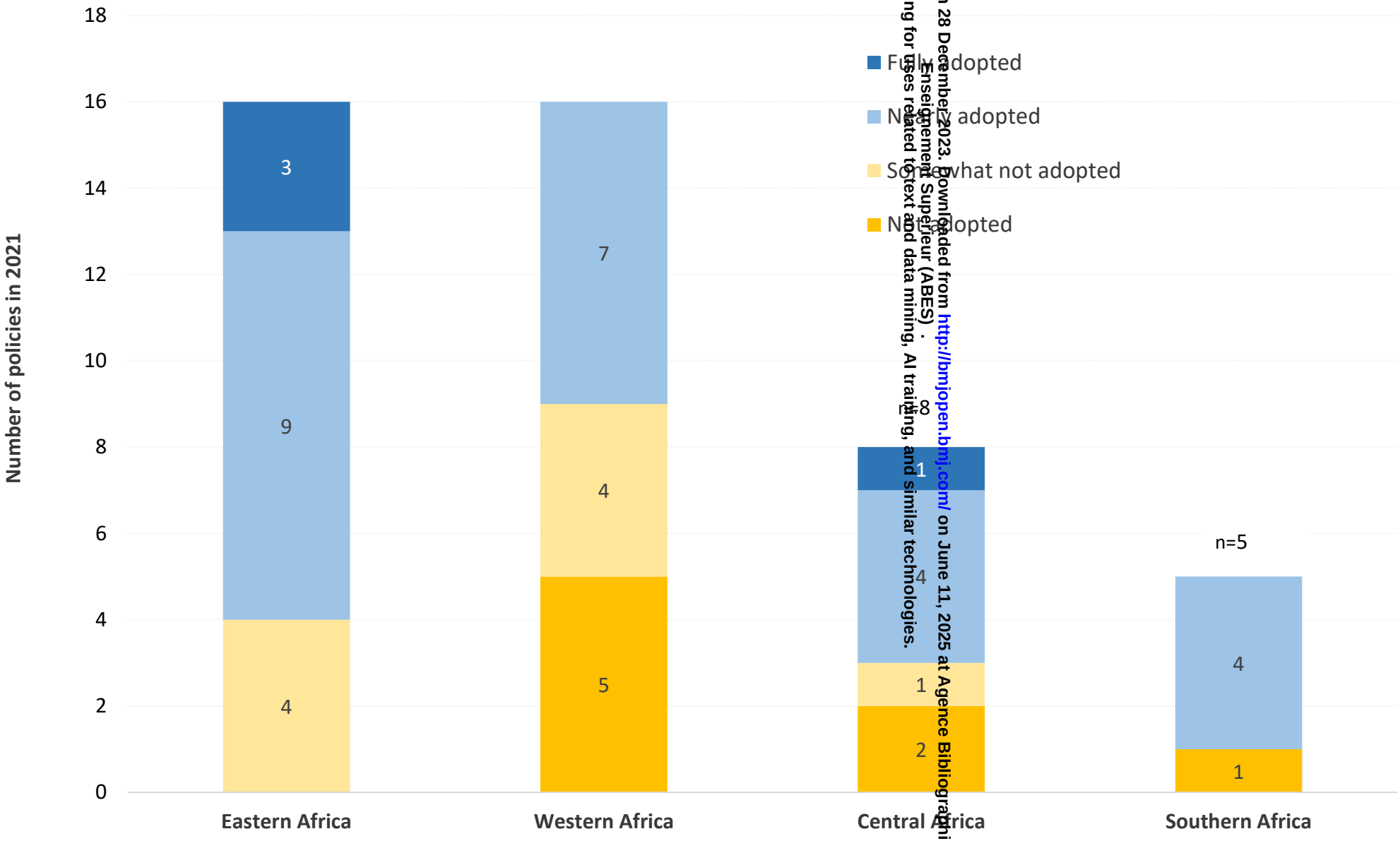
## Figure legends

**Figure 1.** Countries from the WHO African Region with HIV testing policies identified (in blue) and included in the analysis (n=45/47). The two countries not included in the review are indicated in the map.

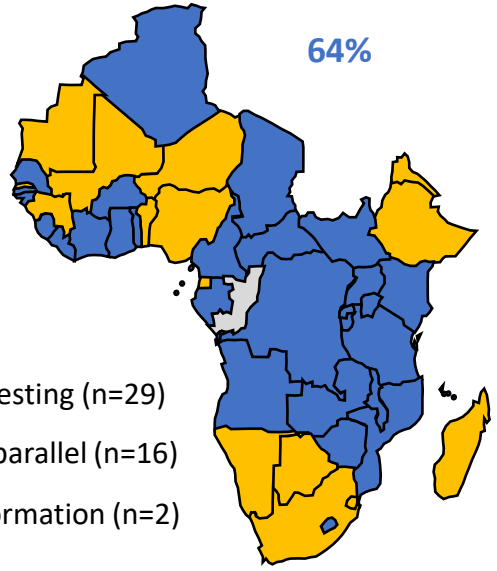
**Figure 2.** Overall adoption of 2019 WHO HIV testing strategies in Africa by subregion in 2021.

**Figure 3.** Policy adoption in 2021 of six specific WHO HIV testing recommendations in the WHO African Region.



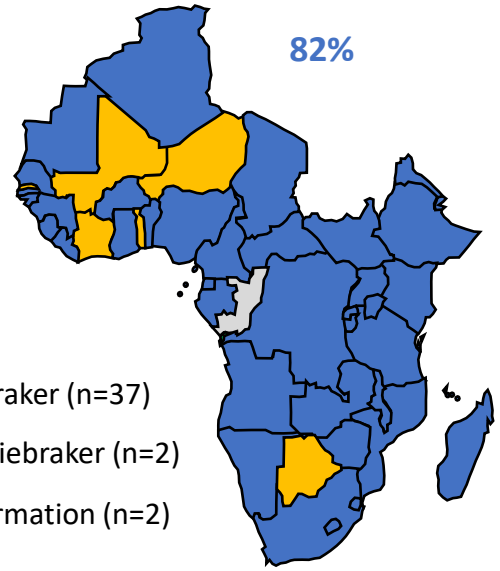


**1.** Policy adoption of serial testing strategy



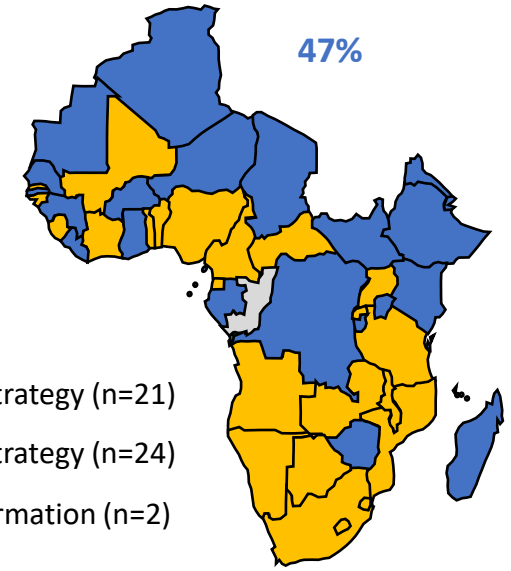

Serial testing (n=29)
Serial/parallel (n=16)
No information (n=2)

**2.** Policy adoption of discontinuation of tiebreaker



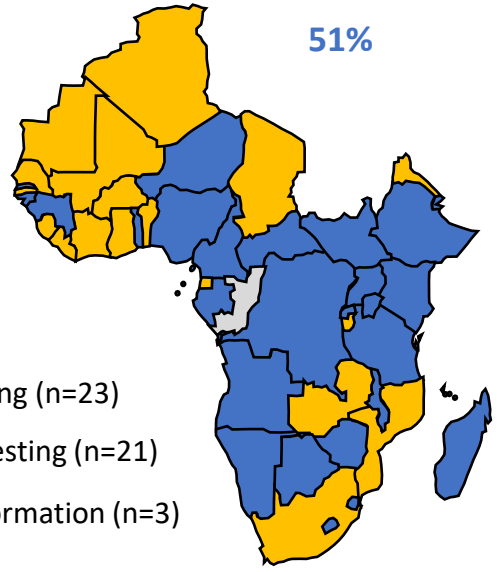

No tiebraker (n=37)
Use of tiebraker (n=2)
No information (n=2)

**3.** Policy adoption of universal 3-test strategy



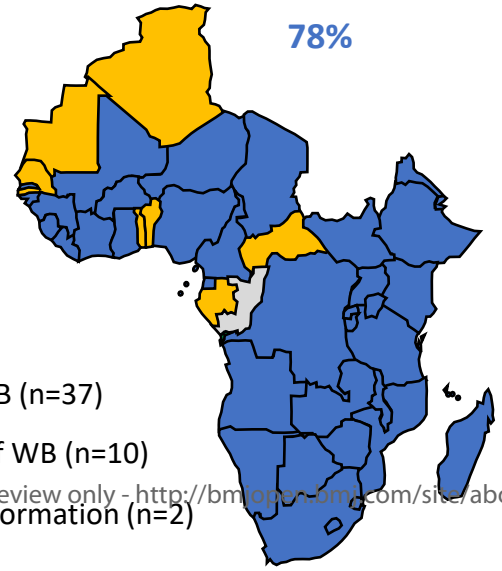

3-test strategy (n=21)
2-test strategy (n=24)
No information (n=2)

**4.** Policy adoption of retesting prior to ART initiation



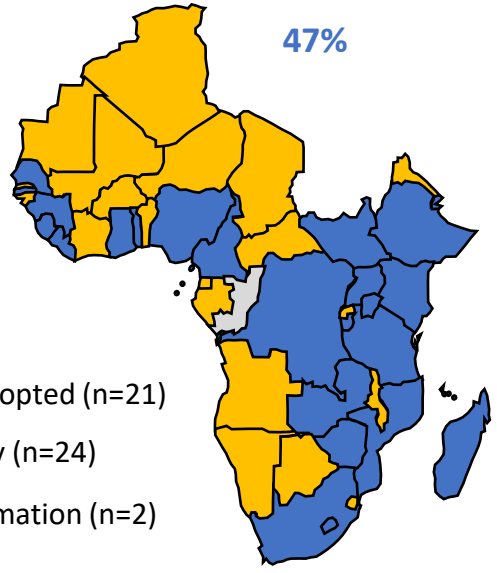

Retesting (n=23)
No retesting (n=21)
No information (n=3)

**5.** Policy adoption of discontinuation of Western Blot (WB)




No WB (n=37)
Use of WB (n=10)
No information (n=2)

**6.** Policy adoption of dual HIV/Syphilis test in ANC



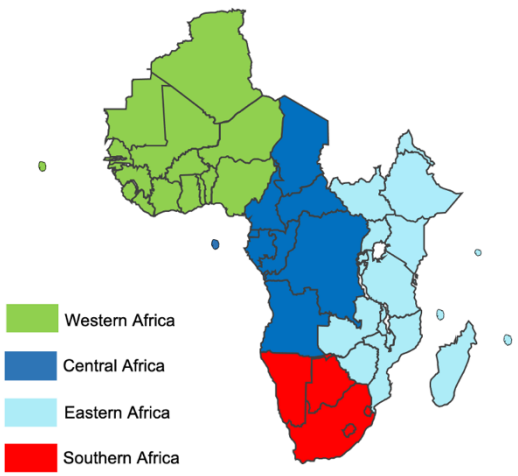

Policy adopted (n=21)
No policy (n=24)
No information (n=2)

**Supplementary Appendix**

Country adoption of WHO 2019 guidance on HIV testing strategies and algorithms: a policy review across the WHO African region

Emmanuel Fajardo,[1] Céline Lastrucci,[1] Nayé Bah,[2] Casimir Manzengo Mingiedi,[3] Ndoungou Salla Ba,[4] Fausta Shakiwa Mosha,[5] Frank John Lule,[6] Margaret Alia Sampson Paul,[6] Lago Hughes,[6] Magdalena Barr-DiChiara,[1] Muhammad Shahid Jamil,[1] Anita Sands,[7] Rachel Baggeley,[1] Cheryl Johnson[1]

**Supplementary Figure 1.** Countries in the WHO African Region and grouping by subregion




| WHO African Region (n=47) | | | |
|---|---|---|---|
| Western Africa (n=17) | Central Africa (n=9) | Eastern Africa (n=16) | Southern Africa (n=5) |
| Algeria | Angola | Burundi | Botswana |
| Cabo Verde | Cameroon | Comoros | eSwatini |
| Burkina Faso | CAR | Eritrea | Lesotho |
| Benin | Chad | Ethiopia | Namibia |
| Ghana | DRC | Kenya | South Africa |
| Guinea | Equotorial Guinea | Madagascar | |
| Guinea-Bissau | Gabon | Malawi | |
| Ivory Coast | Republic of the Congo | Mauritius | |
| Liberia | Sao Tome and Principe | Mozambique | |
| Mauritania | | Rwanda | |
| Mali | | Seychelles | |
| Niger | | South Sudan | |
| Nigeria | | Tanzania | |
| Senegal | | Uganda | |
| Sierra Leone | | Zambia | |
| The Gambia | | Zimbabwe | |
| Togo | | | |

