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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

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2	policy review across the WHO African region
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25	ABSTRACT
26	Introduction: In 2019, the World Health Organization (WHO) released updated guidelines on
27	HIV testing services (HTS) recommending: use of serial testing, a standard 3-assay testing
28	strategy requiring three consecutive reactive serology test results to make an HIV-positive
29	diagnosis; discontinuation of the use of a tie-breaker to rule-in HIV infection, discontinuation
30	of western blotting (WB) for HIV diagnosis, retesting prior to ART initiation, and dual
31	HIV/syphilis rapid diagnostic tests (RDTs) as the first test in antenatal care (ANC). Here we
32	update previous policy reviews conducted in 2014 and 2018 to assess policy adoption of
33	updated recommendations in the WHO African region.
34	
35	Methods: Between May and December 2021, we undertook a comprehensive desk review of
36	national HTS policies. Adoption of WHO recommendations was assessed based on the
37	number of WHO 2019 HTS recommendations adopted and then compared to 2014 and 2018
38	baseline information.
39	
40	Results: National policies were reviewed for 96% (n=45/47) of countries in the WHO African
41	region, 40% (n=18) were published before 2019, and 62% (n=28) adopted WHO guidance.
42	Between 2018 and 2021, adoption in the region increased from 28% (n=9/32) to 62%
43	(n=28/45). Using a 2-assay testing strategy was the most common form of non-adoption: 31%
44	(n=14) and 22% (n=10) in low (<5%) and high (\geq 5%) prevalence countries. Ten policies (22%)
45	recommended the use of WB in their HIV testing algorithm, and 51% (n=23) recommended
46	retesting before ART initiation. Dual HIV/syphilis RDTs were recommended in 47% (n=21/45)

- 47 of policies.

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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 3asssay testing strategy and dual HIV/syphilis RDTs.

5 Word count/limit: 299

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

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} ↓	72	STRENGTHS AND LIMITATIONS OF THIS STUDY
, ,	73	\Rightarrow Compared to the 2018 global review where six WHO Regions were included, by focusing
3	74	only on the WHO African region, we were able to include thirteen additional national
0 1 2	75	policy documents in this review (n=45 in 2021 vs n=32 in 2018).
2 3 4	76	\Rightarrow We employed robust searching methods and a standardized data extraction tool.
5 6 7	77	\Rightarrow We didn't find out how HTS policies were being implemented in each country. Countries
7 8 9	78	may be executing HIV testing plans that diverge from those specified in official policy
20 21	79	papers, resulting in misclassification of adoption status. It's likely that decentralization in
22 23 24	80	some countries has resulted in changes in testing procedures and strategies at the
25 26	81	subnational level that this evaluation overlooked even though we did not include
27 28 29	82	subnational policy documents.
80 81	83	\Rightarrow Notably, during our review we also identified countries in the process of adopting WHO
2 3 4	84	recommendations – particularly the use of 3-test strategy and dual HIV/syphilis RDTs for
5 6	85	ANC. Thus, our estimates of adoption of WHO testing guidelines may be conservative.
57 18 19	86	
9 0 1	87	INTRODUCTION
2 3 4	88	HIV Testing Services (HTS) is the critical gateway to accessing HIV-related care and treatment
14 15 16	89	for those diagnosed as HIV-positive and as a means to accessing prevention services for those
7 8	90	who test HIV-negative.[1, 2] Despite considerable progress, reaching the first UNAIDS 95 HIV
19 50 51	91	target by 2025 will require increased testing uptake, particularly among populations with
52 53	92	testing gaps such as key population, youth and men.[3] Further, the global emergency caused
54 55 56	93	by the COVID-19 pandemic in 2020 has disrupted many health services including HIV testing
57 58 59	94	services, and supply chains of key commodities such as rapid diagnostic tests (RDTs) have

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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.

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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 (\geq 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

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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.

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142 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.

<u>2</u> 3 150

151 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).

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> 160 To determine the proportion of countries adopting WHO guidance, country policies 161 categorised as 'fully adopted and 'nearly adopted' were considered adopted and those 162 categorised as 'somewhat not adopted' or 'not adopted' were considered non-adopted.

> 163 Descriptive analyses disaggregated by subregions (Western, Central, Eastern and Southern 164 Africa; online supplementary figure 1) were also conducted to determine rates of adherence

⁵⁹ 165 by subregion. All analyses were conducted in Microsoft Excel.

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Patient and public involvement 66

RESULTS

67 Patients and/or the public were not involved in the design, conduct, reporting, or 68 dissemination plans of this study.

71 We identified updated national policies or HIV testing algorithms for 41 countries out of 47 72 (87%) in 2021. Previous policies for 6 countries (Algeria, Botswana, eSwatini, Cote d'Ivoire, 73 Malawi, and Zimbabwe) identified in the 2018 review were included in this current analysis, 74 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 75 76 document. In total, we included 96% of countries from the WHO African region (n=45/47). 77 Two countries, Republic of the Congo and Cabo Verde, were not included because we were 78 unable to obtain their national policies (figure 1).

80 Of the 45 policies providing information on HIV testing strategies, 16 were from Western 81 Africa (36%), 16 from Eastern Africa (36%), 8 from Central Africa (18%), and 5 from Southern 82 Africa (11%). Policies were published in English (n=22), French (n=18), Portuguese (n=4) and 83 Spanish (n=1). Policy publication dates ranged from 2013 to 2021 and 40% of policies 84 (n=18/45) were published before 2019. Based on the most recent national HIV prevalence 85 reported by UNAIDS[1], 34 countries (76%) had a low prevalence (<5%) and 11 countries 86 (24%) had a high prevalence (\geq 5%) (online supplementary table 2).

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190 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

- 196 (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).

subregions (countries) Year All (n=47)		icies revie	2021		rall adop	otion	Serial t	esting str	ategy	tieb	reaker* te	•	28 D ec	ART	3-test	HIV/syphilis	No use of Western Blot
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All (n=47)		2018	2021	2011						strategy		ទ្តី ឮកម្មtiation		strategy	test**		
(n=47)	25			2014	2018	2021	2014	2018	2021	2014	2018	2021	المور 2023. settignethel s fèlated t	2021	2021	2021	2021
		32	45	2	9	28	21	26	29	15	26	37	2023 1000 1000	23	21	21	35
	(53%)	(68%)	(96%)	(8%)	(28%)	(62%)	(84%)	(81%)	(64%)	(60%)	(81%)	(82%)	1578	(51%)	(47%)	(47%)	(78%)
Western	6	9	16	0	2	7	5	7	9	4	5	9	wnlo wpe	5	8	7	10
(n=17)	(35%)	(53%)	(94%)	(0%)	(22%)	(44%)	(83%)	(78%)	(56%)	(67%)	(56%)	(56%)	wnloaged Superieur (ext and dat	(31%)	(50%)	(44%)	(63%)
Central	4	5	8	1	1	5	4	5	7	3	4	7	AB (AB	5	3	2	6
(n=9)	(44%)	(56%)	(89%)	(25%)	(20%)	(63%)	(100%)	(100%)	(88%)	(75%)	(80%)	(88%)	d from atta (ABES) . ata mining	(63%)	(38%)	(25%)	(75%)
Eastern	11	13	16	1	3	12	10	10	12	5	12	16	, 9 <mark>8</mark>	9	9	9	14
(n=16)	(69%)	(81%)	(100%)	(9%)	(23%)	(75%)	(91%)	(77%)	(75%)	(45%)	(92%)	(100%)	a 69%	(56%)	(56%)	(56%)	(88%)
Southern	4	5	5	0	3	4	2	4	1	3	5	5	pen.b. 5	4	1	3	5
(n=5)	(80%)	(100%)	(100%)	(0%)	(60%)	(80%)	(40%)	(80%)	(20%)	(75%)	(100%)	(100%)		(80%)	(20%)	(60%)	(100%)
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226 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.

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3 4	249	Discontinuation of a tiebreaker testing strategy
5 6 7	250	The discontinuation of a third assay to rule in HIV infection (i.e., tiebreaker) was
7 8 9	251	recommended in 82% of national policies (n=37/45) (figure 3_2). The subregions with the
10 11 12	252	highest adoption were Southern Africa and Eastern Africa (100% each) followed by Central
12 13 14	253	Africa (88%), whereas Western Africa had the lowest adoption (56%) (table 1).
15 16	254	
17 18 19	255	Of the eight policies recommending a tiebreaker testing strategy, seven were from Western
20 21	256	Africa and one from Central Africa. Seven policies specified the type of A3 to be used, for
22 23 24	257	example, RDT (n=4), RDT or EIA (n=1), nucleic acid testing (NAT: n=2) and LIA (n=1).
25 26	258	
27 28 29	259	Adoption of WHO standard 3-assay testing strategy
30 31	260	The use of three consecutive HIV-reactive tests for the diagnosis of HIV was recommended by
32 33 34	261	47% of the policies (n=21/45) (figure 3_3). The adoption of this WHO recommendation was
34 35 36	262	highest in Eastern Africa (56%) and Western Africa (50%) and lowest in Southern Africa (20%)
37 38	263	(table 1). Most policies recommending a 3-assay testing strategy (n=20/21) were from low
39 40 41	264	HIV-burden countries. Among high HIV-burden countries, only 18% of policies (n=2/11)
42 43	265	recommended the use of a 3-assay testing strategy and this corresponded to two countries,
44 45 46	266	Malawi and Zimbabwe, respectively.
47 48	267	
49 50 51	268	Compared to the 2018 review, 10 policies that previously recommended a 2-assay testing
52 53	269	strategy transitioned to a 3-assay testing strategy in 2021 (Burkina Faso, Burundi, Chad,
54 55 56	270	Ethiopia, Ghana, Kenya, Lesotho, Malawi, Madagascar, and Zimbabwe, respectively).
50 57 58	271	Of policies supporting a 3-assay testing strategy, only 53% (n=11/21) also recommended the
59 60	272	use of dual HIV/syphilis RDTs among pregnant women.

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273	Adoption of retesting to verify positive status prior to ART initiation
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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.

284 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).

⁷ 291 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).

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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, Mozambigue and United Republic of Tanzania); three national policies from Southern Africa (Eswatini, Lesotho and Namibia); two policies from Central Africa

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319 (Angola and Sao Tomé et Principe); and one national policy from Western Africa (Guinea320 Bissau).

321 Two policies employed NAT as the third assay (A3) of the algorithm while the remaining 8 322 policies recommended NAT to resolve persistent inconclusive/indeterminate test results 323 (referring either to viral load, PCR or DNA-PCR).

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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.