**Supplementary Table 1.** Categories for data extraction

| | |
|---|---|
| **1. Policy Information** | |
| ▪ Country<br>▪ WHO region<br>▪ HIV testing policy identified? | ▪ Year of policy publication<br>▪ Type of policy document<br>▪ National HIV prevalence |
| **2. HIV testing algorithm (after 18 months of age)** | |
| ▪ HIV testing algorithm provided?<br>▪ Image or text format?<br>▪ Type of scenario in which algorithm is used<br>▪ Number of assays used in algorithm<br>▪ Serial or parallel strategy<br>▪ Use of tiebreaker?<br>▪ Use of Western Blot or LIA?<br>▪ Mention of test order relating to sens/spec?<br>▪ High or low prevalence strategy used?<br>▪ Type of tests mentioned?<br>▪ Brand of tests mentioned?<br>▪ Are assays pre-qualified by WHO?<br>▪ A1 test name<br>▪ A1 type of assay | ▪ A1 sens-/spec<br>▪ A2 test name<br>▪ A2 type of assay<br>▪ A2 sens-/spec<br>▪ A3 test name<br>▪ A3 type of assay<br>▪ A3 sens-/spec<br>▪ Source of assay sens/spec<br>▪ Mention of in-country assay validation<br>▪ Alignment with WHO policy?<br>▪ Primary reason(s) algorithm fails to meet WHO recommendations<br>▪ Other notes about testing strategy |
| **3. HIV testing algorithm among pregnant women using dual HIV/Syphilis RDTs** | |
| ▪ HIV testing algorithm provided?<br>▪ Image or text format?<br>▪ Type of scenario in which algorithm is used<br>▪ Type of scenario in which algorithm should not be used (women on ART, already diagnosed/treated for syphilis, retesting for HIV)<br>▪ What is there syphilis testing strategy for women with HIV?<br>▪ Is dual test used as A1 or A0?<br>▪ Is the dual test algorithm aligned with the national HIV testing algorithm?<br>▪ Is the dual test algorithm aligned with the national syphilis testing algorithm?<br>▪ Brand of dual test mentioned? | ▪ Is dual test prequalified by WHO?<br>▪ Dual test name<br>▪ Mention of penicillin treatment for reactive TP?<br>▪ Mention of further testing for reactive TP?<br>▪ Mention of in-country assay validation<br>▪ Alignment with WHO policy?<br>▪ Primary reason(s) algorithm fails to meet WHO recommendations<br>▪ Other notes about testing strategy |
| **4. Retesting prior to ART initiation** | |
| ▪ Retest required before starting ART?<br>▪ Retest strategy same as national algorithm?<br>▪ Notes about retesting strategy | |

**Supplementary Table 2.** List of national policies on HIV testing services in the WHO African Region collected in 2018 and 2021 by subregion

| Subregion | Count | Country | Policy reviewed in 2018? | New policy or algorithm identified? | Publication year | Type of document | Language | Algorithm provided? | National HIV prevalence |
|---|---|---|---|---|---|---|---|---|---|
| Central Africa | 1 | Angola | Yes, 2015 | Yes | 2020 | HTS | Portuguese | Yes | Low |
| | 2 | Cameroon | Yes, 2015 | Yes | 2019 | ART | French | Yes | Low |
| | 3 | CAR | Yes, 2010 | Yes | 2018 | ART | French | Yes | Low |
| | 4 | Chad | Yes, 2011 | Yes | 2017 | HTS | French | Yes | Low |
| | 5 | DRC | Yes, 2017 | Yes | 2020 | ART | French | Yes | Low |
| | 6 | Equatorial Guinea | No | Yes | 2018 | ART | Spanish | Yes | Low |
| | 7 | Gabon | No | Yes | 2017 | HTS | French | Yes | Low |
| | 8 | Republic of the Congo | No | **No** | – | – | | – | – |
| | 9 | São Tomé e Principe | No | Yes | 2018 | Algorithm | Portuguese | Yes | Low |
| Eastern Africa | 10 | Burundi | Yes, 2016 | Yes | 2020 | HTS | French | Yes | Low |
| | 11 | Comoros | Yes, 2007 | Yes | 2016 | HTS | French | Yes | Low |
| | 12 | Eritrea | No | Yes | 2019 | HTS | English | Yes | Low |
| | 13 | Ethiopia | Yes, 2017 | Yes | 2018 | ART | English | Yes | Low |
| | 14 | Kenya | Yes, 2017 | Yes | 2021 | HTS | English | Yes | Low |
| | 15 | Madagascar | Yes, 2011 | Yes | 2018 | HTS | French | Yes | Low |
| | 16 | Malawi* | Yes, 2016 | Yes* | 2016 | HTS | English | Yes | High |
| | 17 | Mauritius | No | Yes | 2020 | HTS | English | Yes | Low |
| | 18 | Mozambique | Yes, 2016 | Yes | 2020 | PMTCT | Portuguese | Yes | High |
| | 19 | Rwanda | Yes, 2016 | Yes | 2018 | HTS | English | Yes | Low |
| | 20 | Seychelles | No | Yes | 2019 | HTS | English | Yes | Low |
| | 21 | South Sudan | Yes, 2017 | Yes | 2020 | ART | English | Yes | Low |
| | 22 | Tanzania | Yes, 2017 | Yes | 2021 | HTS | English | Yes | High |
| | 23 | Uganda | Yes, 2016 | Yes | 2020 | ART | English | Yes | High |
| | 24 | Zambia | Yes, 2018 | Yes | 2020 | HTS | English | Yes | High |
| | 25 | Zimbabwe* | Yes, 2016 | Yes* | 2016 | Other | English | Yes | High |
| Southern Africa | 26 | Botswana** | Yes, 2016 | **No** | 2016 | ART | English | Yes | High |
| | 27 | eSwatini** | Yes, 2018 | **No** | 2018 | ART | English | Yes | High |
| | 28 | Lesotho | Yes, 2016 | Yes | 2021 | PMTCT | English | Yes | High |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 29 | Namibia | Yes, 2016 | Yes | 2018 | HTS | English | Yes | High |
| | 30 | South Africa | Yes, 2016 | Yes | 2020 | ART | English | Yes | High |
| Western Africa | 31 | Algeria** | Yes, 2013 | **No** | 2013 | HTS | French | Yes | Low |
| | 32 | Benin | No | Yes | 2017 | HTS | French | Yes | Low |
| | 33 | Burkina Faso | Yes, 2008 | Yes | 2021 | ART | French | Yes | Low |
| | 34 | Cabo Verde | No | **No** | – | – | – | – | – |
| | 35 | Ghana | Yes, 2014 | Yes | 2019 | ART | English | Yes | Low |
| | 36 | Guinea | No | Yes | 2019 | HTS | French | Yes | Low |
| | 37 | Guinea-Bissau | No | Yes | 2021 | ART | Portuguese | Yes | Low |
| | 38 | Ivory Coast** | Yes, 2016 | **No** | 2016 | HTS | French | Yes | Low |
| | 39 | Liberia | Yes, 2015 | Yes | 2020 | HTS | English | Yes | Low |
| | 40 | Mauritania | No | Yes | 2020 | HTS | French | Yes | Low |
| | 41 | Mali | No | Yes | 2017 | HTS | French | Yes | Low |
| | 42 | Niger | No | Yes | 2020 | HTS | French | Yes | Low |
| | 43 | Nigeria | Yes, 2016 | Yes | 2020 | ART | English | Yes | Low |
| | 44 | Senegal | Yes, 2017 | Yes | 2018 | HTS | French | Yes | Low |
| | 45 | Sierra Leone | Yes, 2017 | Yes | 2020 | ART | English | Yes | Low |
| | 46 | The Gambia | Yes, 2014 | Yes | 2019 | ART | English | Yes | Low |
| | 47 | Togo | No | Yes | 2019 | HTS | French | Yes | Low |

*These countries provided an updated HIV testing algorithm despite having an old HIV testing guideline

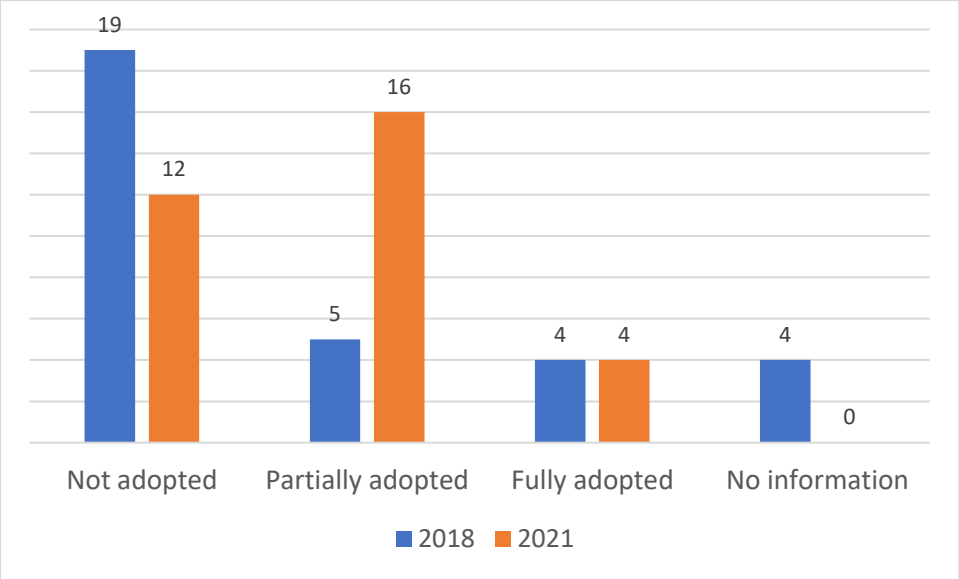
** These countries did not provide an update HIV testing guideline but were included in the analysis

**Supplementary Table 3.** Progress on policy adoption in the WHO African Region from 2018 to 2021

| Subregion | Count | Country | Policy reviewed in 2018? | Adherence in 2018 | Policy reviewed in 2021 | Adherence in 2021 |
|---|---|---|---|---|---|---|
| Central Africa | 1 | Angola | Yes, 2015 | Not adopted | 2020 | Mostly adopted |
| | 2 | Cameroon | Yes, 2015 | Not adopted | 2019 | Mostly adopted |
| | 3 | CAR | Yes, 2010 | Not adopted | 2018 | Not adopted |
| | 4 | Chad | Yes, 2011 | Not adopted | 2017 | Mostly adopted |
| | 5 | DRC | Yes, 2017 | Adopted | 2020 | Adopted |
| | 6 | Equatorial Guinea | No | – | 2018 | Not adopted |
| | 7 | Gabon | No | – | 2017 | Mostly adopted |
| | 8 | Republic of the Congo | No | – | – | – |
| | 9 | São Tomé e Principe | No | – | 2018 | Not adopted |
| Eastern Africa | 10 | Burundi | Yes, 2016 | Not adopted | 2020 | Mostly adopted |
| | 11 | Comoros | Yes, 2007 | No information | 2016 | Not adopted |
| | 12 | Eritrea | No | – | 2019 | Not adopted |
| | 13 | Ethiopia | Yes, 2017 | No information | 2018 | Mostly adopted |
| | 14 | Kenya | Yes, 2017 | Mostly adopted | 2021 | Adopted |
| | 15 | Madagascar | Yes, 2011 | No information | 2018 | Mostly adopted |
| | 16 | Malawi | Yes, 2016 | Not adopted | 2016 | Mostly adopted |
| | 17 | Mauritius | No | – | 2020 | Not adopted |
| | 18 | Mozambique | Yes, 2016 | Not adopted | 2020 | Mostly adopted |
| | 19 | Rwanda | Yes, 2016 | Not adopted | 2018 | Mostly adopted |
| | 20 | Seychelles | No | – | 2019 | Not adopted |
| | 21 | South Sudan | Yes, 2017 | Not adopted | 2020 | Adopted |
| | 22 | Tanzania | Yes, 2017 | Not adopted | 2021 | Mostly adopted |
| | 23 | Uganda | Yes, 2016 | Mostly adopted | 2020 | Mostly adopted |
| | 24 | Zambia | Yes, 2018 | Not adopted | 2020 | Not adopted |
| | 25 | Zimbabwe | Yes, 2016 | Adopted | 2016 | Adopted |
| Southern Africa | 26 | Botswana | Yes, 2016 | Mostly adopted | 2016 | Not adopted |
| | 27 | eSwatini | Yes, 2018 | Not adopted | 2018 | Not adopted |
| | 28 | Lesotho | Yes, 2016 | Adopted | 2021 | Mostly adopted |
| | 29 | Namibia | Yes, 2016 | No information | 2018 | Not adopted |
| | 30 | South Africa | Yes, 2016 | Mostly adopted | 2020 | Not adopted |
| Western Africa | 31 | Algeria | Yes, 2013 | Adopted | 2013 | Not adopted |
| | 32 | Benin | No | – | 2017 | Not adopted |
| | 33 | Burkina Faso | Yes, 2008 | Not adopted | 2021 | Mostly adopted |
| | 34 | Cabo Verde | No | – | – | – |
| | 35 | Ghana | Yes, 2014 | Not adopted | 2019 | Mostly adopted |
| | 36 | Guinea | No | – | 2019 | Mostly adopted |
| | 37 | Guinea-Bissau | No | – | 2021 | Not adopted |
| | 38 | Ivory Coast | Yes, 2016 | Not adopted | 2016 | Not adopted |
| | 39 | Liberia | Yes, 2015 | Not adopted | 2020 | Mostly adopted |
| | 40 | Mauritania | No | – | 2020 | Not adopted |
| | 41 | Mali | No | – | 2017 | Not adopted |
| | 42 | Niger | No | – | 2020 | Not adopted |
| | 43 | Nigeria | Yes, 2016 | Not adopted | 2020 | Mostly adopted |
| | 44 | Senegal | Yes, 2017 | Mostly adopted | 2018 | Not adopted |
| | 45 | Sierra Leone | Yes, 2017 | Not adopted | 2020 | Not adopted |
| | 46 | The Gambia | Yes, 2014 | Not adopted | 2019 | Not adopted |
| | 47 | Togo | No | – | 2019 | Not adherent |