² 335

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

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3 4	343	recently in 2019,[11] low resource countries in the WHO African region has been at the
5 6 7	344	forefront of implementing HIV RDTs compared to other WHO regions as a way to rapidly
, 8 9	345	expand and increase access to HIV testing services.[12]
10 11	346	
12 13 14	347	Having said that, our review found that a dozen of countries, mostly in Western Africa, still
15 16	348	use western blotting as part of the HIV testing algorithms, hindering same-day diagnoses and
17 18 19	349	rapid access to ART and Pre-exposure prophylaxis (PrEP).[11] Despite observing a 1.43 fold
20 21	350	increase in the number of countries recommending retesting prior to ART initiation compared
22 23	351	to 2018 (23 vs 16), we noted virtually no progress in the proportion of countries with
24 25 26	352	supportive policy, with 51% in 2021 and 50% in 2018.
27 28	353	The WHO's recommendations with a lower country uptake were the use of a standard 3-assay
29 30 31	354	testing strategy (47%) and the use of dual HIV/syphilis RDT among pregnant women (47%),
32 33	355	both recommendations released in 2019.[6]
34 35 36	356	
37 38	357	Before 2019, WHO recommended the use of a 2-assay testing strategy in high HIV prevalence
39 40 41	358	settings (≥5%) and the use of a 3-assay testing strategy in low HIV prevalence settings (<5%)
42 43	359	to maintain at least a 99% positive predictive value (PPV).[1] However, as HTS and ART have
44 45		
46	360	been scaled up substantially and fewer people undergoing HTS are HIV-positive, the national
46 47 48	360 361	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
47 48 49 50		
47 48 49	361	HTS positivity has also declined, even in high HIV burden settings.[13] Given this changes in
47 48 49 50 51 52 53 54 55	361 362	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
47 48 49 50 51 52 53 54	361 362 363	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

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treatment-adjusted prevalence, rather than the national HIV prevalence, and national HTSpositivity 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]

55 387

388 We found that among low-prevalence countries (n=34), a significant proportion (41%) still use 389 a suboptimal testing strategy with 2 assays to make an HIV positive diagnosis, which will

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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

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> 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

1 2

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

tachnology in favour of RDTs. Countries should plan to accolorate their transition to WHO

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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	-
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Contributors	
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452 Stillson), Evidence Action Group (Anna Konstantinova and Emilie Efroson) and staff from 453 Ministry of Health in Mozambique (Helga Guambe) and Guinea Bissau (David da Silva Té) for 454 their support in identifying latest national HIV testing policies.

456 Contributors

457 CJ devised and supervised the review. EF updated the study protocol and conducted the 458 screening, data extraction and analysis. CL acted as a second reviewer and CJ as third 459 reviewer. All authors reviewed the draft, provided critical review and read and approved the 460 final version of the manuscript.

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

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8 9	488	through these resources, please contact the authors of this review for additional information.
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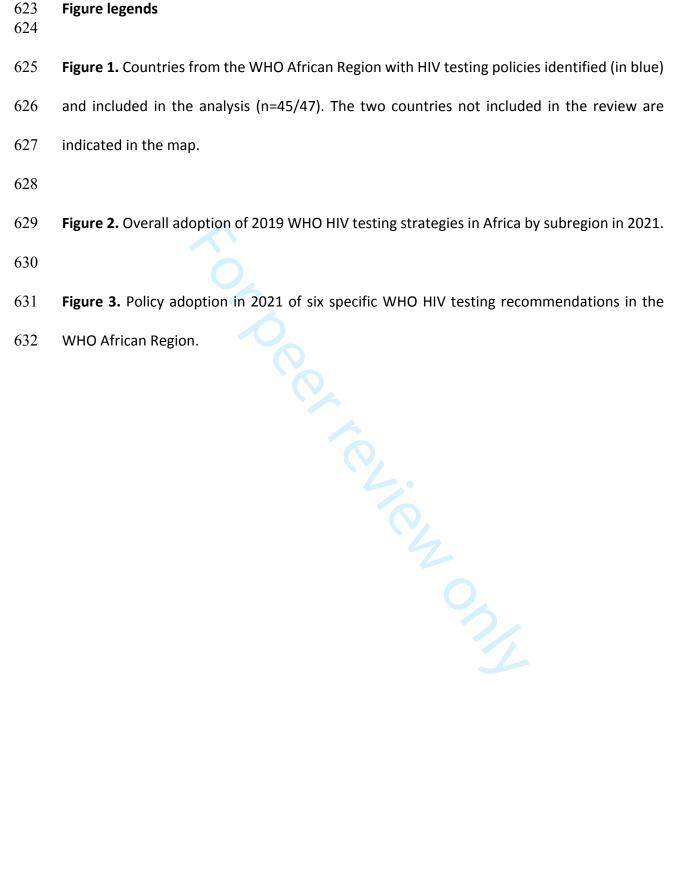
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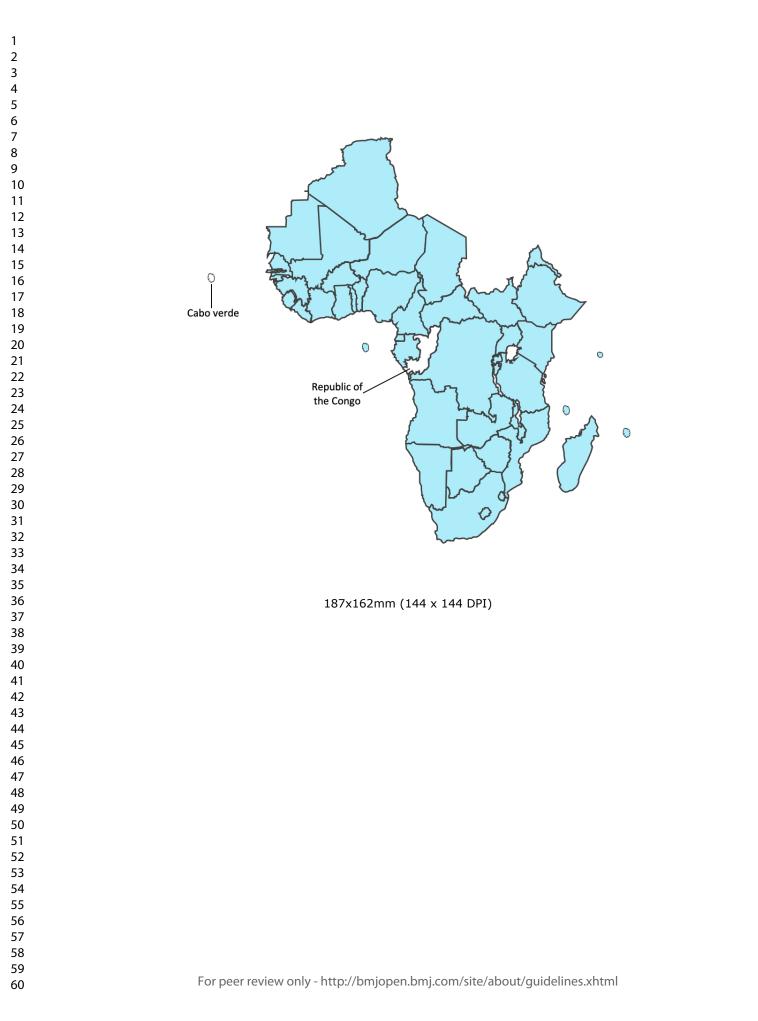
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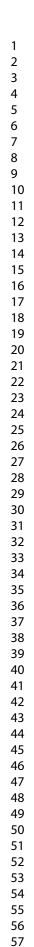
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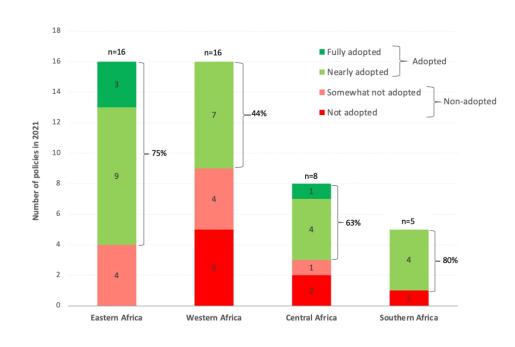
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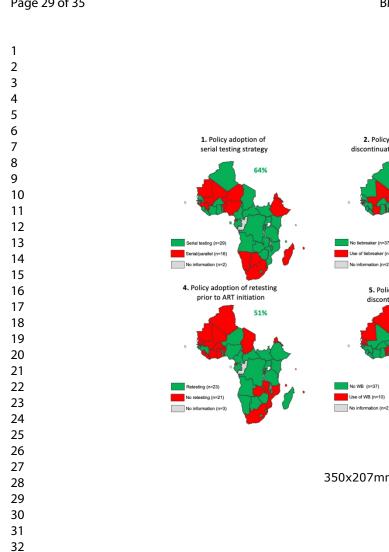
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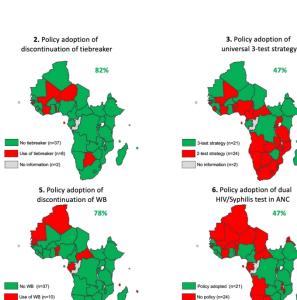


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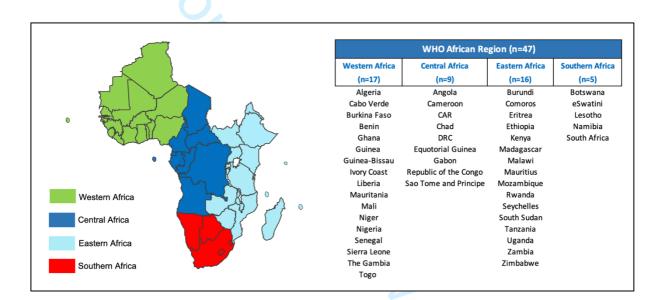
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Supplementary Appendix

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 Johnson¹

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



Supplementary Table 1. Categories for data extraction

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

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Subregion	Count	Country	Policy reviewed in 2018?	New policy or algorithm identified?	Publication year	Type of document	uding for us	Algorithm provided?	National HIV prevalence
	1	Angola	Yes, 2015	Yes	2020	HTS	us mense Portuguese	Yes	Low
	2	Cameroon	Yes, 2015	Yes	2019	ART	Fre	Yes	Low
	3	CAR	Yes, 2010	Yes	2018	ART	Fre	Yes	Low
Control	4	Chad	Yes, 2011	Yes	2017	HTS	Fre	Yes	Low
Central Africa	5	DRC	Yes, 2017	Yes	2020	ART	Fre	Yes	Low
AITICa	6	Equatorial Guinea	No	Yes	2018	ART	Spaneisno	Yes	Low
	7	Gabon	No	Yes	2017	HTS	Frege	Yes	Low
	8	Republic of the Congo	No	No	-	_	Fred fr	-	-
	9	São Tomé e Principe	No	Yes	2018	Algorithm	Portuz	Yes	Low
	10	Burundi	Yes, 2016	Yes	2020	HTS	Freise R	Yes	Low
	11	Comoros	Yes, 2007	Yes	2016	HTS	French	Yes	Low
	12	Eritrea	No	Yes	2019	HTS	Engue Sh	Yes	Low
	13	Ethiopia	Yes, 2017	Yes	2018	ART	Engessh 🖁	Yes	Low
	14	Kenya	Yes, 2017	Yes	2021	HTS	Enge sh 🖁	Yes	Low
	15	Madagascar	Yes, 2011	Yes	2018	HTS	Fregch 3	Yes	Low
	16	Malawi*	Yes, 2016	Yes*	2016	HTS	English 8	Yes	High
Eastern	17	Mauritius	No	Yes	2020	HTS	Eng e sh २	Yes	Low
Africa	18	Mozambique	Yes, 2016	Yes	2020	PMTCT	Portuguese	Yes	High
	19	Rwanda	Yes, 2016	Yes	2018	HTS	Engesh	Yes	Low
	20	Seychelles	No	Yes	2019	HTS	Engedsh -	Yes	Low
	21	South Sudan	Yes, 2017	Yes	2020	ART	Engalsh	Yes	Low
	22	Tanzania	Yes, 2017	Yes	2021	HTS	Enguish 2	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
	26	Botswana**	Yes, 2016	No	2016	ART	English	Yes	High
Southern	27	eSwatini**	Yes, 2018	No	2018	ART	English 🖳	Yes	High
Africa	28	Lesotho	Yes, 2016	Yes	2021	PMTCT	English	Yes	High