A total of 32 countries had policies reviewed in 2018 and 2021. Those highlighted in red are policies reviewed in 2018 that were updated (n=28). Number of policies deemed adopted in 2018 (n=7) and number deemed adopted in 2021 (n=20)

**Supplementary Figure 2.** Comparing policy adoption across countries, 2018 vs 2021



**Supplementary Table 4.** Policy adoption of 2019 WHO-recommended HIV testing strategies in the WHO African region, 2014-2021

| AFRO subregions (countries) | Policies reviewed | | | Serial testing strategy | | | Discontinuation of tiebreaker* testing strategy | | | Retesting prior to ART initiation | | Universal 3-test strategy | Use of dual HIV/syphilis test** | No use of Western Blot |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year | 2014 | 2018 | 2021 | 2014 | 2018 | 2021 | 2014 | 2018 | 2021 | 2018 | 2021 | 2021 | 2021 | 2021 |
| All (n=47) | 25 (53%) | 32 (68%) | 45 (96%) | 21 (84%) | 26 (81%) | 29 (64%) | 15 (60%) | 26 (81%) | 37 (82%) | 16 (50%) | 23 (51%) | 21 (47%) | 21 (47%) | 35 (78%) |
| Western (n=17) | 6 (35%) | 9 (53%) | 16 (94%) | 5 (83%) | 7 (78%) | 9 (56%) | 4 (67%) | 5 (56%) | 9 (56%) | 1 (11%) | 5 (31%) | 8 (50%) | 7 (44%) | 10 (63%) |
| Central (n=9) | 4 (44%) | 5 (56%) | 8 (89%) | 4 (100%) | 5 (100%) | 7 (88%) | 3 (75%) | 4 (80%) | 7 (88%) | 1 (20%) | 5 (63%) | 3 (38%) | 2 (25%) | 6 (75%) |
| Eastern (n=16) | 11 (69%) | 13 (81%) | 16 (100%) | 10 (91%) | 10 (77%) | 12 (75%) | 5 (45%) | 12 (92%) | 16 (100%) | 9 (69%) | 9 (56%) | 9 (56%) | 9 (56%) | 14 (88%) |
| Southern (n=5) | 4 (80%) | 5 (100%) | 5 (100%) | 2 (40%) | 4 (80%) | 1 (20%) | 3 (75%) | 5 (100%) | 5 (100%) | 5 (100%) | 4 (80%) | 1 (20%) | 3 (60%) | 5 (100%) |

*Use of a third assay to rule-in HIV infection

**Dual HIV/syphilis RDT as first test in ANC

**Supplementary Table 5.** Short name of products used as part of the 2-assay or 3-assay HIV testing algorithm in 28 HIV national testing policy documents reviewed in 2021

| Strategy | Count | Country | Assay 1 | Assay 2 | Assay 3 |
|---|---|---|---|---|---|
| 2-assay | 1 | Angola | Determine | Uni-Gold | – |
| | 2 | Cameroon | Determine or Uni-Gold | OraQuick or Shanghai | – |
| | 3 | CAR | Determine | Uni-Gold | – |
| | 4 | Cote D'Ivoire | Determine | SD Bioline or GenieFast | StatPak or EIA (as tiebreaker) |
| | 5 | Equatorial Guinea | Determine | Hexagon | Uni-Gold (for discordants) |
| | 6 | eSwatini | Determine | Uni-Gold | – |
| | 7 | Gambia | Determine | SD Bioline or First Response | – |
| | 8 | Guinea Bissau | Determine | First Response | PCR (as tiebreaker) |
| | 9 | Mali | Alere Combo | SD Bioline | First Response (as tiebreaker) |
| | 10 | Mozambique | Determine | Uni-Gold | – |
| | 11 | Rwanda | Alere Combo | StatPak | – |
| | 12 | São Tomé e Principe | Determine | SD Bioline | PCR (as tiebreaker) |
| | 13 | Sierra Leone | Determine | SD Bioline | Uni-Gold (as tiebreaker) |
| | 14 | Uganda | Determine | StatPak | SD Bioline (for discordants) |
| | 15 | Nigeria | Determine<br>Uni-Gold<br>Stat-Pak<br>Double Check Gold<br>Sure Check<br>HIV Quick Check | Determine<br>Uni-Gold<br>Stat-Pak<br>Double Check Gold<br>Sure Check<br>HIV Quick Check | Determine<br>Uni-Gold<br>Stat-Pak<br>Double Check Gold<br>Sure Check<br>HIV Quick Check<br>(as tiebreaker) |
| | 16 | Togo | Murex HIV Ag/Ab<br>Apdia HIV Ag/Ab<br>Determine<br>Alere Combo<br>Vikia HIV 1/2<br>Wanta Rapid Test<br>ABON HIV 1/2/0<br>Standard Q<br>Hexagon<br>Genie Fast<br>SD Bioline<br>First Response<br>SD Bioline HIV/Syphilis<br>OraQuick HIV Self-Test | ABON HIV 1/2/0<br>Standard Q<br>SD Bioline<br>First Response<br>HIV Tri-Dot | INNOLIA or Genius (as tiebreaker) |
| 3-assay | 17 | Burundi | Alere Combo or Determine | SD Bioline or Uni-Gold | Wondfo One Step |
| | 18 | Gabon | Alere Combo | Determine | SD Bioline |
| | 19 | Ghana | First Response | OraQuick | SD Bioline |
| | 20 | Guinea | Determine | SD Bioline | Multisure |
| | 21 | Kenya | INSTI | Uni-Gold | SD Bioline |
| | 22 | Liberia | Determine | SD Bioline | Uni-Gold |
| | 23 | Madagascar | Determine | Uni-Gold | SD Bioline |
| | 24 | Mauritius | GenScreen Ultra Ag/Ab | Alere Combo | Western Blot |
| | 25 | Malawi | INSTI | Uni-Gold | SD Bioline |

| | | | | | |
|---|---|---|---|---|---|
| | 26 | Niger | Alere Combo | Wondfo One Step | SD Bioline |
| | 27 | Senegal | Determine | SD Bioline | Multisure |
| | 28 | Zimbabwe | Determine | Chembio | INSTI |
| | 29 | Burkina Faso | 3rd generation:<br>Determine<br>Double check Gold Ultra<br>Onsite HIV1+2 Plus Combo<br>VIKIA HIV 1/2<br>4th generation:<br>Alere Ag/Ab Combo<br>OnSite HIV Ab/Ag (CTK) | HIV TriDot<br>ImmunoFlow<br>OnSite HIV 1/2 Ab Plus (CTK)<br>SD Bioline | Any of those not selected as A1 or A2 |

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# Country adoption of WHO 2019 guidance on HIV testing strategies and algorithms: a policy review across the WHO African region

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**Title:** Country adoption of WHO 2019 guidance on HIV testing strategies and algorithms: a policy review across the WHO African region

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## ABSTRACT

**Objectives:** In 2019, the World Health Organization (WHO) released guidelines on HIV testing services (HTS). We aim to assess adoption of six of these recommendations on HIV testing strategies among African countries.

**Design:** Policy review

**Setting:** 47 countries within the WHO African region.

**Participants:** National HTS policies from the WHO African region as of December 2021.

Primary and secondary outcome measures: Uptake of WHO recommendations across national HTS policies including the standard 3-test strategy; discontinuation of a tie-breaker test to rule in HIV infection; discontinuation of western blotting (WB) for HIV diagnosis; retesting prior to ART initiation; and the use of dual HIV/syphilis rapid diagnostic tests (RDTs) in antenatal care (ANC). Country policy adoption was assessed on a continuum, based on varying levels of complete adoption.

**Results:** National policies were reviewed for 96% (n=45/47) of countries in the WHO African region, 38% (n=18) were published before 2019, and 60% (n=28) adopted WHO guidance. Among countries that had not fully adopted WHO guidance, not yet adopting a 3-test strategy was the most common reason for misalignment (45%, 21/47); of which 31% and 22% were in low- (<5%) and high-prevalence (≥5%) countries respectively. Ten policies (21%) recommended the use of WB and 49% (n=23) recommended retesting before ART initiation. Dual HIV/syphilis RDTs were recommended in 45% (n=21/47) of policies.

**Conclusions:** Many countries in the African region have adopted WHO-recommended HIV testing strategies, however efforts are still needed to fully adopt WHO guidance. Countries should accelerate their efforts to adopt and implement a 3-test strategy, retesting prior to ART initiation and the use of dual HIV/syphilis RDTs.

**Keywords:** HIV, diagnosis, rapid test, dual HIV/syphilis, policy, guideline, Africa, algorithm

**Strengths and limitations of this study**

- This study provided a comprehensive review of existing national HTS policies in the African region and was able to identify current policies for 45 countries.
- Data was collected using a robust search and global repository developed by WHO, as well as a standardised extraction tool to synthesise national policy information.
- The review focused on published policies and did not assess country implementation at the national, subnational, or site level.
- The review focused on WHO recommendations related to HIV testing strategies for individuals ≥18 months of age.
- The review identified African countries which reported that they were in the process of adopting WHO recommendations – particularly the use of 3-test strategy and dual HIV/syphilis RDTs.

## INTRODUCTION

HIV Testing Services (HTS) is the critical gateway to accessing HIV-related care and treatment for those diagnosed as HIV-positive and as a means to accessing prevention services for those who test HIV-negative.[1, 2] Despite considerable progress, reaching the UNAIDS 95-95-95 targets by 2025 will require increased testing uptake, particularly among populations with testing gaps such as key population, youth and men.[3] Further, the global emergency caused by the COVID-19 pandemic in 2020 has disrupted many health services including HIV testing services, and supply chains of key commodities such as rapid diagnostic tests (RDTs) have

been stretched.[4] In 2021, it was estimated that 85% of people living with HIV globally were aware of their serostatus.[5]

In 2019, the World Health Organization (WHO) published consolidated guidelines on HIV testing services (HTS),[6] bringing together existing and new recommendations specific to testing strategies and algorithms. This includes existing guidance on the use of serial testing rather than parallel testing (WHO, 2012),[7] discontinuation of a tiebreaker strategy to rule-in HIV infection (WHO, 2015),[1] and retesting prior to antiretroviral treatment (ART) initiation, recommended since 2014.[1] As well as three new recommendations on: (1) the use of a standard 3-test strategy which uses three consecutive HIV-reactive tests to provide and HIV-positive diagnosis, (2) the discontinuation of western blot (WB) and line immunoassays (LIA) and, (3) the use of dual HIV/syphilis RDTs as first assay in HTS in antenatal care (ANC). In light of these testing modalities, ensuring that HIV testing is accessible and adheres to the "5 C's" including voluntary consent, confidentiality, counselling, correct results, and linkage to care, is of upmost importance.

These recommendations have been prioritised because they are essential to achieving global 95-95-95 goals by making testing accurate, affordable and high impact. [3,6] By moving away from testing services with WB, programmes will no longer have long turnaround times which delay the ability to offer same day ART or PrEP initiation.[6] Adoption of innovative tools such as the dual HIV/syphilis RDTs will enable more people to be tested and treated for syphilis, which is essential for achieving triple elimination goals.[6] Additionally, many countries still use the 2015 WHO recommendation of using the national HIV prevalence to determine whether a two-assay (≥5%) or three-assay testing strategy (<5%) should be used.[1] However, as ART coverage has expanded HIV positivity and the proportion of people with HIV who are

undiagnosed and not in care will continue to decline. As a result, the positive predictive value of previous testing strategies will also decline and lead to an increase in false positive diagnoses. In relation to the guideline development process, WHO now recommends all countries use a standard 3-test strategy.[8] WHO also recommends that countries planning to update their HIV testing algorithms undertake a verification study to select appropriate HIV serology products and ensure they do not cross-react in order to minimize the risk of misdiagnosis.[9]

**Box 1. WHO recommendations for HIV testing strategies for individuals ≥18 months of age, 2019**

- Western blotting and line immunoassays should not be used in national HIV testing strategies and algorithms.
- Dual HIV/syphilis RDTs can be the first test in HIV testing strategies and algorithms in ANC settings.
- In response to changes in the HIV epidemic, WHO recommends countries use three consecutive reactive tests to provide an HIV-positive diagnosis.
- Testing strategies should use tests serially, not in parallel, and should not use a tiebreaker to rule-in HIV infection. Instead, those with discrepant test results should be ruled inconclusive and referred for further testing in 14 days to rule-in or rule-out seroconversion.
- WHO recommends that all HIV testing algorithms use a combination of RDTs and/or EIAs to achieve at least 99% positive predictive value and use a combination of tests with ≥99% sensitivity and ≥98% specificity. WHO does not recommend the use of NAT techniques within HIV testing algorithms for individuals ≥18 months of age.

- The first test in an HIV testing strategy and algorithm should have the highest sensitivity, followed by a second and third test of the highest specificity. Algorithms should be validated and verified to ensure high quality and accurate testing.
- All people newly diagnosed with HIV should be retested to verify their HIV status prior to starting ART, using the same testing strategy and algorithm as the initial test. To minimize the risk of misdiagnosis, this approach should be maintained in settings in which rapid ART initiation is being implemented.

*Source: WHO 2019, [6]*

To support the implementation of the 2019 guidelines, WHO launched and disseminated the guidance at the Africa Society of Laboratory Medicine and the International Conference on AIDS and STIs in Africa. Following this, WHO also provided detailed country support to adopt the guidelines along with developing an application to access the guidelines more easily. In addition to dissemination and country support, [10] it is critical to monitor and track the implementation of WHO policy uptake to understand policy priorities and challenges overtime. Such tracking not only provides valuable insights but can help guide revisions to future guidance and can help target country policy support [11—12].

A global review of national HIV testing policies was conducted by WHO in 2018 to assess adoption of its testing recommendations and policies.[13] Of 91 policies reviewed only 24 (25%) adhered to WHO guidance. This policy review follows on from the previous review and seeks to assess country uptake of six 2019 WHO recommendations related to HIV testing strategies. Here we focus on the WHO African region, which hosts several countries with a high HIV burden and with large HIV testing programmes. The same policy review across the

remaining five WHO regions is underway as part of the update to the 2023 WHO HTS guidelines.

## METHODS

### Search strategy

We carried out a comprehensive desk review of national HIV testing policies in 47 Member States in the WHO African region (online supplementary figure 1) using a policy repository maintained by WHO, scanning government websites, and by contacting government officials or other relevant informants through December 2021. The most current policy documents containing information on the HTS policy were included, but when this was unavailable, we included the most recent HIV testing algorithm, but if that was also unavailable, we opted to include previous national policies. Documents of all languages were included. Other supporting documents related to algorithm validation and PMTCT guidelines were identified, when possible, either through references provided in the national HTS policy or through contact with key informants. The full protocol for the review was previously developed and published in 2018. [13]

### Data extraction

Data were extracted from each policy document by one reviewer (EF) into standardised coding forms on policy information, HIV testing strategy/algorithm (>18 months of age), dual HIV/syphilis testing strategy/algorithm, and retesting prior to ART initiation (online supplementary table 1). When reported the order, type of test kits and name brand of diagnostics used within the HIV testing algorithm was summarised descriptively, as well as information on whether the algorithm was verified or validated.

A second reviewer (CL) carried out crosschecking of the data. Differences between coders were resolved through a third reviewer (CJ). To prevent misclassification, items were marked as 'unclear' during data extraction when lack of information prevented complete understanding. Reviewers than worked to contact key informant to provide further detail and clarity wherever possible.

**Analysis**

We assessed national adoption of WHO HTS guidance using six specific recommendations related to testing strategies and algorithms for those ≥18 months of age set forth in the WHO 2019 HIV testing guidelines, namely: (1) use of serial testing, (2) use of a 3-test strategy, (3) discontinuation of a tie-breaker to rule in HIV infection, (4) discontinuation of WB/LIA, (5) retesting prior to ART initiation, and (6) use of dual HIV/syphilis RDT in ANC. Additional qualitative details about the national testing algorithm, such as the order of and name brand of test kits used in testing algorithms, were also reviewed when reported and assessed according to WHO recommendations (see Box 1).

Based on the number of recommendations adopted, national policies were categorized as: adopted (6); nearly adopted (5 to 4); somewhat not adopted: (3); and not adopted: (2 or less). We then provide simplified reporting (adopted, partially adopted and not adopted) for national policies which reviewed in 2018 and 2021 to assess changes overtime. Notably, these categories were initially developed as part of the 2018 policy review and maintained to assist with future updates and policy tracking.

Descriptive analyses were then stratified by subregions (Western, Central, Eastern and Southern Africa; online supplementary figure 1) to determine rates of adherence. All analyses were conducted in Microsoft Excel. Countries which had policies reviewed in 2018 and 2021 were also compared to assess changes in alignment with WHO recommendations over time.

**Patient and public involvement**

Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans of this study.

**RESULTS**

In total, we were able to identify policy documents from 96% of countries from the WHO African region (n=45/47); 71% of countries had a policy reviewed in both 2018 and 2021 (n=32/45). Two countries, Republic of the Congo and Cabo Verde, were not included because we were unable to obtain their national policies and sufficient information (figure 1). Out of all these policies, 91% (41/45) had updated their national policies as of December 2021. Policy publication dates ranged from 2013 to 2021. Out of the six country policies that had not been fully updated since 2018 (Algeria, Botswana, eSwatini, Cote d'Ivoire, Malawi, and Zimbabwe), one country (Zimbabwe) provided a new HIV testing algorithm that was included in the review.

Of the 45 policies providing information on HIV testing strategies, 16 were from Western Africa (36%), 16 were from Eastern Africa (36%), 8 were from Central Africa (18%), and 5 were from Southern Africa (11%). Policies were published in English (n=22), French (n=18), Portuguese (n=4) and Spanish (n=1). Based on the most recent national HIV prevalence

reported by UNAIDS [1], 34 countries (76%) had a low HIV prevalence (<5%) and 11 countries (24%) had a high HIV prevalence (≥5%) (online supplementary table 2).

**Overall adoption of WHO-recommended HIV testing strategies**

In 2021, 59% of national testing strategies (n=28/45) were either fully or partially aligned with WHO 2019 HTS recommendations and 36% (n=17/47) had not adopted the recommendations (table 1). When the analysis was restricted to a subset of countries with policies in both the 2018 and 2021 review (n=32), the proportion adopting WHO guidance in 2018 was 28% (n=9/32) *vs* 62% (n=20/32) in the current (2021) review (see online supplementary table 3; supplementary figure 2). Across the sub-regions, Southern (80%) and Eastern (75%) Africa had the greatest level of alignment, whilst Central Africa (63%) and Western Africa (44%) had the lowest adoption rates (table 1; figure 2).

In low-prevalence countries (n=34), 53% of policies (n=18/34) had fully or mostly adopted the guidance and 47% (n=16/34) had generally not adopted guidance. The most common reasons for non-adoption were not using a dual HIV/syphilis RDT in ANC (n=15/34), no retesting prior to ART initiation (n=14/34) and using only two assays to make an HIV-positive diagnosis (n=10/34). In high-prevalence countries (n=11), 91% of policies (n=10/11) had fully or nearly adopted WHO guidance and 9% had not adopted WHO guidance (1/11). The most common reasons for not fully adopting WHO guidance were continuing to use a 2-test strategy to make an HIV-positive diagnosis (n=10/11), employing both serial and parallel testing strategies (n=4/11), not adopting dual HIV/syphilis RDTs in ANC (n=4/11) and not implementing retesting prior to ART initiation (n=3/11). Overall, only one out of eleven high HIV-burden countries, Zimbabwe, recommended the use of a 3-assay testing strategy (18%).

**Table 1.** Policy adoption of 2019 WHO-recommended HIV testing strategies in the WHO African region, 2023

| AFRO subregions (countries) | Policies reviewed | Serial testing strategy | Discontinuation of tiebreaker* testing strategy | Retesting prior to ART initiation | Recommended 3-test strategy** | Use of dual HIV/syphilis test*** | No use of Western Blot |
|---|---|---|---|---|---|---|---|
| **All (n=47)** | 45 (96%) | 29 (62%) | 37 (79%) | 23 (49%) | 21 (45%) | 21 (45%) | 35 (74%) |
| **Western (n=17)** | 16 (94%) | 9 (53%) | 9 (53%) | 5 (29%) | 8 (47%) | 7 (41%) | 10 (59%) |
| **Central (n=9)** | 8 (89%) | 7 (78%) | 7 (78%) | 5 (56%) | 3 (33%) | 2 (22%) | 6 (67%) |
| **Eastern (n=16)** | 16 (100%) | 12 (75%) | 16 (100%) | 9 (56%) | 9 (56%) | 9 (56%) | 14 (88%) |
| **Southern (n=5)** | 5 (100%) | 1 (20%) | 5 (100%) | 4 (80%) | 1 (20%) | 3 (60%) | 5 (100%) |

*Use of a third assay to rule-in HIV infection

**At the time of the review some countries noted that they were in the process of transitioning to a 3-test strategy, however they were not included as in compliance because their national guidance and testing strategy was not yet finalized.

**Dual HIV/syphilis RDT as first test in ANC. Note that at the time of the review, five countries were using test outside of WHO guidance at the time. Two countries had non-compliant algorithms (Lesotho and Zambia) and three countries (Liberia, Madagascar and Uganda) were using the test outside pregnant women and among key populations and partners of pregnant women. However, as of 2023, use of the dual test is recommended among key populations and those with high ongoing risk.

**Adoption of serial testing strategy**

In 2021, 62% of national testing strategies (n=29/47) adopted the use of serial testing and 36% (n=16/47) recommended the mix use of serial and parallel testing (figure 3_1). The subregions with the highest adoption were Central (78%) and Eastern Africa (75%), followed by Western Africa (38%); Southern Africa had the lowest adoption rate (20%) (table 1). However, fewer countries in southern Africa recommended serial testing in 2021 (n=1) than in 2018 (n=4) (supplementary table 4). Most policies recommending serial or parallel testing (n=15/16) conducted simultaneous testing of assay 1 (A1) and assay 2 (A2) in case of discrepant test results, and the Namibian policy recommended parallel testing of A2 and A3 after a reactive A1.

Only 43% of policies (n=20/47) provided guidance on the assay order in relation to their sensitivity and specificity. The proportion of HIV testing strategies/algorithms using two consecutive HIV-reactive tests to make an HIV-positive diagnosis was 51% (n=24/47) whereas 45% (n=21/47) recommended the use 3 consecutive HIV-reactive tests.

Sixty-four percent of the HIV testing strategies reviewed (n=29/45) included information on the testing algorithms, i.e., contained specific product names and all of them included WHO prequalified products. Determine HIV 1/2 (Abbott Diagnostics Medical Co., Ltd, Japan) was the most common product used as A1 and Bioline HIV 1/2 3.0 (Abbott Diagnostics Korea Inc., Republic of Korea) or Uni-Gold HIV (Trinity Biotech, Ireland) as A2 or A3 (see online supplementary table 5). Only 31% of reviewed policies (n=14/45) mentioned the need to locally verify or validate the HIV testing algorithm.

**Discontinuation of a tiebreaker testing strategy**

The discontinuation of a third assay to rule in HIV infection (i.e., tiebreaker) was recommended in 78% of national policies (n=37/47) (figure 3_2). The subregions with the highest adoption were in Southern Africa and Eastern Africa (100%, each) followed by Central Africa (78%), whereas Western Africa had the lowest adoption (53%) (table 1).

Of the eight policies recommending a tiebreaker testing strategy, seven were from Western Africa and one from Central Africa. Seven policies specified the type of A3 to be used, for example, RDT (n=4), RDT or EIA (n=1), nucleic acid testing (NAT: n=2) and LIA (n=1).

**Adoption of WHO standard 3-assay testing strategy**

The use of three consecutive HIV-reactive tests for the diagnosis of HIV was recommended by 45% of the policies (n=21/47) (figure 3_3). The adoption of this WHO recommendation was highest in Eastern Africa (56%) and Western Africa (47%) and lowest in Southern Africa (20%) (table 1). Most policies recommending a 3-test strategy (n=20/21) were from low HIV-prevalence countries. Among high HIV-prevalence countries, only one out of eleven countries (9%) officially recommended the use of a 3-test strategy, which was Zimbabwe.