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

Page	33	of	35
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	29	Namibia	Yes, 2016	Yes	2018	HTS	Eng a sh 1	Yes	High
	30	South Africa	Yes, 2016	Yes	2020	ART	Eng f ish o	Yes	High
-	31	Algeria**	Yes, 2013	No	2013	HTS	Freach	Yes	Low
	32	Benin	No	Yes	2017	HTS	Fre ថ្មី ch 🖉	Yes	Low
	33	Burkina Faso	Yes, 2008	Yes	2021	ART	Freßichense	Yes	Low
	34	Cabo Verde	No	No	_	_	nbe nse eş r	_	_
	35	Ghana	Yes, 2014	Yes	2019	ART	Engen 2023	Yes	Low
	36	Guinea	No	Yes	2019	HTS	Fre	Yes	Low
	37	Guinea-Bissau 🦯	No	Yes	2021	ART	Portugues	Yes	Low
Western	38	Ivory Coast**	Yes, 2016	No	2016	HTS	Fre	Yes	Low
	39	Liberia	Yes, 2015	Yes	2020	HTS	Eng	Yes	Low
Africa	40	Mauritania	No	Yes	2020	HTS	Fre	Yes	Low
	41	Mali	No	Yes	2017	HTS	Freadcast	Yes	Low
	42	Niger	No	Yes	2020	HTS	Free Constant	Yes	Low
-	43	Nigeria	Yes, 2016	Yes	2020	ART	Engaisti 🛃	Yes	Low
	44	Senegal	Yes, 2017	Yes	2018	HTS	Freigch	Yes	Low
	45	Sierra Leone	Yes, 2017	Yes	2020	ART	Eng	Yes	Low
	46	The Gambia	Yes, 2014	Yes	2019	ART	Eng	Yes	Low
	47	Togo	No	Yes	2019	HTS	Free ch	Yes	Low
		ovided an updated HIV lid not provide an upda							
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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
	10	Burundi	Yes, 2016	Not adopted	2020	Mostly adopted
Eastern Africa	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
	26	Botswana	Yes, 2016	Mostly adopted	2016	Not adopted
	27	eSwatini	Yes, 2018	Not adopted	2018	Not adopted
Southern	28	Lesotho	Yes, 2016	Adopted	2021	Mostly adopted
Africa	29	Namibia	Yes, 2016	No information	2018	Not adopted
	30	South Africa	Yes, 2016	Mostly adopted	2020	Not adopted
Western Africa Tho	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
	40	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
	44	Sierra Leone	Yes, 2017	Not adopted	2018	Not adopted
	45	The Gambia	Yes, 2014	Not adopted	2019	Not adopted
				Not auopteu		
	47 se highlig	Togo hted in red are policies	No reviewed in 2018 i	 that were updated	2019 (n=28), Number of	Not adher

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
	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)
2-assay	14	Uganda	Determine	StatPak	SD Bioline (for discordants)
,	15	Nigeria	Determine Uni-Gold Stat-Pak Double Check Gold Sure Check HIV Quick Check	Determine Uni-Gold Stat-Pak Double Check Gold Sure Check HIV Quick Check	Determine Uni-Gold Stat-Pak Double Check Gol Sure Check HIV Quick Check (as tiebreaker)
	16	Togo	Murex HIV Ag/Ab Apdia HIV Ag/Ab Determine Alere Combo Vikia HIV 1/2 Wanta Rapid Test ABON HIV 1/2/0 Standard Q Hexagon Genie Fast SD Bioline First Response SD Bioline HIV/Syphilis OraQuick HIV Self-Test	ABON HIV 1/2/0 Standard Q SD Bioline First Response HIV Tri-Dot	INNOLIA or Geniu (as tiebreaker)
	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
2	20	Guinea	Determine	SD Bioline	Multisure
3-assay	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

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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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3	1	Title: Country adoption of WHO 2019 guidance on HIV testing strategies and algorithms: a
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- 3 1	25	ABSTRACT
5	26	Objectives: In 2019, the World Health Organization (WHO) released guidelines on HIV testing
, 3 9	27	services (HTS). We aim to understand adoption of these recommendations.
10 11	28	Design: Policy review
2 3 4	29	Setting: 47 countries within the WHO African region.
5 6	30	Participants: National HTS policies from the WHO African region as of December 2021.
7 8 9	31	Primary and secondary outcome measures: Uptake of WHO recommendations across
20 21	32	national HTS policies including the standard 3-test strategy; discontinuation of a tie-breaker
22 23 24	33	test to rule in HIV infection; discontinuation of western blotting (WB) for HIV diagnosis; use
25 26	34	of retesting prior to ART initiation; and the use of dual HIV/syphilis rapid diagnostic tests
27 28 29	35	(RDTs) in antenatal care (ANC). Country policy adoption was assessed on a continuum, based
30 31	36	on varying levels of complete adoption.
32 33	37	Results: National policies were reviewed for 96% (n=45/47) of countries in the WHO African
34 35 36	38	region, 40% (n=18) were published before 2019, and 62% (n=28) adopted WHO guidance. As
37 38	39	of 2021, adoption in the region was 62% (n=28/45). Among countries that had not fully
39 40 41	40	adopted WHO guidance, using a 2-test strategy was the most common reason for
12 13	41	misalignment; 31% (n=14) and 22% (n=10) in low (<5%) and high (25%) prevalence countries,
14 15 16	42	had not yet adopted the 3-test strategy. Ten policies (22%) recommended the use of WB in
40 47 48	43	their HIV testing algorithm, and 51% (n=23) recommended retesting before ART initiation.
19 50	44	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 BMJ Open

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3 4 5 7 8 9 10 11 12	48	WHO recommendations by streamlining efforts to adopt and implement a 3-test strategy and
	49	dual HIV/syphilis RDTs.
	50	Keywords: HIV, diagnosis, rapid test, dual HIV/syphilis, policy, guideline, Africa, algorithm
	51	Strengths and limitations of this study
12 13 14	52	• This study provided a comprehensive review of existing national HTS policies in the
15 16 17 18 19 20 21	53	African region and was able to identify current policies for 45 countries. While this
	54	represents nearly all countries in the region, we were unable to identify policies for
	55	two countries.
22 23 24	56	Data was collected and analyses using a robust search and global repository developed
25 26 27 28 29 30 31 32 33 34	57	by WHO, as well as a standardised extraction tool to synthesise national policy
	58	information. Translation of policies was conducted by the review team.
	59	 The review focused only on published policies and did not assess country
	60	implementation at the national, subnational, or site level. Thus, it is possible that
35 36	61	some practices in country differ than policies reviewed, and level of adoption reported
37 38 39	62	may vary.
40 41	63	• The review focused on WHO recommendations related to HIV testing strategies for
42 43 44	64	individuals ≥18 months of age. HIV testing strategy recommendations, such as early
45 46	65	infant diagnosis, was not included.
47 48 49	66	• The review also identified countries which reported that they were in the process of
50 51	67	adopting WHO recommendations – particularly the use of 3-test strategy and dual
52 53 54 55 56 57 58 59	68	HIV/syphilis RDTs. Thus, our estimates may be conservative an under-estimate policy
	69	adoption in the African region.
	70	
60		

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.

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> 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.

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- 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 Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

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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,

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when possible, either through references provided in the national HTS policy or through

5 6 7	141	contact with key informants. The full protocol for the review was previously developed and
7 8 9	142	published in 2018. [13]
10 11 12	143	
12 13 14	144	Data extraction
15 16 17	145	Data were extracted from each policy document by one reviewer (EF) into standardised
18 19	146	coding forms on policy information, HIV testing strategy/algorithm (>18 months of age), dual
20 21 22	147	HIV/syphilis testing strategy/algorithm, and retesting prior to ART initiation (online
23 24	148	supplementary table 1). When reported the order, type of test kits and name brand of
25 26 27	149	diagnostics used within the HIV testing algorithm was summarised descriptively, as well as
28 29	150	information on whether the algorithm was verified or validated.
30 31 32	151	
33 34	152	A second reviewer (CL) carried out crosschecking of the data. Differences between coders
35 36 37	153	were resolved through a third reviewer (CJ). To prevent misclassification, items were marked
38 39	154	as 'unclear' during data extraction when lack of information prevented complete
40 41 42	155	understanding. Reviewers than worked to contact key informant to provide further detail and
42 43 44	156	clarity wherever possible.
45 46 47	157	
47 48 49	158	Analysis
50 51 52	159	We assessed national adoption of WHO HTS guidance using six specific recommendations
52 53 54	160	related to testing strategies and algorithms for those ≥ 18 months of age set forth in the WHO
55 56	161	2019 HIV testing guidelines, namely: (1) use of serial testing, (2) use of a 3-test strategy, (3)
57 58 59	162	discontinuation of a tie-breaker to rule in HIV infection, (4) discontinuation of WB/LIA, (5)
60	163	retesting prior to ART initiation, and (6) use of dual HIV/syphilis RDT in ANC. Additional

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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.

- 181 Patient and public involvement

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

2 184

5 185 **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

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2 3 4	188	(n=32/45). Two countries, Republic of the Congo and Cabo Verde, were not included because
5 6 7 8 9 10 11 12 13 14 15 16	189	we were unable to obtain their national policies and sufficient information (figure 1). Out of
	190	all these policies, 91% (41/45) had updated their national policies as of December 2021. Policy
	191	publication dates ranged from 2013 to 2021. Out of the six country policies that had not been
	192	fully updated since 2018 (Algeria, Botswana, eSwatini, Cote d'Ivoire, Malawi, and Zimbabwe),
	193	two (Malawi and Zimbabwe) provided new HIV testing algorithms that were included in the
17 18 19	194	review.
20 21	195	
22 23 24	196	Of the 45 policies providing information on HIV testing strategies, 16 were from Western
25 26	197	Africa (36%), 16 were from Eastern Africa (36%), 8 were from Central Africa (18%), and 5 were
27 28 20	198	from Southern Africa (11%). Policies were published in English (n=22), French (n=18),
29 30 31 32 33	199	Portuguese (n=4) and Spanish (n=1). Based on the most recent national HIV prevalence
	200	reported by UNAIDS [1], 34 countries (76%) had a low HIV prevalence (<5%) and 11 countries
34 35 36	201	(24%) had a high HIV prevalence (≥5%) (online supplementary table 2).
37 38	202	
39 40 41	203	Overall adoption of WHO-recommended HIV testing strategies
42 43	204	In 2021, 62% of national testing strategies (n=28/45) were either fully or partially aligned with
44 45 46	205	WHO 2019 HTS recommendations and 38% (n=17/45) had not adopted the recommendations
47 48 49 50 51 52 53 54 55	206	(table 1). When the analysis was restricted to a subset of countries with policies in both the
	207	2018 and 2021 review (n=32), the proportion adopting WHO guidance in 2018 was 28%
	208	(n=9/32) vs 62% (n=20/32) in the current (2021) review (see online supplementary table 3;
	209	supplementary figure 2). Across the sub-regions, Southern (80%) and Eastern (75%) Africa had
56 57 58	210	the greatest level of alignment, whilst Central Africa (63%) and Western Africa (44%) had the
59 60	211	lowest adoption rates (table 1; figure 2).

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

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3	Table 1. Policy adoption of 2019 WHO-recommended HIV testing strategies in the WHO African region	inanudin	119 8 -on	

AFRO	Policies reviewed	Serial testing	Discontinuation of	Retesting prior to	Recommended	Use of dual	No use of
subregions		strategy	tiebreaker* testing strategy	ART initiation	3-test strateg	HIV/syphilis	Western Blot
(countries)					nber 1seig 3s rel	test**	
All	45	29	37	23	21 ted	21	35
(n=47)	(96%)	(64%)	(82%)	(51%)	(47%) (47%) (47%)	(47%)	(78%)
Western	16	9	9	5	8 supe	7	10
(n=17)	(94%)	(56%)	(56%)	(31%)	(50%)d	(44%)	(63%)
Central	8	7	7	5	3 to 5	2	6
(n=9)	(89%)	(88%)	(88%)	(63%)	(38%Hir	(25%)	(75%)
Eastern	16	12	16	9	9 0 9	9	14
(n=16)	(100%)	(75%)	(100%)	(56%)	Alt mjo	(56%)	(88%)
Southern	5	1	5	4		3	5
(n=5)	(100%)	(20%)	(100%)	(80%)	1 ing (20%) n	(60%)	(100%)
Use of a th	ird assay to rule-ir	HIV infection			<u> </u>		
*Dual HIV/	syphilis RDT as firs	st test in ANC			similar		
					÷ (
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47 48 49	255
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52 53 54	257
54 55 56	258
57 58	250
59 60	259

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36 Adoption of serial testing strategy

7 In 2021, 64% of national testing strategies (n=29/45) adopted the use of serial testing and 8 36% (n=16/45) recommended the mix use of serial and parallel testing (figure 3 1). The 9 subregions with the highest adoption were Central (88%) and Eastern Africa (75%), followed 0 by Western Africa (58%); Southern Africa had the lowest adoption rate (20%) (table 1). -1 However, fewer countries in southern Africa recommended serial testing in 2021 (n=1) than -2 in 2018 (n=4) (supplementary table 4). Most policies recommending serial or parallel testing .3 (n=15/16) conducted simultaneous testing of assay 1 (A1) and assay 2 (A2) in case of 4 discrepant test results, and the Namibian policy recommended parallel testing of A2 and A3 -5 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. BMJ Open

1 2		
2 3 4	260	Discontinuation of a tiebreaker testing strategy
5 6 7	261	The discontinuation of a third assay to rule in HIV infection (i.e., tiebreaker) was
7 8 9	262	recommended in 82% of national policies (n=37/45) (figure 3_2). The subregions with the
10 11	263	highest adoption were in Southern Africa and Eastern Africa (100%, each) followed by Central
12 13 14	264	Africa (88%), whereas Western Africa had the lowest adoption (56%) (table 1).
15 16	265	
17 18 10	266	Of the eight policies recommending a tiebreaker testing strategy, seven were from Western
19 20 21	267	Africa and one from Central Africa. Seven policies specified the type of A3 to be used, for
22 23	268	example, RDT (n=4), RDT or EIA (n=1), nucleic acid testing (NAT: n=2) and LIA (n=1).
24 25 26	269	
27 28	270	Adoption of WHO standard 3-assay testing strategy
29 30 31	271	The use of three consecutive HIV-reactive tests for the diagnosis of HIV was recommended by
32 33	272	47% of the policies (n=21/45) (figure 3_3). The adoption of this WHO recommendation was
34 35 36	273	highest in Eastern Africa (56%) and Western Africa (50%) and lowest in Southern Africa (20%)
30 37 38	274	(table 1). Most policies recommending a 3-test strategy (n=20/21) were from low HIV-burden
39 40	275	countries. Among high HIV-burden countries, only 18% of policies (n=2/11) recommended the
41 42 43	276	use of a 3-test strategy and this corresponded to two countries, Malawi and Zimbabwe,
44 45	277	respectively.
46 47 48	278	
49 50	279	Overall, across countries which had policies reviewed in both 2018 and 2021, 10 policies that
51 52	280	previously recommended a 2-assay testing strategy transitioned to a 3-test strategy as of
53 54 55	281	2021 (Burkina Faso, Burundi, Chad, Ethiopia, Ghana, Kenya, Lesotho, Malawi, Madagascar,
56 57	282	and Zimbabwe, respectively).
58 59 60	283	

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284	Adoption of retesting to verify positive status prior to ART initiation	
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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).

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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. Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

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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

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3 4	355	hinder policy change and to support country-led technical working groups to drive policy
5 6 7	356	change [11—12].
7 8 9	357	
10 11	358	The recommendations with highest adoption were the discontinuation of a tiebreaker (82%)
12 13 14	359	and western blotting (78%) as well as the use of serial testing (64%). Half of countries (51%)
15 16	360	also recommend retesting prior to ART initiation. One likely explanation for the higher policy
17 18 19	361	adoption is that these WHO's recommendations were first published in 2012, 2014 and 2015,
20 21	362	respectively (save for discontinuation of western blotting) providing national HIV
22 23 24	363	programmes ample time to incorporate these recommendations into their national HIV
24 25 26	364	testing guidelines. Although moving away from western blotting was recommended more
27 28	365	recently in 2019,[14] low resource countries in the WHO African region have been at the
29 30 31	366	forefront of implementing HIV RDTs compared to other WHO regions as a way to rapidly
32	267	
33	367	expand and increase access to HIV testing services.[15]
33 34 35	367	expand and increase access to HIV testing services.[15]
33 34		Having said that, our review found that a dozen of countries, mostly in Western Africa, still
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379 country was implementing when compared to 2018. Retesting prior to ART initiation remains 380 an important quality assurance strategy, however if countries are struggling to adopt this 381 recommendation it may be important for WHO to provide alternative approaches and 382 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 (\geq 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

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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]

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

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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]

50 446

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 Page 23 of 41

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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 Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

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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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We would like to express our gratitude to WHO colleagues in the respective countries of the WHO African region for their support in locating updated national policy documents. We would also like to thank staff at the Global Fund (Youssouf Sawadogo, Ghislaine Grasser and Jacqueline Papo), CHAI (Katherine Guerra, Gillian Leitch, Megan Ginivan and Christian Stillson), Evidence Action Group (Anna Konstantinova and Emilie Efroson) and staff from Ministry of Health in Mozambique (Helga Guambe) and Guinea Bissau (David da Silva Té) for their support in identifying latest national HIV testing policies.

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499	Contributors
500	CJ and AS devised and

500 CJ and AS devised and CJ and RB supervised the review. EF led the study protocol 501 developments, conducted the screening, data extraction and analysis. NB, CM, NSB, FSM, FJL, 502 MASP, LH assisted with acquisition of policies, data collection and results interpretation. CL 503 acted as a second reviewer and CJ as third reviewer. AS, MSJ, MBD and RB assisted with 504 assessing policies and interpreting results. EF led manuscript writing along with CJ, with 505 support from all authors. CL, NB, CM, NSB, FSM, FJL, MASP, LH, MBD, MSJ, AS, RB all reviewed 506 the first draft, provided critical review and input and approved the final version of the 507 manuscript.