Overall, across countries which had policies reviewed in both 2018 and 2021, 9 policies that previously recommended a 2-test strategy transitioned to a 3-test strategy as of 2021 (Burkina Faso, Burundi, Chad, Ethiopia, Ghana, Kenya, Lesotho, Madagascar, and Zimbabwe, respectively).

Further, we identified that twenty-one percent of national policies (n=10) recommended the use of NAT as part of the testing algorithm for the diagnosis of HIV infection in individuals ≥18 months of age. Four policies were from Eastern Africa (Malawi, Mauritius, Mozambique and United Republic of Tanzania); three national policies from Southern Africa (Eswatini, Lesotho and Namibia); two policies from Central Africa (Angola and Sao Tomé et Principe); and one national policy from Western Africa (Guinea Bissau). While generally not in alignment with WHO guidance, two policies employed NAT as the third assay (A3) of the algorithm while the remaining eight policies recommended NAT to resolve persistent inconclusive/indeterminate test results (referring either to viral load, PCR or DNA-PCR).

**Adoption of retesting to verify positive status prior to ART initiation**

In 2021, 49% of national strategies (n=23/47) recommended retesting prior to ART initiation (figure 3_4). The regions with the highest level of policy adoption were in Southern Africa (80%) followed by Central (56%) and Eastern Africa (56%) (table 1). However, fewer countries in southern Africa recommended retesting before ART initiation in 2021 (n=4) than in 2018 (n=5) (supplementary table 5). Sixty-five percent of the retesting policies (n=15/23) recommended retesting using the same national HIV testing algorithm in a new specimen run by a different operator in a different testing site; 26% (n=6/23) did not specify how retesting was carried out and 9% of policies (n=2/23) utilized retesting strategies that differed from the national HIV testing algorithm, which included parallel testing of A1/A2 in Botswana and Malawi.

**Discontinuation of Western Blotting**

The proportion of national policies not including WB or LIA as part of the HIV testing algorithm was 74% (n=35/47) (figure 3_5). This proportion was highest in Southern Africa (100%) and

Eastern Africa (88%) followed by Central Africa (67%) and Western Africa (59%) (table 1). Most countries with a supporting policy in favour of WB or LIA (n=9/10) recommended its use to manage persistent inconclusive/indeterminate test results and one policy used WB as A3 (Mauritius).

**Adoption of dual HIV/syphilis RDT in ANC settings**

Forty-five percent (n=21/47) of policies reviewed supported the use of dual HIV/syphilis RDTs among pregnant women in ANC as recommended by WHO (figure 3_6). The region with the highest policy uptake was Southern Africa (60%), followed by Eastern (56%), Western (41%) and Central Africa (22%) (table 1). And of policies supporting a 3-test strategy, only 53% (n=11/21) also recommended the use of dual HIV/syphilis RDTs among pregnant women. The majority of policies (n=20/21) recommended the use of dual HIV/syphilis RDT as A1 among pregnant women and only one policy (Lesotho) recommended its use as a triage test (A0) as an interim algorithm while waiting for the results of a national verification study.

The dual HIV/syphilis testing algorithm was not aligned with the national HIV testing algorithm in one country (Zambia): while Determine HIV-1/2 (Abbott Diagnostics Medical Co., Ltd, Japan) and SD Bioline HIV-1/2 3.0 (Abbott Diagnostics Korea Inc, Republic of Korea) products were used as A1 and A2 in the national testing algorithm, Bioline HIV/Syphilis Duo (Abbott Diagnostics Korea Inc, Republic of Korea) and Rapid Test for Antibody to Human Immunodeficiency Virus (HIV) (Colloidal Gold Device) (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China) were used as A1 and A2 in the ANC testing algorithm.

In addition to the use in ANC settings as recommended by WHO in 2019, three countries also recommended testing with dual HIV/syphilis RDTs among other populations such as male partners of pregnant women and key populations (Liberia, Madagascar and Uganda). Only 50% of policies (n=11/21) specified the brand name of the dual HIV/syphilis RDT in the testing algorithm, and among the policies mentioning the brand name, Bioline HIV/Syphilis Duo (Abbott Diagnostics Korea Inc, Republic of Korea) was the most employed RDT (100%). Only 57% of policies (n=12/21) mentioned whether syphilis treatment was provided immediately after a reactive syphilis test result.

## DISCUSSION

The current review found a significant improvement in the overall policy uptake of the latest WHO-recommended HIV testing strategies with 60% of countries in the African region adopting WHO guidance in 2021. When directly comparing 32 countries with policies reviewed in 2018 and 2021, [13] policy adoption increased more than 2-fold (20 vs 9). As of the 2021 review, 38% of policies were published before 2019 which underscores the need to update national testing policies at more regular intervals.

Given the rapid changes in HIV testing landscape, greater efforts are needed to support national programmes to update their national HIV testing policies at more regular intervals to keep up with latest WHO guidance. This is particularly critical now as WHO is now updating HTS guidance in 2023 and it will be essential for WHO to continue policy tracking, [10] to allocate sufficient resources, to conduct implementation science research to understand bottlenecks hinder policy change and to support country-led technical working groups to drive policy change [11—12].

The recommendations with highest adoption were the discontinuation of a tiebreaker (79%) and western blotting (74%) as well as the use of serial testing (62%). One likely explanation for the higher policy adoption is that these WHO´s recommendations were first published between 2012 and 2015, with the exception of the discontinuation of western blotting which was recommended in 2019. Thus, national HIV programmes have had more time to fully incorporate these recommendations into their national guidelines. Although moving away from western blotting was recommended more recently, [14] resource-limited countries in the WHO African region have been at the forefront of implementing HIV RDTs compared to other WHO regions as a way to rapidly expand and increase access to HIV testing services.[15]

Having said that, our review found that a dozen of countries, mostly in Western Africa, still use western blotting as part of the HIV testing algorithms, hindering same-day diagnoses and rapid access to ART and pre-exposure prophylaxis (PrEP). Additionally, between 2018 and 2021, countries in southern Africa appeared to be the one sub-region which shifted away from serial testing to parallel testing strategies. This shift has likely increased testing costs as it requires more test kits per individual tested. Further follow-up with countries is needed to understand their policies and should continue to promote serial testing.

Despite observing that many countries recommended retesting prior to ART initiation in 2021, we noted that progress in policy adoption was minimal and that in southern Africa one less country was implementing when compared to 2018. And only half of countries (49%) had adopted retesting prior to ART initiation in their policies. Retesting prior to ART initiation remains an important quality assurance strategy, however if countries are struggling to adopt

this recommendation it may be important for WHO to provide alternative quality assurance approaches and address implementation challenges.

The WHO´s recommendations with the lowest uptake were the use of a standard 3-test strategy (45%) and the use of dual HIV/syphilis RDT among pregnant women (45%), both recommendations released in 2019.[6] Before 2019, WHO recommended the use of a 2-test strategy in high HIV prevalence settings (≥5%) and the use of a 3-test strategy in low HIV prevalence settings (<5%) to maintain at least a 99% positive predictive value.[1] However, as HTS and ART have been scaled up substantially and fewer people undergoing HTS are HIV-positive, the national HTS positivity has also declined, even in high HIV burden settings.[16] Given these changes in the epidemic, WHO now recommends that all settings move toward using a 3-test strategy to ensure high-quality testing.[16]

Transition to a 3-test strategy should be a priority, particularly for the high HIV burden countries that were using a 2-test strategy at the time of this review. This review found that only 9% (n=1/11) of the high-burden countries in the WHO African region has a supportive policy on a 3-assay testing strategy. A likely explanation for this slower policy adoption is programmes needing to prioritise limited resources and efforts to address the COVID-19 pandemic. Many programmes, including those focused on HIV testing, were affected by disruptions during COVID-19 and updates and changes to national policies were delayed.[4] Changing a testing algorithm also takes time and planning to implement, including provider training, quality assurance, procurement, inventory management and budget implications to the national programme.[6,16] Many countries indicated they were in the process of transitioning to a 3-test strategy but needed to finalize guidance, complete verification

studies, conduct tendering process for products, and garner consensus and support among partners. For example, after the review was completed, Malawi updated their guidance and currently recommends a 3-test strategy. However, some countries have yet to prioritise adopting the 3-test strategy because they were focused on higher yield testing approaches alone, [17—18] or delayed the transition due to costs concerns. While countries will need to develop a plan and identify the optimal time for the transition, in terms of costs, a modelling study found that the total cost of the 3-test strategy would have a very limited impact on costs.[19] Further, in Ghana after transitioning to a 3-test strategy they found that while there were lessons learned about logistics and training, the new strategy was found to be feasible, improved testing quality and reduced costs due to preventing misdiagnosis.[20]

We found that among low-prevalence countries (n=34), a significant proportion (41%) still use a suboptimal testing strategy with 2 assays to make an HIV positive diagnosis, which will increase the likelihood of false-positive diagnosis.[19—21] A retrospective study in Nigeria using household survey data found that the performance of the 2-test strategy in a low prevalence setting of about 1.4% was poor with a PPV of 94% and a false-positive rate of 5.5%.[22] This positive predictive value is similar to a modelling study assessing the accuracy of the 2015 and 2019 WHO HIV testing algorithms, which was 95.4% using a 2-assay testing strategy.[19]

Considering that the recommendation to use dual HIV/syphilis RDTs in ANC was released only in 2019,[6, 23] its adoption by 21 countries has been encouraging. The number of countries adopting dual HIV/syphilis RDTs among pregnant women continues to increase and may be in practice higher considering that preliminary National Commitments and Policy Instrument

(NCPI) survey data reported that a total of 26 countries in the WHO African region adopted the use of dual HIV/syphilis RDTs in ANC. [24] The differences likely reflect district methodologies (policy reviews versus policy survey). Often annual global policy surveys, like NCPI, may reflect a mixture of policies and anecdotal practices, including unofficial policies not yet within published guidelines. Although the findings of this review likely provide a conservative estimate of policy adoption, they do highlight the need to ensure official national policies are updated accordingly.

Some countries may choose not to introduce dual HIV/syphilis RDT for pregnant women. For example, in Malawi where dual HIV/syphilis RDT introduction has been considered but not adopted, the national programme has opted to retain stand-alone HIV and syphilis RDTs in ANC to prioritize point-of-care test options for HIV and syphilis while maintaining a single HIV testing algorithm in a resource limited context. At the time of this review, three countries also had policies using the dual test outside of pregnant women, including key populations and male partners of pregnant women. As of 2023, WHO now recommends dual HIV/syphilis testing for key populations and those with high ongoing HIV risk and this may further increase its use in HIV testing algorithms in national programmes. [25] It is an important option to increase HIV and syphilis detection and treatment and a recent modelling study in Viet Nam shows that it was cost saving or cost-effective.[26]

As countries update their national HIV testing guidelines to incorporate WHO guidance and adapt their national HIV testing strategies and algorithms to shift toward using three consecutive reactive serology tests to diagnose HIV, introduce dual HIV/syphilis RDTs among pregnant women and key populations, move away from western blotting, reinforcing

retesting prior to ART initiation as well as design flexible algorithms to address kit shortages, WHO encourages national programmes to conduct a verification study to provide objective evidence, before national scale-up, that a specific combination of products work well together without sharing false-reactivity, thus reducing the risk of misdiagnosis.[6, 9] To assist countries, WHO has put together a practical toolkit to accelerate policy adoption.[27] To date, the following African countries worked directly with WHO to update their testing algorithm: Burkina Faso, Cameroon, Chad, Central African Republic, Cote D´Ivoire, Democratic Republic of Congo, eSwatini, Kenya, Lesotho, Malawi, Mali, South Sudan and Zambia.

This policy review has strengths as well as weaknesses. Firstly, this review provides a comprehensive review of existing national HTS policies in the African region and was able to identify current policies for 45 countries. While this represents nearly all countries in the region, we were unable to identify policies for two countries. Secondly, unlike other policy surveys this study reviewed official policies for each country that were collected through a robust global search and triangulated data with additional information provided by country-level key informants. Despite this, the review was unable to assess unpublished policies and those in development at the time of the analysis. During the review some countries indicated that they were in the process of updating their guidance, particularly around adoption of a 3-test strategy. We were unable to fully include this information in the review, and thus our reported level of adoption of WHO recommendations may be an underestimate. Thirdly, this review did not assess policy implementation at the national, subnational, or site level. Thus, it is possible that some practices in country differ than policies reviewed, and level of adoption reported may vary. Lastly, we focused on HIV testing strategies for individuals ≥18 months of

age. As a result, we were unable to report on the adoption of HIV testing strategy recommendations for children, such as early infant diagnosis.