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516 Map disclaimer

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3 4	523	Competing interests
5 6 7	524	The authors declare no competing interests. The contents in this article are those of the
, 8 9	525	authors and do not necessarily reflect the view of the World Health Organization.
10 11 12	526	
12 13 14	527	Patient consent for publication
15 16 17	528	Not required.
17 18 19	529	
20 21 22	530	Ethics approval
22 23 24	531	This study does not involve human participants and ethical approval was therefore not
25 26 27	532	required.
28 29	533	
30 31 32	534	Data availability statement
32 33 34	535	All data generated in the study are included in the article or uploaded as supplementary
35 36	536	information. National policies may be publicly available. Some policies included in this review
37 38 39	537	may be available through the following websites: (1)
40 41	538	https://aidsfree.usaid.gov/resources/guidance-data/hts. (2)
42 43 44	539	http://www.hivpolicywatch.org/database.html. If information on a policy cannot be found
45 46		through these resources, please contact the authors of this review for additional information.
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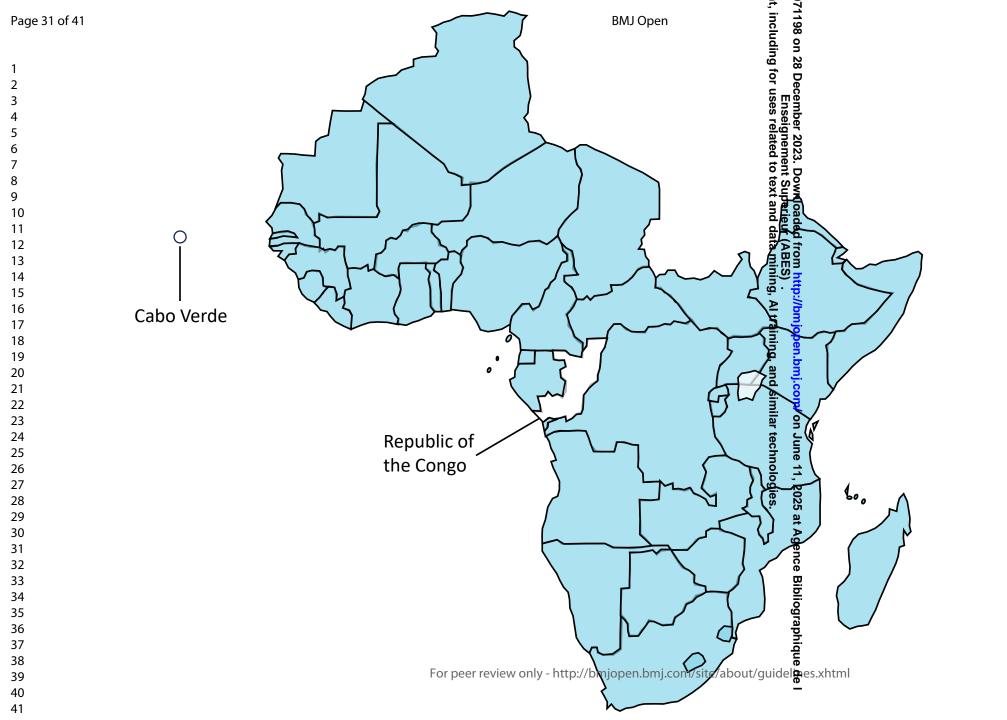
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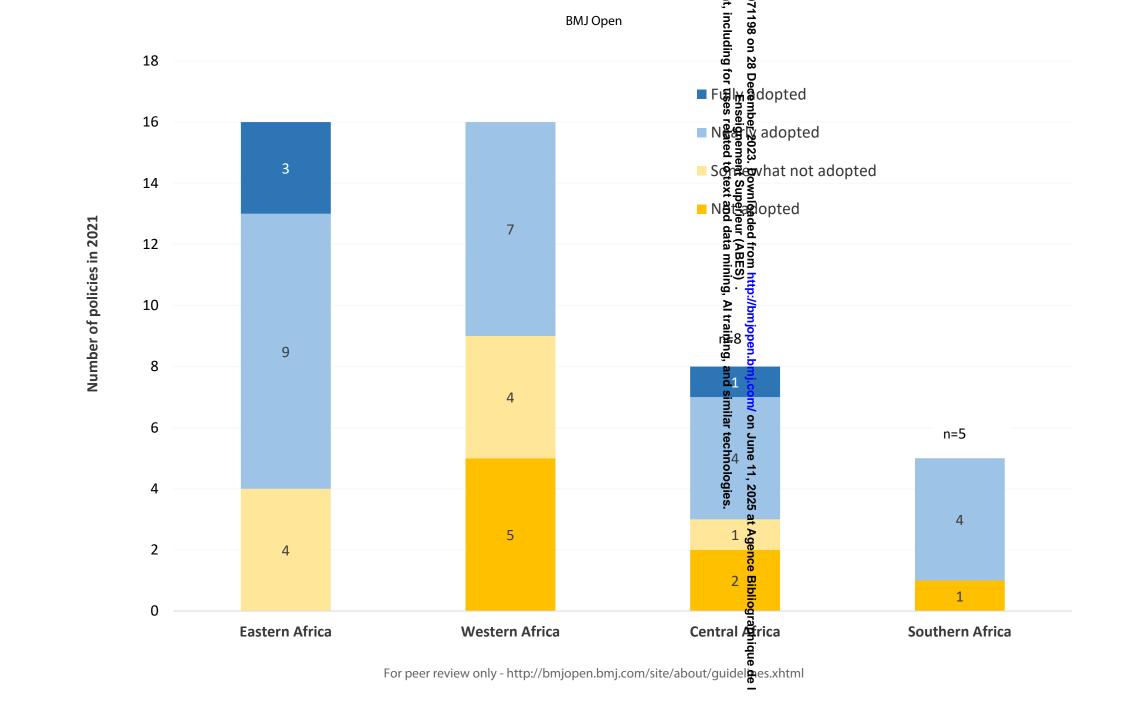
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3 4 5	687 688	Figure legends
6 7 8	689	Figure 1. Countries from the WHO African Region with HIV testing policies identified (in blue)
9 10	690	and included in the analysis (n=45/47). The two countries not included in the review are
11 12 13	691	indicated in the map.
14 15	692	
16 17 18	693	Figure 2. Overall adoption of 2019 WHO HIV testing strategies in Africa by subregion in 2021.
19 20	694	
21 22	695	Figure 3. Policy adoption in 2021 of six specific WHO HIV testing recommendations in the
23 24 25	696	WHO African Region.
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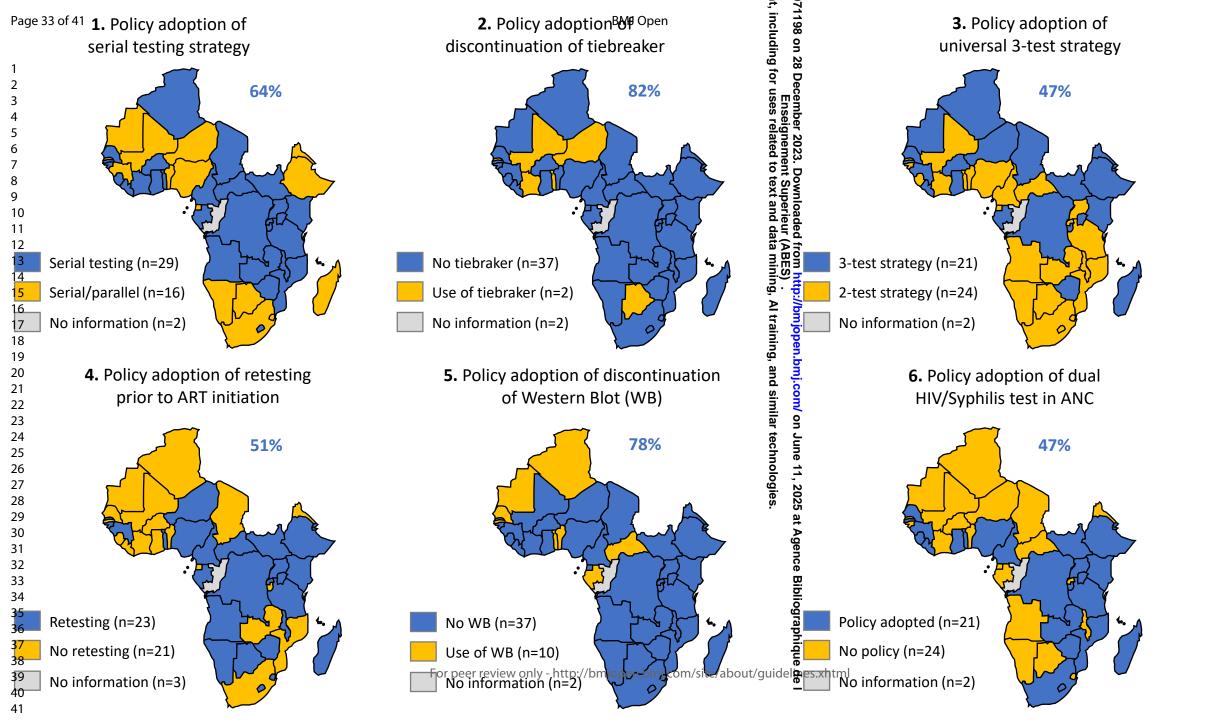
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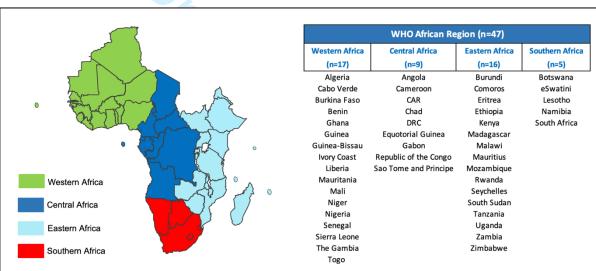


Supplementary Appendix

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 Johnson¹

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



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Supplementary Table 1. Categories for data extraction

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

Subregion	Count	Country	Policy reviewed in 2018?	New policy or algorithm identified?	Publication year	Type of document	h 28 Dece Langor us	Algorithm provided?	National HIV prevalence
	1	Angola	Yes, 2015	Yes	2020	HTS	Portu	Yes	Low
	2	Cameroon	Yes, 2015	Yes	2019	ART	Fre	Yes	Low
	3	CAR	Yes, 2010	Yes	2018	ART	Fre	Yes	Low
Control	4	Chad	Yes, 2011	Yes	2017	HTS	Fre ð ca g	Yes	Low
Central Africa	5	DRC	Yes, 2017	Yes	2020	ART	Fre	Yes	Low
AITICa	6	Equatorial Guinea	No	Yes	2018	ART	Spanis	Yes	Low
	7	Gabon	No	Yes	2017	HTS	Frege	Yes	Low
	8	Republic of the Congo	No	No	-	-	Fredata	-	_
	9	São Tomé e Principe	No	Yes	2018	Algorithm	Portuz	Yes	Low
	10	Burundi	Yes, 2016	Yes	2020	HTS	Fregen	Yes	Low
	11	Comoros	Yes, 2007	Yes	2016	HTS	French	Yes	Low
	12	Eritrea	No	Yes	2019	HTS	Enguish	Yes	Low
	13	Ethiopia	Yes, 2017	Yes	2018	ART	Engesh 🖁	Yes	Low
	14	Kenya	Yes, 2017	Yes	2021	HTS	Engaish 🖁	Yes	Low
	15	Madagascar	Yes, 2011	Yes	2018	HTS	Fregch 🛓	Yes	Low
	16	Malawi*	Yes, 2016	Yes*	2016	HTS	Eng ji sh <mark>8</mark>	Yes	High
Eastern	17	Mauritius	No	Yes	2020	HTS	Enge sh 💐	Yes	Low
Africa	18	Mozambique	Yes, 2016	Yes	2020	PMTCT	Portuguese	Yes	High
	19	Rwanda	Yes, 2016	Yes	2018	HTS	Engesh 5	Yes	Low
	20	Seychelles	No	Yes	2019	HTS	Engaish 🕰	Yes	Low
	21	South Sudan	Yes, 2017	Yes	2020	ART	Engesh 🖌	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	26	Botswana**	Yes, 2016	No	2016	ART	English 🛱	Yes	High
Africa	27	eSwatini**	Yes, 2018	No	2018	ART	English e	Yes	High
AITICd	28	Lesotho	Yes, 2016	Yes	2021	PMTCT	English	Yes	High