**Conclusions**

Adoption of WHO-recommended HIV testing strategies has improved in the African region. While WB was only used in a few countries, concerted efforts are still needed to phase out this technology in favour of RDTs. Countries should plan to accelerate their transition to WHO recommendations by streamlining efforts to adopt and implement a 3-asssay testing strategy, retesting before ART initiation and use of dual HIV/syphilis RDTs. Conducting verification of testing algorithms and using appropriate assays can ensure accurate HIV diagnosis in a cost-efficient and time-efficient manner. Greater efforts are needed now to ensure countries implement high-quality testing services as they are essential for the global goal to achieve and maintain low HIV incidence.

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## Contributors

CJ and AS devised and CJ and RB supervised the review. EF led the study protocol developments, conducted the screening, data extraction and analysis. NB, CM, NSB, FSM, FJL, MASP, LH assisted with acquisition of policies, data collection and results interpretation. CL acted as a second reviewer and CJ as third reviewer. AS, MSJ, MBD and RB assisted with assessing policies and interpreting results. EF led manuscript writing along with CJ, with support from all authors. CL, NB, CM, NSB, FSM, FJL, MASP, LH, MBD, MSJ, AS, RB all reviewed the first draft, provided critical review and input and approved the final version of the manuscript.

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## Competing interests

The authors declare no competing interests. The contents in this article are those of the authors and do not necessarily reflect the view of the World Health Organization.

## Patient consent for publication

Not required.

## Ethics approval

This study does not involve human participants and ethical approval was therefore not required.

## Data availability statement

All data generated in the study are included in the article or uploaded as supplementary information. National policies may be publicly available. Some policies included in this review may be available through the following websites: (1) https://aidsfree.usaid.gov/resources/guidance-data/hts. (2) http://www.hivpolicywatch.org/database.html. If information on a policy cannot be found through these resources, please contact the authors of this review for additional information.

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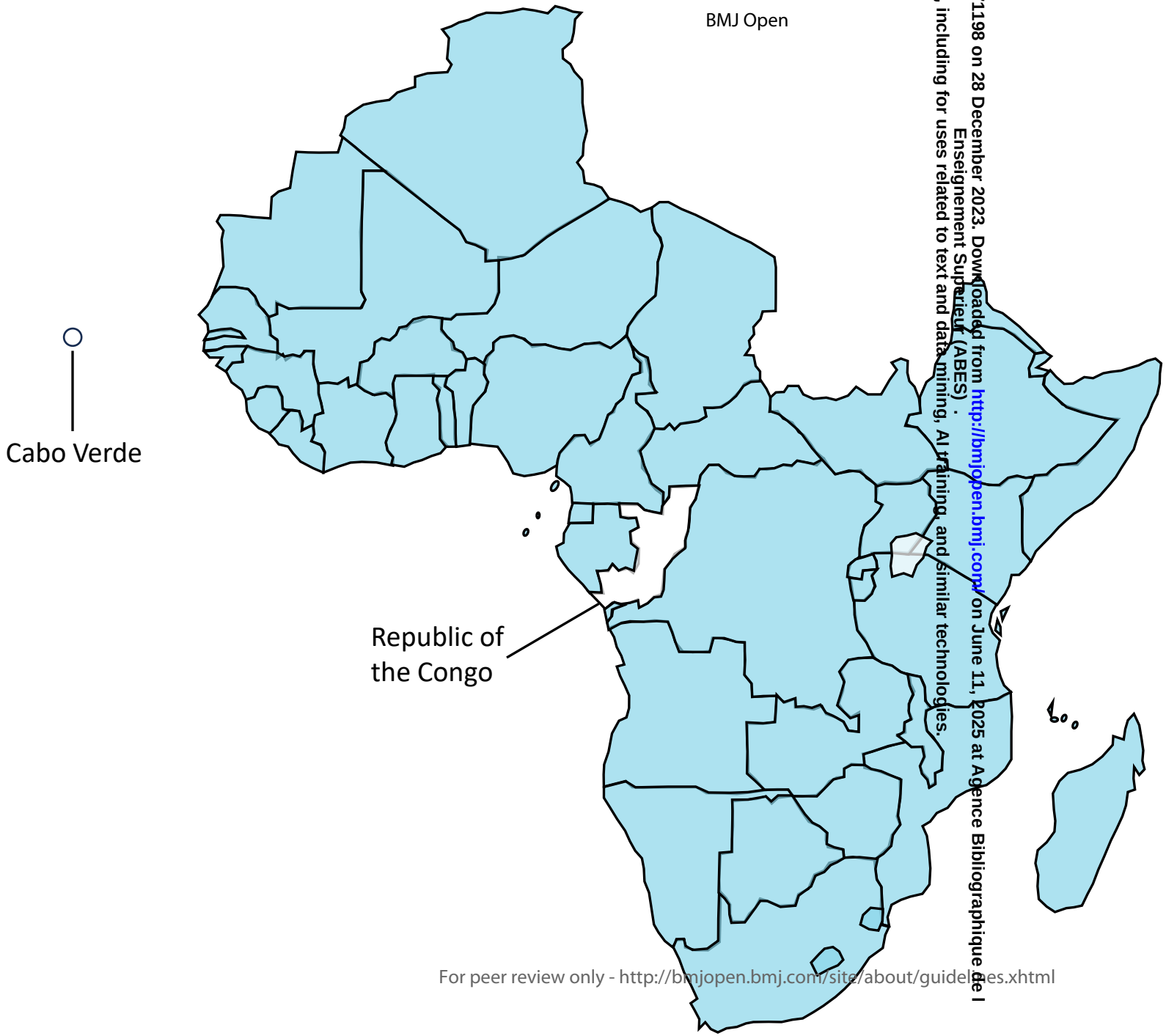
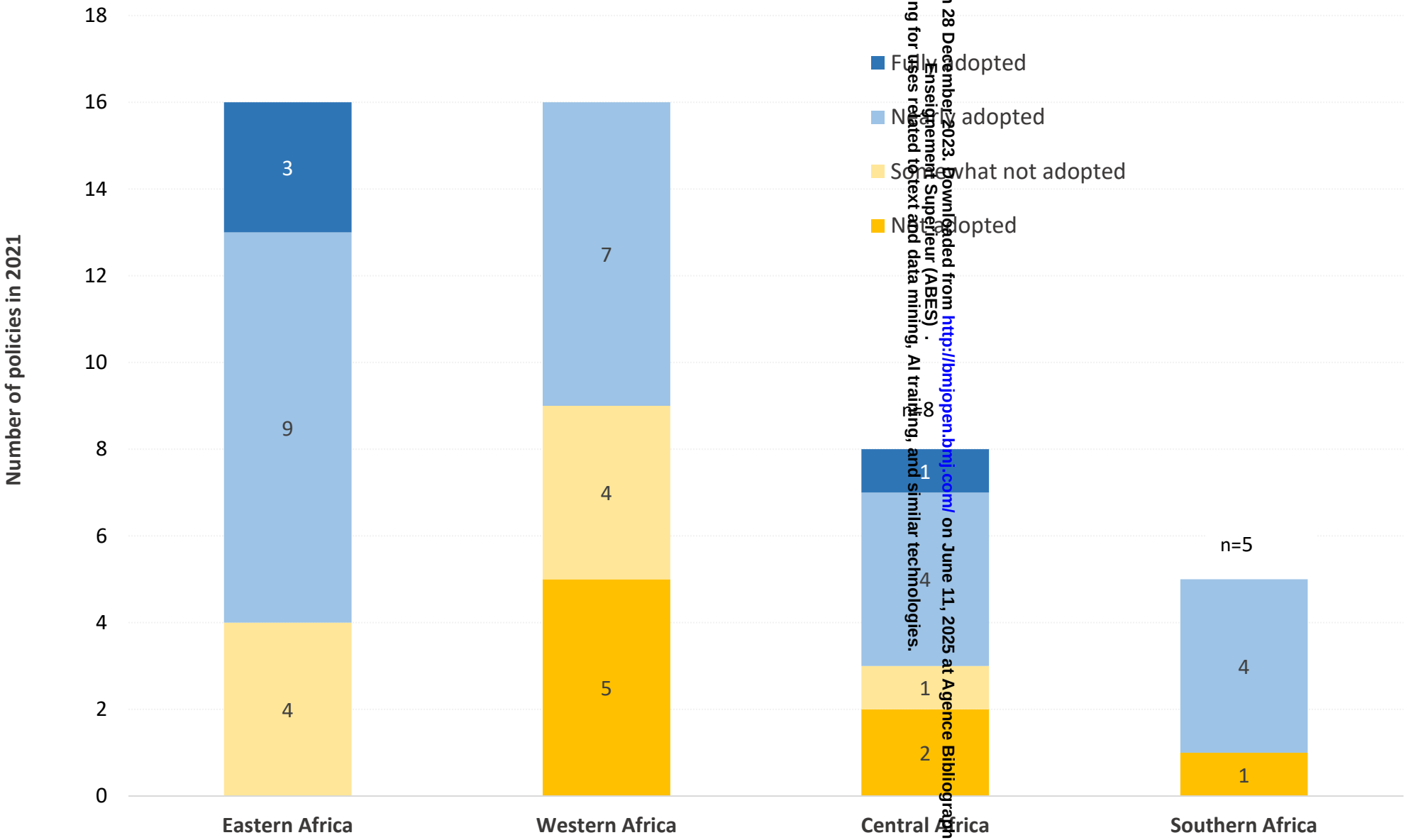
## Figure legends

**Figure 1.** Countries from the WHO African Region with HIV testing policies identified (in blue) and included in the analysis (n=45/47). The two countries not included in the review are indicated in the map.

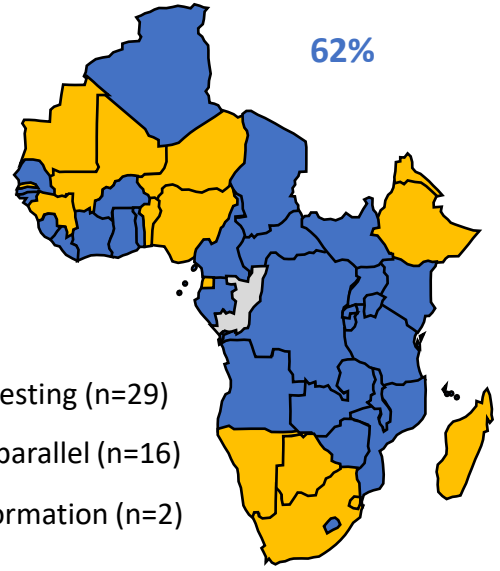
**Figure 2.** Overall adoption of 2019 WHO HIV testing strategies in Africa by subregion in 2021.

**Figure 3.** Policy adoption in 2021 of six specific WHO HIV testing recommendations in the WHO African Region.



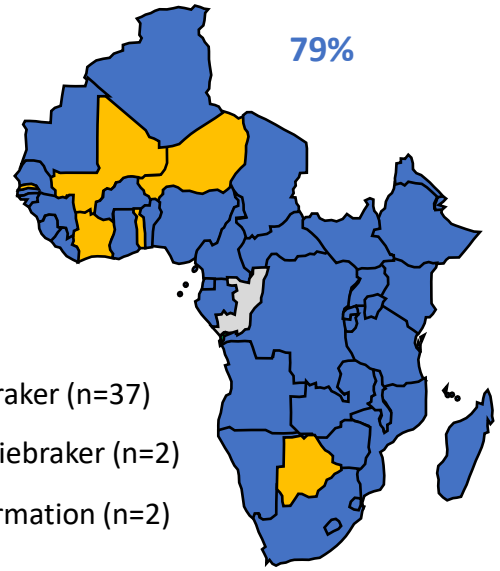


**1.** Policy adoption of serial testing strategy



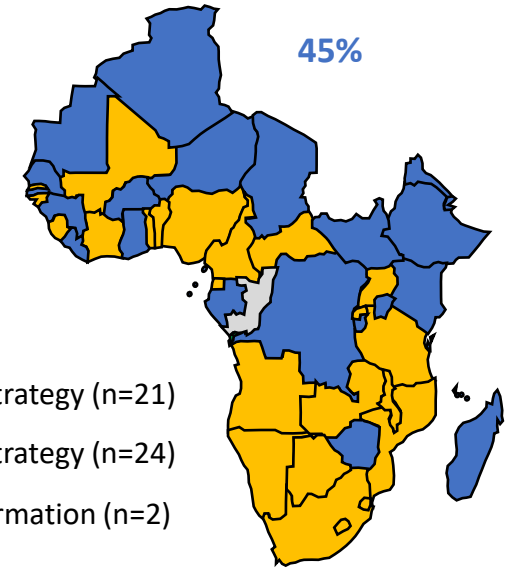

Serial testing (n=29)
Serial/parallel (n=16)
No information (n=2)

**2.** Policy adoption of discontinuation of tiebreaker



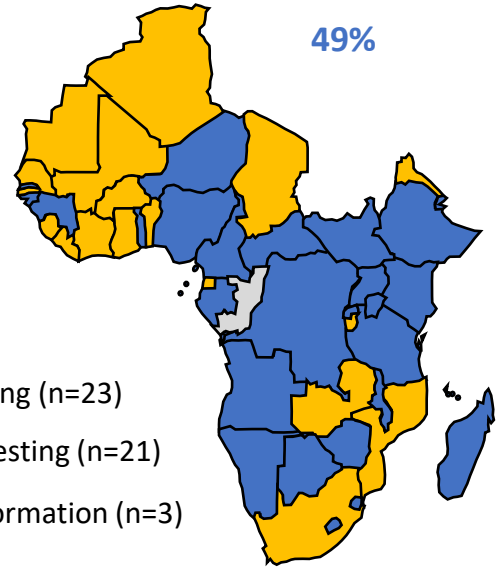

No tiebraker (n=37)
Use of tiebraker (n=2)
No information (n=2)

**3.** Policy adoption of universal 3-test strategy



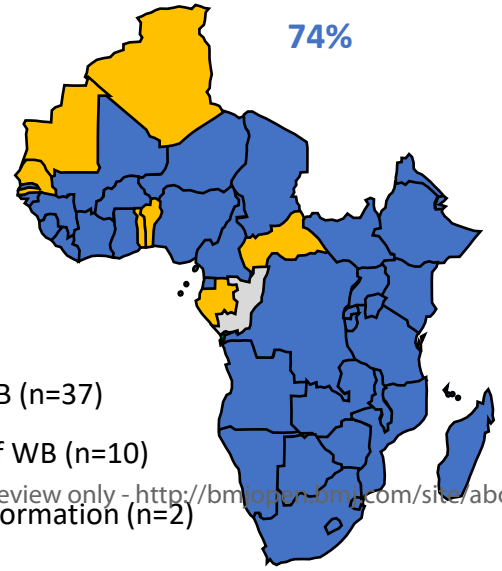

3-test strategy (n=21)
2-test strategy (n=24)
No information (n=2)

**4.** Policy adoption of retesting prior to ART initiation



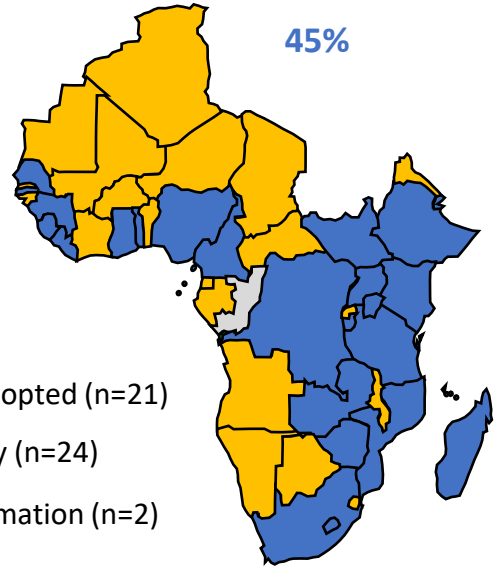

Retesting (n=23)
No retesting (n=21)
No information (n=3)

**5.** Policy adoption of discontinuation of Western Blot (WB)




No WB (n=37)
Use of WB (n=10)
No information (n=2)

**6.** Policy adoption of dual HIV/Syphilis test in ANC




Policy adopted (n=21)
No policy (n=24)
No information (n=2)

**Supplementary Appendix**

Country adoption of WHO 2019 guidance on HIV testing strategies and algorithms: a policy review across the WHO African region

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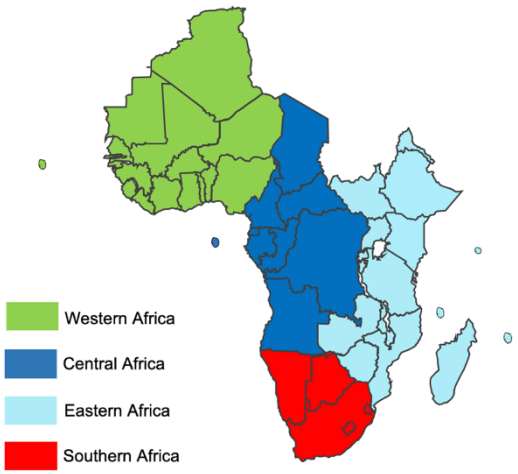
**Supplementary Figure 1.** Countries in the WHO African Region and grouping by subregion




| WHO African Region (n=47) | | | |
|---|---|---|---|
| Western Africa (n=17) | Central Africa (n=9) | Eastern Africa (n=16) | Southern Africa (n=5) |
| Algeria | Angola | Burundi | Botswana |
| Cabo Verde | Cameroon | Comoros | eSwatini |
| Burkina Faso | CAR | Eritrea | Lesotho |
| Benin | Chad | Ethiopia | Namibia |
| Ghana | DRC | Kenya | South Africa |
| Guinea | Equotorial Guinea | Madagascar | |
| Guinea-Bissau | Gabon | Malawi | |
| Ivory Coast | Republic of the Congo | Mauritius | |
| Liberia | Sao Tome and Principe | Mozambique | |
| Mauritania | | Rwanda | |
| Mali | | Seychelles | |
| Niger | | South Sudan | |
| Nigeria | | Tanzania | |
| Senegal | | Uganda | |
| Sierra Leone | | Zambia | |
| The Gambia | | Zimbabwe | |
| Togo | | | |

**Supplementary Table 1.** Categories for data extraction

| | |
|---|---|
| **1. Policy Information** | |
| ▪ Country<br>▪ WHO region<br>▪ HIV testing policy identified? | ▪ Year of policy publication<br>▪ Type of policy document<br>▪ National HIV prevalence |
| **2. HIV testing algorithm (after 18 months of age)** | |
| ▪ HIV testing algorithm provided?<br>▪ Image or text format?<br>▪ Type of scenario in which algorithm is used<br>▪ Number of assays used in algorithm<br>▪ Serial or parallel strategy<br>▪ Use of tiebreaker?<br>▪ Use of Western Blot or LIA?<br>▪ Mention of test order relating to sens/spec?<br>▪ High or low prevalence strategy used?<br>▪ Type of tests mentioned?<br>▪ Brand of tests mentioned?<br>▪ Are assays pre-qualified by WHO?<br>▪ A1 test name<br>▪ A1 type of assay | ▪ A1 sens-/spec<br>▪ A2 test name<br>▪ A2 type of assay<br>▪ A2 sens-/spec<br>▪ A3 test name<br>▪ A3 type of assay<br>▪ A3 sens-/spec<br>▪ Source of assay sens/spec<br>▪ Mention of in-country assay validation<br>▪ Alignment with WHO policy?<br>▪ Primary reason(s) algorithm fails to meet WHO recommendations<br>▪ Other notes about testing strategy |
| **3. HIV testing algorithm among pregnant women using dual HIV/Syphilis RDTs** | |
| ▪ HIV testing algorithm provided?<br>▪ Image or text format?<br>▪ Type of scenario in which algorithm is used<br>▪ Type of scenario in which algorithm should not be used (women on ART, already diagnosed/treated for syphilis, retesting for HIV)<br>▪ What is there syphilis testing strategy for women with HIV?<br>▪ Is dual test used as A1 or A0?<br>▪ Is the dual test algorithm aligned with the national HIV testing algorithm?<br>▪ Is the dual test algorithm aligned with the national syphilis testing algorithm?<br>▪ Brand of dual test mentioned? | ▪ Is dual test prequalified by WHO?<br>▪ Dual test name<br>▪ Mention of penicillin treatment for reactive TP?<br>▪ Mention of further testing for reactive TP?<br>▪ Mention of in-country assay validation<br>▪ Alignment with WHO policy?<br>▪ Primary reason(s) algorithm fails to meet WHO recommendations<br>▪ Other notes about testing strategy |
| **4. Retesting prior to ART initiation** | |
| ▪ Retest required before starting ART?<br>▪ Retest strategy same as national algorithm?<br>▪ Notes about retesting strategy | |

**Supplementary Table 2.** List of national policies on HIV testing services in the WHO African Region collected in 2018 and 2021 by subregion

| Subregion | Count | Country | Policy reviewed in 2018? | New policy or algorithm identified? | Publication year | Type of document | Language | Algorithm provided? | National HIV prevalence |
|---|---|---|---|---|---|---|---|---|---|
| Central Africa | 1 | Angola | Yes, 2015 | Yes | 2020 | HTS | Portuguese | Yes | Low |
| | 2 | Cameroon | Yes, 2015 | Yes | 2019 | ART | French | Yes | Low |
| | 3 | CAR | Yes, 2010 | Yes | 2018 | ART | French | Yes | Low |
| | 4 | Chad | Yes, 2011 | Yes | 2017 | HTS | French | Yes | Low |
| | 5 | DRC | Yes, 2017 | Yes | 2020 | ART | French | Yes | Low |
| | 6 | Equatorial Guinea | No | Yes | 2018 | ART | Spanish | Yes | Low |
| | 7 | Gabon | No | Yes | 2017 | HTS | French | Yes | Low |
| | 8 | Republic of the Congo | No | **No** | – | – | | – | – |
| | 9 | São Tomé e Principe | No | Yes | 2018 | Algorithm | Portuguese | Yes | Low |
| Eastern Africa | 10 | Burundi | Yes, 2016 | Yes | 2020 | HTS | French | Yes | Low |
| | 11 | Comoros | Yes, 2007 | Yes | 2016 | HTS | French | Yes | Low |
| | 12 | Eritrea | No | Yes | 2019 | HTS | English | Yes | Low |
| | 13 | Ethiopia | Yes, 2017 | Yes | 2018 | ART | English | Yes | Low |
| | 14 | Kenya | Yes, 2017 | Yes | 2021 | HTS | English | Yes | Low |
| | 15 | Madagascar | Yes, 2011 | Yes | 2018 | HTS | French | Yes | Low |
| | 16 | Malawi* | Yes, 2016 | Yes* | 2016 | HTS | English | Yes | High |
| | 17 | Mauritius | No | Yes | 2020 | HTS | English | Yes | Low |
| | 18 | Mozambique | Yes, 2016 | Yes | 2020 | PMTCT | Portuguese | Yes | High |
| | 19 | Rwanda | Yes, 2016 | Yes | 2018 | HTS | English | Yes | Low |
| | 20 | Seychelles | No | Yes | 2019 | HTS | English | Yes | Low |
| | 21 | South Sudan | Yes, 2017 | Yes | 2020 | ART | English | Yes | Low |
| | 22 | Tanzania | Yes, 2017 | Yes | 2021 | HTS | English | Yes | High |
| | 23 | Uganda | Yes, 2016 | Yes | 2020 | ART | English | Yes | High |
| | 24 | Zambia | Yes, 2018 | Yes | 2020 | HTS | English | Yes | High |
| | 25 | Zimbabwe* | Yes, 2016 | Yes* | 2016 | Other | English | Yes | High |
| Southern Africa | 26 | Botswana** | Yes, 2016 | **No** | 2016 | ART | English | Yes | High |
| | 27 | eSwatini** | Yes, 2018 | **No** | 2018 | ART | English | Yes | High |
| | 28 | Lesotho | Yes, 2016 | Yes | 2021 | PMTCT | English | Yes | High |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 29 | Namibia | Yes, 2016 | Yes | 2018 | HTS | English | Yes | High |
| | 30 | South Africa | Yes, 2016 | Yes | 2020 | ART | English | Yes | High |
| Western Africa | 31 | Algeria** | Yes, 2013 | **No** | 2013 | HTS | French | Yes | Low |
| | 32 | Benin | No | Yes | 2017 | HTS | French | Yes | Low |
| | 33 | Burkina Faso | Yes, 2008 | Yes | 2021 | ART | French | Yes | Low |
| | 34 | Cabo Verde | No | **No** | – | – | – | – | – |
| | 35 | Ghana | Yes, 2014 | Yes | 2019 | ART | English | Yes | Low |
| | 36 | Guinea | No | Yes | 2019 | HTS | French | Yes | Low |
| | 37 | Guinea-Bissau | No | Yes | 2021 | ART | Portuguese | Yes | Low |
| | 38 | Ivory Coast** | Yes, 2016 | **No** | 2016 | HTS | French | Yes | Low |
| | 39 | Liberia | Yes, 2015 | Yes | 2020 | HTS | English | Yes | Low |
| | 40 | Mauritania | No | Yes | 2020 | HTS | French | Yes | Low |
| | 41 | Mali | No | Yes | 2017 | HTS | French | Yes | Low |
| | 42 | Niger | No | Yes | 2020 | HTS | French | Yes | Low |
| | 43 | Nigeria | Yes, 2016 | Yes | 2020 | ART | English | Yes | Low |
| | 44 | Senegal | Yes, 2017 | Yes | 2018 | HTS | French | Yes | Low |
| | 45 | Sierra Leone | Yes, 2017 | Yes | 2020 | ART | English | Yes | Low |
| | 46 | The Gambia | Yes, 2014 | Yes | 2019 | ART | English | Yes | Low |
| | 47 | Togo | No | Yes | 2019 | HTS | French | Yes | Low |