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

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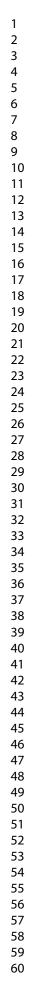
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							22-07 [.] right,		
	29	Namibia	Yes, 2016	Yes	2018	HTS	Eng a sh 🔂	Yes	High
	30	South Africa	Yes, 2016	Yes	2020	ART	Engesh 2	Yes	High
	31	Algeria**	Yes, 2013	No	2013	HTS	Fregich S	Yes	Low
	32	Benin	No	Yes	2017	HTS	Fre ថ្មី ch 🖉	Yes	Low
	33	Burkina Faso	Yes, 2008	Yes	2021	ART	Fre	Yes	Low
	34	Cabo Verde	No	No	_	-	mbu nse eş ı	_	_
	35	Ghana	Yes, 2014	Yes	2019	ART	Freisigen es region Engen	Yes	Low
	36	Guinea	No	Yes	2019	HTS	Fre	Yes	Low
	37	Guinea-Bissau 🦯	No	Yes	2021	ART	Portugines	Yes	Low
Wastorp	38	Ivory Coast**	Yes, 2016	No	2016	HTS	Fre	Yes	Low
Western Africa	39	Liberia	Yes, 2015	Yes	2020	HTS	Engesting	Yes	Low
Annca	40	Mauritania	No	Yes	2020	HTS	Fre	Yes	Low
	41	Mali	No	Yes	2017	HTS	Fread of a transfer	Yes	Low
	42	Niger	No	Yes	2020	HTS	Fre	Yes	Low
	43	Nigeria	Yes, 2016	Yes	2020	ART		Yes	Low
	44	Senegal	Yes, 2017	Yes	2018	HTS	Freigch	Yes	Low
	45	Sierra Leone	Yes, 2017	Yes	2020	ART	Eng li sh <mark>3</mark>	Yes	Low
	46	The Gambia	Yes, 2014	Yes	2019	ART	Eng	Yes	Low
These cou	47 ntries pro	Togo ovided an updated HIV	No ' testing algorithm	Yes n despite havir	2019 ng an old HIV	HTS testing guid	Fregach	Yes	Low
These cou * These co	47 ntries pro ountries d	Togo ovided an updated HIV did not provide an upd	No ' testing algorithm ate HIV testing gu	Yes n despite havir ideline but we	2019 ng an old HIV ere included	HTS testing guid in the analy	Freight, and similar technologies.	Yes	Low

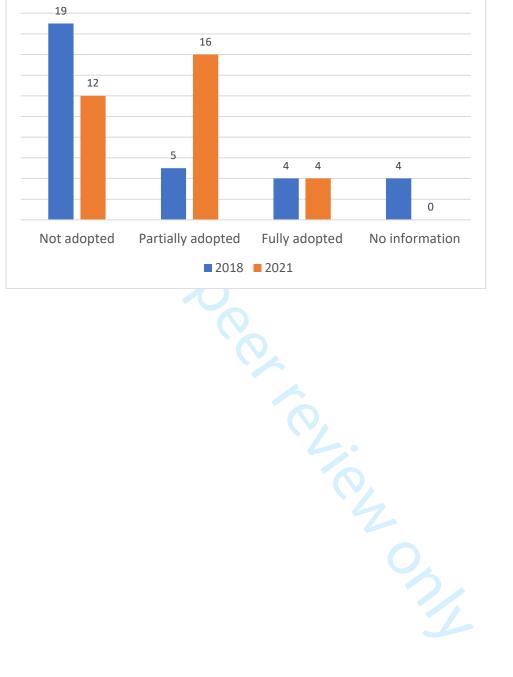
Supplementary Table 3. Progress on policy adoption in the WHO African Region from 2018 to 2021

Subregion	Count	Country	Policy reviewed in 2018?	Adherence in 2018	Policy reviewed in 2021	Adherence in 2021
	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
Central	4	Chad	Yes, 2011	Not adopted	2017	Mostly adopted
Africa	5	DRC	Yes, 2017	Adopted	2020	Adopted
Africa	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
	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
Eastern	17	Mauritius	No	_	2020	Not adopted
Africa	18	Mozambique	Yes, 2016	Not adopted	2020	Mostly adopted
	19	Rwanda	Yes, 2016	Not adopted	2018	Mostly adopted
	20	Seychelles	No	_	2019	Not adopted
ľ	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
	26	Botswana	Yes, 2016	Mostly adopted	2016	Not adopted
Couthorn	27	eSwatini	Yes, 2018	Not adopted	2018	Not adopted
Southern	28	Lesotho	Yes, 2016	Adopted	2021	Mostly adopted
Africa	29	Namibia	Yes, 2016	No information	2018	Not adopted
	30	South Africa	Yes, 2016	Mostly adopted	2020	Not adopted
	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
Western	39	Liberia	Yes, 2015	Not adopted	2020	Mostly adopted
Africa	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
-		The Gambia	Yes, 2014	Not adopted	2019	Not adopted
	46	THE Gallipia				

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)







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subregions	Pol	icies revie	wed	Serial t	esting str	ategy		reaker* te		to A	•••	3-test or	0	V/syphilis	No use of Western Blot
(countries)								strategy		initia	tion	strategy	Ens	test**	
Year	2014	2018	2021	2014	2018	2021	2014	2018	2021	2018	2021	2021 ea	eign	2021	2021
All	25	32	45	21	26	29	15	26	37	16	23	21	eme	3 21	35
(n=47)	(53%)	(68%)	(96%)	(84%)	(81%)	(64%)	(60%)	(81%)	(82%)	(50%)	(51%)	(47%) ố tế	ent Su		(78%)
Western	6	9	16	5	7	9	4	5	9	1	5	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	adr	7	10
(n=17)	(35%)	(53%)	(94%)	(83%)	(78%)	(56%)	(67%)	(56%)	(56%)	(11%)	(31%)	(50%) da	rieur	(44%)	(63%)
Central	4	5	8	4	5	7	3	4	7	1	5	₃ ta m	AB	2	6
(n=9)	(44%)	(56%)	(89%)	(100%)	(100%)	(88%)	(75%)	(80%)	(88%)	(20%)	(63%)	(38%) lining	ES)	(25%)	(75%)
Eastern	11	13	16	10	10	12	5	12	16	9	9	9 , A		9	14
(n=16)	(69%)	(81%)	(100%)	(91%)	(77%)	(75%)	(45%)	(92%)	(100%)	(69%)	(56%)	(56%) train		. (56%)	(88%)
Southern	4	5	5	2	4	1	3	5	5	5	4	1 ng	en.	3	5
(n=5)	(80%)	(100%)	(100%)	(40%)	(80%)	(20%)	(75%)	(100%)	(100%)	(100%)	(80%)	(20%) and		(60%)	(100%)

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

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

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

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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
	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)
2-assay	14	Uganda	Determine	StatPak	SD Bioline (for discordants)
	15	Nigeria	Determine Uni-Gold Stat-Pak Double Check Gold Sure Check HIV Quick Check	Determine Uni-Gold Stat-Pak Double Check Gold Sure Check HIV Quick Check	Determine Uni-Gold Stat-Pak Double Check Gol Sure Check HIV Quick Check (as tiebreaker)
	16	Togo	Murex HIV Ag/Ab Apdia HIV Ag/Ab Determine Alere Combo Vikia HIV 1/2 Wanta Rapid Test ABON HIV 1/2/0 Standard Q Hexagon Genie Fast SD Bioline First Response SD Bioline HIV/Syphilis OraQuick HIV Self-Test	ABON HIV 1/2/0 Standard Q SD Bioline First Response HIV Tri-Dot	INNOLIA or Geniu (as tiebreaker)
	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
2 2000	20	Guinea	Determine	SD Bioline	Multisure
3-assay	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

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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: Determine Double check Gold Ultra Onsite HIV1+2 Plus Combo VIKIA HIV 1/2 4th generation: Alere Ag/Ab Combo OnSite HIV Ab/Ag (CTK)	HIV TriDot ImmunoFlow OnSite HIV 1/2 Ab Plus (CTK) 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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Keywords: Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, HIV & AIDS < INFECTIOUS DISEASES, Diagnostic microbiology < INFECTIOUS DISEASES	Keywords:	HIV & AIDS < INFECTIOUS DISEASES, Diagnostic microbiology <





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1	Title: Country adoption of WHO 2019 guidance on HIV testing strategies and algorithms: a
2	policy review across the WHO African region
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25 ABSTRACT26 Objectives: In 2

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.

29 **Design:** Policy review

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

31 **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.

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

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.9	Keywords: HIV, diagnosis, rapid test, dual HIV/syphilis, policy, guideline, Africa, algorithm
0	Strengths and limitations of this study
1	• This study provided a comprehensive review of existing national HTS policies in the
2	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

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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 Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.

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> 95 undiagnosed and not in care will continue to decline. As a result, the positive predictive value 96 of previous testing strategies will also decline and lead to an increase in false positive 97 diagnoses. In relation to the guideline development process, WHO now recommends all 98 countries use a standard 3-test strategy.[8] WHO also recommends that countries planning 99 to update their HIV testing algorithms undertake a verification study to select appropriate HIV 100 serology products and ensure they do not cross-react in order to minimize the risk of 101 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.

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• 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]

104 To support the implementation of the 2019 guidelines, WHO launched and disseminated the 105 guidance at the Africa Society of Laboratory Medicine and the International Conference on 106 AIDS and STIs in Africa. Following this, WHO also provided detailed country support to adopt 107 the guidelines along with developing an application to access the guidelines more easily. In 108 addition to dissemination and country support, [10] it is critical to monitor and track the 109 implementation of WHO policy uptake to understand policy priorities and challenges 110 overtime. Such tracking not only provides valuable insights but can help guide revisions to 111 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

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

122 METHODS

123 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]

136 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. Page 9 of 40

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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.

149 Analysis

50 We assessed national adoption of WHO HTS guidance using six specific recommendations 51 related to testing strategies and algorithms for those \geq 18 months of age set forth in the WHO 52 2019 HIV testing guidelines, namely: (1) use of serial testing, (2) use of a 3-test strategy, (3) 53 discontinuation of a tie-breaker to rule in HIV infection, (4) discontinuation of WB/LIA, (5) 54 retesting prior to ART initiation, and (6) use of dual HIV/syphilis RDT in ANC. Additional 55 qualitative details about the national testing algorithm, such as the order of and name brand 56 of test kits used in testing algorithms, were also reviewed when reported and assessed 57 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.

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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

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3 4	190	reported by UNAIDS [1], 34 countries (76%) had a low HIV prevalence (<5%) and 11 countries
5 6 7	191	(24%) had a high HIV prevalence (≥5%) (online supplementary table 2).
, 8 9	192	
10 11 12	193	Overall adoption of WHO-recommended HIV testing strategies
12 13 14	194	In 2021, 59% of national testing strategies (n=28/45) were either fully or partially aligned with
15 16	195	WHO 2019 HTS recommendations and 36% (n=17/47) had not adopted the recommendations
17 18 19	196	(table 1). When the analysis was restricted to a subset of countries with policies in both the
20 21	197	2018 and 2021 review (n=32), the proportion adopting WHO guidance in 2018 was 28%
22 23 24	198	(n=9/32) vs 62% (n=20/32) in the current (2021) review (see online supplementary table 3;
25 26	199	supplementary figure 2). Across the sub-regions, Southern (80%) and Eastern (75%) Africa had
27 28 29	200	the greatest level of alignment, whilst Central Africa (63%) and Western Africa (44%) had the
30 31	201	lowest adoption rates (table 1; figure 2).
32 33 34	202	
34 35 36	203	In low-prevalence countries (n=34), 53% of policies (n=18/34) had fully or mostly adopted the
37 38	204	guidance and 47% (n=16/34) had generally not adopted guidance. The most common reasons
39 40 41	205	for non-adoption were not using a dual HIV/syphilis RDT in ANC (n=15/34), no retesting prior
42 43	206	to ART initiation (n=14/34) and using only two assays to make an HIV-positive diagnosis
44 45 46	207	(n=10/34). In high-prevalence countries (n=11), 91% of policies (n=10/11) had fully or nearly
47 48	208	adopted WHO guidance and 9% had not adopted WHO guidance (1/11). The most common
49 50 51	209	reasons for not fully adopting WHO guidance were continuing to use a 2-test strategy to make
52 53	210	an HIV-positive diagnosis (n=10/11), employing both serial and parallel testing strategies
54 55 56	211	(n=4/11), not adopting dual HIV/syphilis RDTs in ANC (n=4/11) and not implementing
57 58	212	retesting prior to ART initiation ($n=3/11$). Overall, only one out of eleven high HIV-burden
59 60	213	countries, Zimbabwe, recommended the use of a 3-assay testing strategy (18%).

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 BMJ Open Table 1. Policy adoption of 2019 WHO-recommended HIV testing strategies in the WHO African region, difference of the testing strategies in the WHO African region, and the testing strategies in the WHO African region, and the testing strategies in the WHO African region, and the testing strategies in the WHO African region, and the testing strategies in the WHO African region, and the testing strategies in the WHO African region, and the testing strategies in the WHO African region, and the testing strategies in testing strategies in the testing strategies in testing strategies strategies in testing strategies in testing strategies strategie

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

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

*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 attentiated 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, $\mathbf{\hat{s}}$ s of 2023, use of the dual test is recommended among key populations and those with high ongoing risk. Agence Bibliographique de l

1 2		
3 4	226	Adoption of serial testing strategy
5 6 7	227	In 2021, 62% of national testing strategies (n=29/47) adopted the use of serial testing and
7 8 9	228	36% (n=16/47) recommended the mix use of serial and parallel testing (figure 3_1). The
10 11	229	subregions with the highest adoption were Central (78%) and Eastern Africa (75%), followed
12 13 14	230	by Western Africa (38%); Southern Africa had the lowest adoption rate (20%) (table 1).
14 15 16	231	However, fewer countries in southern Africa recommended serial testing in 2021 (n=1) than
17 18	232	in 2018 (n=4) (supplementary table 4). Most policies recommending serial or parallel testing
19 20 21	233	(n=15/16) conducted simultaneous testing of assay 1 (A1) and assay 2 (A2) in case of
22 23	234	discrepant test results, and the Namibian policy recommended parallel testing of A2 and A3
24 25 26	235	after a reactive A1.
27 28	236	
29 30	237	Only 43% of policies (n=20/47) provided guidance on the assay order in relation to their
31 32	238	sensitivity and specificity. The proportion of HIV testing strategies/algorithms using two
33 34 35	239	consecutive HIV-reactive tests to make an HIV-positive diagnosis was 51% (n=24/47) whereas
36 37	240	45% (n=21/47) recommended the use 3 consecutive HIV-reactive tests.
38 39	241	
40 41 42	242	Sixty-four percent of the HIV testing strategies reviewed (n=29/45) included information on
43 44	243	the testing algorithms, i.e., contained specific product names and all of them included WHO
45 46	244	prequalified products. Determine HIV 1/2 (Abbott Diagnostics Medical Co., Ltd, Japan) was
47 48 49	245	the most common product used as A1 and Bioline HIV 1/2 3.0 (Abbott Diagnostics Korea Inc.,
50 51	246	Republic of Korea) or Uni-Gold HIV (Trinity Biotech, Ireland) as A2 or A3 (see online
52 53 54	247	supplementary table 5). Only 31% of reviewed policies (n=14/45) mentioned the need to
55 56	248	locally verify or validate the HIV testing algorithm.
57 58 59	249	
59 60		

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3 4	250	Discontinuation of a tiebreaker testing strategy
5 6 7	251	The discontinuation of a third assay to rule in HIV infection (i.e., tiebreaker) was
7 8 9	252	recommended in 78% of national policies (n=37/47) (figure 3_2). The subregions with the
10 11	253	highest adoption were in Southern Africa and Eastern Africa (100%, each) followed by Central
12 13 14	254	Africa (78%), whereas Western Africa had the lowest adoption (53%) (table 1).
14 15 16	255	
17 18	256	Of the eight policies recommending a tiebreaker testing strategy, seven were from Western
19 20 21	257	Africa and one from Central Africa. Seven policies specified the type of A3 to be used, for
22 23	258	example, RDT (n=4), RDT or EIA (n=1), nucleic acid testing (NAT: n=2) and LIA (n=1).
24 25 26	259	
20 27 28	260	Adoption of WHO standard 3-assay testing strategy
29 30	261	The use of three consecutive HIV-reactive tests for the diagnosis of HIV was recommended by
31 32 33	262	45% of the policies (n=21/47) (figure 3_3). The adoption of this WHO recommendation was
34 35	263	highest in Eastern Africa (56%) and Western Africa (47%) and lowest in Southern Africa (20%)
36 37 38	264	(table 1). Most policies recommending a 3-test strategy (n=20/21) were from low HIV-
39 40	265	prevalence countries. Among high HIV-prevalence countries, only one out of eleven countries
41 42 43	266	(9%) officially recommended the use of a 3-test strategy, which was Zimbabwe.
44 45	267	
46 47	268	Overall, across countries which had policies reviewed in both 2018 and 2021, 9 policies that
48 49 50	269	previously recommended a 2-test strategy transitioned to a 3-test strategy as of 2021
51 52	270	(Burkina Faso, Burundi, Chad, Ethiopia, Ghana, Kenya, Lesotho, Madagascar, and Zimbabwe,
53 54 55	271	respectively).
56 57	272	
58 59	_, _	
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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).

283 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.

⁷₅ 294 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.

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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].

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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

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367 this recommendation it may be important for WHO to provide alternative quality assurance368 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 (\geq 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

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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]

411 Considering that the recommendation to use dual HIV/syphilis RDTs in ANC was released only 412 in 2019,[6, 23] its adoption by 21 countries has been encouraging. The number of countries 413 adopting dual HIV/syphilis RDTs among pregnant women continues to increase and may be 414 in practice higher considering that preliminary National Commitments and Policy Instrument

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(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]

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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

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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

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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-assay 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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3 4	510	Competing interests
5 6 7	511	The authors declare no competing interests. The contents in this article are those of the
8 9	512	authors and do not necessarily reflect the view of the World Health Organization.
10 11	513	
12 13 14	514	Patient consent for publication
15 16	515	Not required.
17 18 19	516	
20 21	517	Ethics approval
22 23 24	518	This study does not involve human participants and ethical approval was therefore not
25 26	519	required.
27 28 29	520	
29 30 31	521	Data availability statement
32 33	522	All data generated in the study are included in the article or uploaded as supplementary
34 35 36	523	information. National policies may be publicly available. Some policies included in this review
37 38	524	may be available through the following websites: (1)
39 40 41	525	https://aidsfree.usaid.gov/resources/guidance-data/hts. (2)
42 43	526	http://www.hivpolicywatch.org/database.html. If information on a policy cannot be found
44 45 46	527	through these resources, please contact the authors of this review for additional information.
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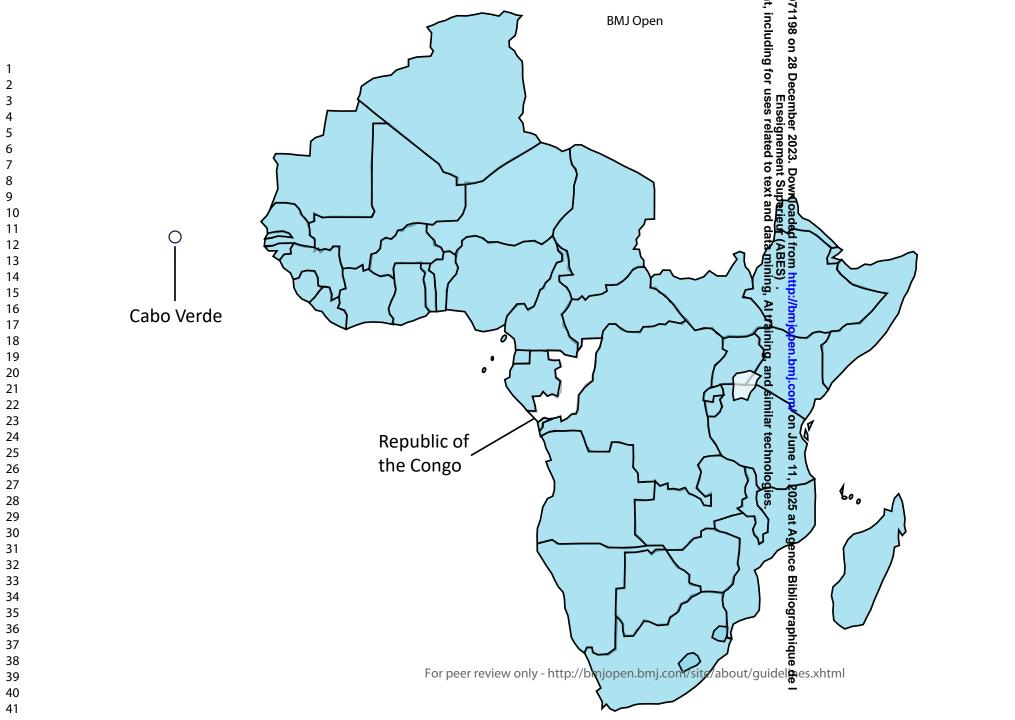
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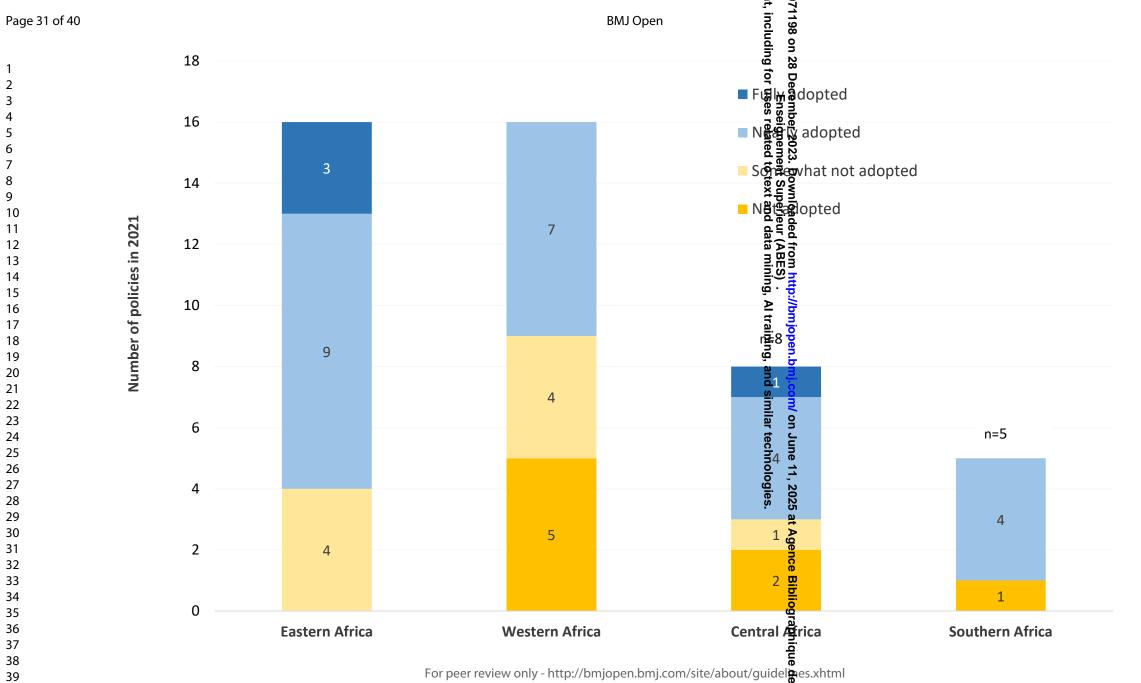
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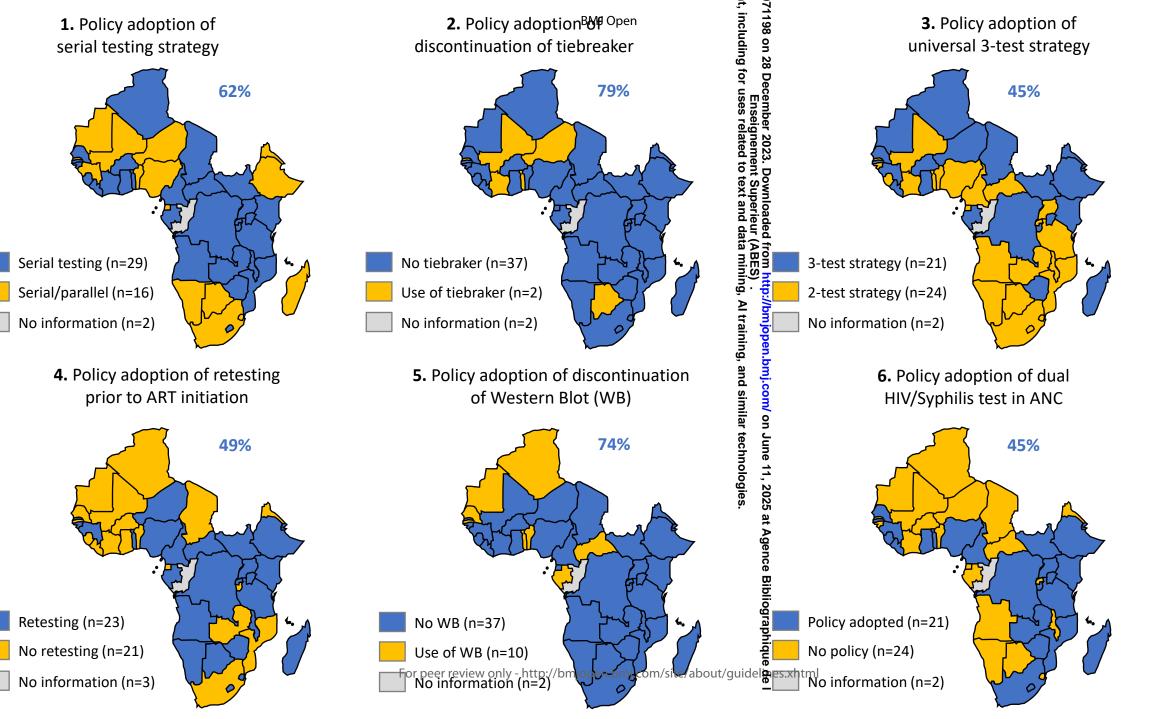
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1 2 3 4 5	674 675	Figure legends
6 7 8	676	Figure 1. Countries from the WHO African Region with HIV testing policies identified (in blue)
9 10	677	and included in the analysis (n=45/47). The two countries not included in the review are
11 12 12	678	indicated in the map.
13 14 15	679	
16 17	680	Figure 2. Overall adoption of 2019 WHO HIV testing strategies in Africa by subregion in 2021.
18 19 20	681	
21 22	682	Figure 3. Policy adoption in 2021 of six specific WHO HIV testing recommendations in the
23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46	683	WHO African Region.
47 48 49 50 51 52 53 54 55 56 57 58 59 60		