*These countries provided an updated HIV testing algorithm despite having an old HIV testing guideline

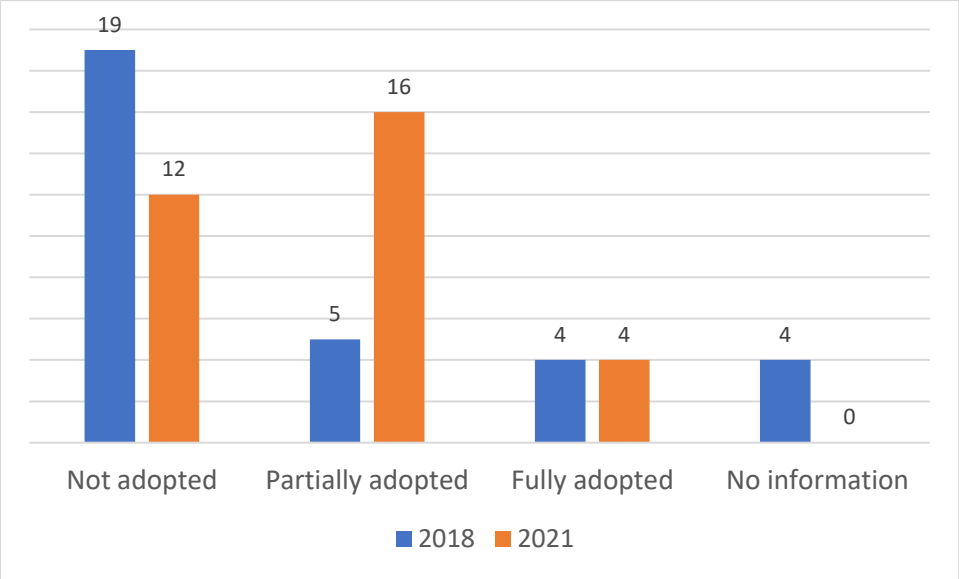
** These countries did not provide an update HIV testing guideline but were included in the analysis

**Supplementary Table 3.** Progress on policy adoption in the WHO African Region from 2018 to 2021

| Subregion | Count | Country | Policy reviewed in 2018? | Adherence in 2018 | Policy reviewed in 2021 | Adherence in 2021 |
|---|---|---|---|---|---|---|
| Central Africa | 1 | Angola | Yes, 2015 | Not adopted | 2020 | Mostly adopted |
| | 2 | Cameroon | Yes, 2015 | Not adopted | 2019 | Mostly adopted |
| | 3 | CAR | Yes, 2010 | Not adopted | 2018 | Not adopted |
| | 4 | Chad | Yes, 2011 | Not adopted | 2017 | Mostly adopted |
| | 5 | DRC | Yes, 2017 | Adopted | 2020 | Adopted |
| | 6 | Equatorial Guinea | No | – | 2018 | Not adopted |
| | 7 | Gabon | No | – | 2017 | Mostly adopted |
| | 8 | Republic of the Congo | No | – | – | – |
| | 9 | São Tomé e Principe | No | – | 2018 | Not adopted |
| Eastern Africa | 10 | Burundi | Yes, 2016 | Not adopted | 2020 | Mostly adopted |
| | 11 | Comoros | Yes, 2007 | No information | 2016 | Not adopted |
| | 12 | Eritrea | No | – | 2019 | Not adopted |
| | 13 | Ethiopia | Yes, 2017 | No information | 2018 | Mostly adopted |
| | 14 | Kenya | Yes, 2017 | Mostly adopted | 2021 | Adopted |
| | 15 | Madagascar | Yes, 2011 | No information | 2018 | Mostly adopted |
| | 16 | Malawi | Yes, 2016 | Not adopted | 2016 | Mostly adopted |
| | 17 | Mauritius | No | – | 2020 | Not adopted |
| | 18 | Mozambique | Yes, 2016 | Not adopted | 2020 | Mostly adopted |
| | 19 | Rwanda | Yes, 2016 | Not adopted | 2018 | Mostly adopted |
| | 20 | Seychelles | No | – | 2019 | Not adopted |
| | 21 | South Sudan | Yes, 2017 | Not adopted | 2020 | Adopted |
| | 22 | Tanzania | Yes, 2017 | Not adopted | 2021 | Mostly adopted |
| | 23 | Uganda | Yes, 2016 | Mostly adopted | 2020 | Mostly adopted |
| | 24 | Zambia | Yes, 2018 | Not adopted | 2020 | Not adopted |
| | 25 | Zimbabwe | Yes, 2016 | Adopted | 2016 | Adopted |
| Southern Africa | 26 | Botswana | Yes, 2016 | Mostly adopted | 2016 | Not adopted |
| | 27 | eSwatini | Yes, 2018 | Not adopted | 2018 | Not adopted |
| | 28 | Lesotho | Yes, 2016 | Adopted | 2021 | Mostly adopted |
| | 29 | Namibia | Yes, 2016 | No information | 2018 | Not adopted |
| | 30 | South Africa | Yes, 2016 | Mostly adopted | 2020 | Not adopted |
| Western Africa | 31 | Algeria | Yes, 2013 | Adopted | 2013 | Not adopted |
| | 32 | Benin | No | – | 2017 | Not adopted |
| | 33 | Burkina Faso | Yes, 2008 | Not adopted | 2021 | Mostly adopted |
| | 34 | Cabo Verde | No | – | – | – |
| | 35 | Ghana | Yes, 2014 | Not adopted | 2019 | Mostly adopted |
| | 36 | Guinea | No | – | 2019 | Mostly adopted |
| | 37 | Guinea-Bissau | No | – | 2021 | Not adopted |
| | 38 | Ivory Coast | Yes, 2016 | Not adopted | 2016 | Not adopted |
| | 39 | Liberia | Yes, 2015 | Not adopted | 2020 | Mostly adopted |
| | 40 | Mauritania | No | – | 2020 | Not adopted |
| | 41 | Mali | No | – | 2017 | Not adopted |
| | 42 | Niger | No | – | 2020 | Not adopted |
| | 43 | Nigeria | Yes, 2016 | Not adopted | 2020 | Mostly adopted |
| | 44 | Senegal | Yes, 2017 | Mostly adopted | 2018 | Not adopted |
| | 45 | Sierra Leone | Yes, 2017 | Not adopted | 2020 | Not adopted |
| | 46 | The Gambia | Yes, 2014 | Not adopted | 2019 | Not adopted |
| | 47 | Togo | No | – | 2019 | Not adherent |

A total of 32 countries had policies reviewed in 2018 and 2021. Those highlighted in red are policies reviewed in 2018 that were updated (n=28). Number of policies deemed adopted in 2018 (n=7) and number deemed adopted in 2021 (n=20)

**Supplementary Figure 2.** Comparing policy adoption across countries, 2018 vs 2021



**Supplementary Table 4.** Policy adoption of 2019 WHO-recommended HIV testing strategies in the WHO African region, 2014-2021

| AFRO subregions (countries) | Policies reviewed | | | Serial testing strategy | | | Discontinuation of tiebreaker* testing strategy | | | Retesting prior to ART initiation | | Universal 3-test strategy | Use of dual HIV/syphilis test** | No use of Western Blot |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year | 2014 | 2018 | 2021 | 2014 | 2018 | 2021 | 2014 | 2018 | 2021 | 2018 | 2021 | 2021 | 2021 | 2021 |
| All (n=47) | 25 (53%) | 32 (68%) | 45 (96%) | 21 (84%) | 26 (81%) | 29 (64%) | 15 (60%) | 26 (81%) | 37 (82%) | 16 (50%) | 23 (51%) | 21 (47%) | 21 (47%) | 35 (78%) |
| Western (n=17) | 6 (35%) | 9 (53%) | 16 (94%) | 5 (83%) | 7 (78%) | 9 (56%) | 4 (67%) | 5 (56%) | 9 (56%) | 1 (11%) | 5 (31%) | 8 (50%) | 7 (44%) | 10 (63%) |
| Central (n=9) | 4 (44%) | 5 (56%) | 8 (89%) | 4 (100%) | 5 (100%) | 7 (88%) | 3 (75%) | 4 (80%) | 7 (88%) | 1 (20%) | 5 (63%) | 3 (38%) | 2 (25%) | 6 (75%) |
| Eastern (n=16) | 11 (69%) | 13 (81%) | 16 (100%) | 10 (91%) | 10 (77%) | 12 (75%) | 5 (45%) | 12 (92%) | 16 (100%) | 9 (69%) | 9 (56%) | 9 (56%) | 9 (56%) | 14 (88%) |
| Southern (n=5) | 4 (80%) | 5 (100%) | 5 (100%) | 2 (40%) | 4 (80%) | 1 (20%) | 3 (75%) | 5 (100%) | 5 (100%) | 5 (100%) | 4 (80%) | 1 (20%) | 3 (60%) | 5 (100%) |

*Use of a third assay to rule-in HIV infection

**Dual HIV/syphilis RDT as first test in ANC

**Supplementary Table 5.** Short name of products used as part of the 2-assay or 3-assay HIV testing algorithm in 28 HIV national testing policy documents reviewed in 2021

| Strategy | Count | Country | Assay 1 | Assay 2 | Assay 3 |
|---|---|---|---|---|---|
| 2-assay | 1 | Angola | Determine | Uni-Gold | – |
| | 2 | Cameroon | Determine or Uni-Gold | OraQuick or Shanghai | – |
| | 3 | CAR | Determine | Uni-Gold | – |
| | 4 | Cote D'Ivoire | Determine | SD Bioline or GenieFast | StatPak or EIA (as tiebreaker) |
| | 5 | Equatorial Guinea | Determine | Hexagon | Uni-Gold (for discordants) |
| | 6 | eSwatini | Determine | Uni-Gold | – |
| | 7 | Gambia | Determine | SD Bioline or First Response | – |
| | 8 | Guinea Bissau | Determine | First Response | PCR (as tiebreaker) |
| | 9 | Mali | Alere Combo | SD Bioline | First Response (as tiebreaker) |
| | 10 | Mozambique | Determine | Uni-Gold | – |
| | 11 | Rwanda | Alere Combo | StatPak | – |
| | 12 | São Tomé e Principe | Determine | SD Bioline | PCR (as tiebreaker) |
| | 13 | Sierra Leone | Determine | SD Bioline | Uni-Gold (as tiebreaker) |
| | 14 | Uganda | Determine | StatPak | SD Bioline (for discordants) |
| | 15 | Nigeria | Determine<br>Uni-Gold<br>Stat-Pak<br>Double Check Gold<br>Sure Check<br>HIV Quick Check | Determine<br>Uni-Gold<br>Stat-Pak<br>Double Check Gold<br>Sure Check<br>HIV Quick Check | Determine<br>Uni-Gold<br>Stat-Pak<br>Double Check Gold<br>Sure Check<br>HIV Quick Check<br>(as tiebreaker) |
| | 16 | Togo | Murex HIV Ag/Ab<br>Apdia HIV Ag/Ab<br>Determine<br>Alere Combo<br>Vikia HIV 1/2<br>Wanta Rapid Test<br>ABON HIV 1/2/0<br>Standard Q<br>Hexagon<br>Genie Fast<br>SD Bioline<br>First Response<br>SD Bioline HIV/Syphilis<br>OraQuick HIV Self-Test | ABON HIV 1/2/0<br>Standard Q<br>SD Bioline<br>First Response<br>HIV Tri-Dot | INNOLIA or Genius (as tiebreaker) |
| 3-assay | 17 | Burundi | Alere Combo or Determine | SD Bioline or Uni-Gold | Wondfo One Step |
| | 18 | Gabon | Alere Combo | Determine | SD Bioline |
| | 19 | Ghana | First Response | OraQuick | SD Bioline |
| | 20 | Guinea | Determine | SD Bioline | Multisure |
| | 21 | Kenya | INSTI | Uni-Gold | SD Bioline |
| | 22 | Liberia | Determine | SD Bioline | Uni-Gold |
| | 23 | Madagascar | Determine | Uni-Gold | SD Bioline |
| | 24 | Mauritius | GenScreen Ultra Ag/Ab | Alere Combo | Western Blot |
| | 25 | Malawi | INSTI | Uni-Gold | SD Bioline |

| | | | | | |
|---|---|---|---|---|---|
| | 26 | Niger | Alere Combo | Wondfo One Step | SD Bioline |
| | 27 | Senegal | Determine | SD Bioline | Multisure |
| | 28 | Zimbabwe | Determine | Chembio | INSTI |
| | 29 | Burkina Faso | 3rd generation:<br>Determine<br>Double check Gold Ultra<br>Onsite HIV1+2 Plus Combo<br>VIKIA HIV 1/2<br>4th generation:<br>Alere Ag/Ab Combo<br>OnSite HIV Ab/Ag (CTK) | HIV TriDot<br>ImmunoFlow<br>OnSite HIV 1/2 Ab Plus (CTK)<br>SD Bioline | Any of those not selected as A1 or A2 |