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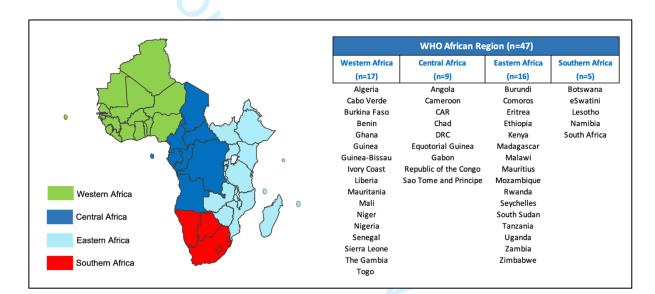
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Supplementary Appendix

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



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

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Subregion	Count	Country	Policy reviewed in 2018?	New policy or algorithm identified?	Publication year	Type of document	Langer us	Algorithm provided?	National HIV prevalence
	1	Angola	Yes, 2015	Yes	2020	HTS	<u>ы</u> Portuguiaes	Yes	Low
	2	Cameroon	Yes, 2015	Yes	2019	ART	Fre	Yes	Low
	3	CAR	Yes, 2010	Yes	2018	ART	Freight	Yes	Low
	4	Chad	Yes, 2011	Yes	2017	HTS	Fre ð 🛱 🙀	Yes	Low
Central	5	DRC	Yes, 2017	Yes	2020	ART	Fregic 2	Yes	Low
Africa	6	Equatorial Guinea	No	Yes	2018	ART	Spaniano	Yes	Low
	7	Gabon	No	Yes	2017	HTS	Freduct fro	Yes	Low
	8	Republic of the Congo	No	No	_	_	id fi iața	-	_
	9	São Tomé e Principe	No	Yes	2018	Algorithm	Portu	Yes	Low
	10	Burundi	Yes, 2016	Yes	2020	HTS	Fregen	Yes	Low
	11	Comoros	Yes, 2007	Yes	2016	HTS	French	Yes	Low
	12	Eritrea	No	Yes	2019	HTS	Engues Sha	Yes	Low
	13	Ethiopia	Yes, 2017	Yes	2018	ART	Engesh S	Yes	Low
	14	Kenya	Yes, 2017	Yes	2021	HTS	Engaish 🗧	Yes	Low
	15	Madagascar	Yes, 2011	Yes	2018	HTS	Fre g ch	Yes	Low
	16	Malawi*	Yes, 2016	Yes*	2016	HTS	Eng ij sh <mark>8</mark>	Yes	High
Eastern	17	Mauritius	No	Yes	2020	HTS	Eng a sh 💐	Yes	Low
Africa	18	Mozambique	Yes, 2016	Yes	2020	PMTCT	Portuguese	Yes	High
	19	Rwanda	Yes, 2016	Yes	2018	HTS	Engeshin	Yes	Low
	20	Seychelles	No	Yes	2019	HTS	Eng ə sh 🕰	Yes	Low
	21	South Sudan	Yes, 2017	Yes	2020	ART	Engash	Yes	Low
	22	Tanzania	Yes, 2017	Yes	2021	HTS	Eng a sh 22	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	26	Botswana**	Yes, 2016	No	2016	ART	English 🛱	Yes	High
Africa	27	eSwatini**	Yes, 2018	No	2018	ART	English E	Yes	High
Anica	28	Lesotho	Yes, 2016	Yes	2021	PMTCT	English g	Yes	High

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

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							22-07 [.] right,		
	29	Namibia	Yes, 2016	Yes	2018	HTS		Yes	High
	30	South Africa	Yes, 2016	Yes	2020	ART	Engesno	Yes	High
	31	Algeria**	Yes, 2013	No	2013	HTS	Fregen k	Yes	Low
	32 Benin		No	Yes	2017	HTS	Fre g ch 🖉	Yes	Low
	33 Burkina Faso Yes, 2008			Yes	2021	ART	Fre	Yes	Low
	34	Cabo Verde No		No	-	-	nbe eş i	-	_
	35	Ghana	Yes, 2014	Yes	2019	ART	Eng∰ase	Yes	Low
	36	Guinea	No	Yes	2019	HTS	Fre	Yes	Low
	37	Guinea-Bissau 🦯	No	Yes	2021	ART	Portugues	Yes	Low
Western	38	Ivory Coast**	Yes, 2016	No	2016	HTS	Fre	Yes	Low
Western Africa	39	Liberia	Yes, 2015	Yes	2020	HTS	Engelsen	Yes	Low
Anica	40	Mauritania	No	Yes	2020	HTS	Fre	Yes	Low
	41	Mali	No	Yes	2017	HTS	Fre	Yes	Low
	42	Niger	No	Yes	2020	HTS	Fre	Yes	Low
	43	Nigeria	Yes, 2016	Yes	2020	ART	Eng	Yes	Low
	44	Senegal	Yes, 2017	Yes	2018	HTS	French	Yes	Low
	45	Sierra Leone	Yes, 2017	Yes	2020	ART	Enguish 🖥	Yes	Low
	46	The Gambia	Yes, 2014	Yes	2019	ART	Eng	Yes	Low
	47	Togo	No	Yes	2019	HTS	Fregen 🕺	Yes	Low
* These co	ountries o	did not provide an upda	ate HIV testing gu	iideline but we	ere included i	in the analy	sis simil		
		ovided an updated HIV did not provide an upda					mj.com/ on June 11, 2025 at Agence and similar technologies. sis		

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
	1	Angola	Yes, 2015	Not adopted	2020	Mostly adopte
Central Africa	2	Cameroon	Yes, 2015	Not adopted	2019	Mostly adopte
	3	CAR	Yes, 2010	Not adopted	2018	Not adopted
	4	Chad	Yes, 2011	Not adopted	2017	Mostly adopte
	5	DRC	Yes, 2017	Adopted	2020	Adopted
	6	Equatorial Guinea	No	_	2018	Not adopted
	7	Gabon	No	_	2017	Mostly adopte
	8	Republic of the Congo	No	-	-	-
	9	São Tomé e Principe	No	_	2018	Not adopted
	10	Burundi	Yes, 2016	Not adopted	2020	Mostly adopte
	11	Comoros	Yes, 2007	No information	2016	Not adopted
	12	Eritrea	No	_	2019	Not adopted
	13	Ethiopia	Yes, 2017	No information	2018	Mostly adopte
	14	Kenya	Yes, 2017	Mostly adopted	2021	Adopted
	15	Madagascar	Yes, 2011	No information	2018	Mostly adopte
	16	Malawi	Yes, 2016	Not adopted	2016	Mostly adopte
Eastern	17	Mauritius	No	_	2020	Not adopted
Africa	18	Mozambique	Yes, 2016	Not adopted	2020	Mostly adopte
	19	Rwanda	Yes, 2016	Not adopted	2018	Mostly adopte
	20	Seychelles	No	_	2019	Not adopted
	21	South Sudan	Yes, 2017	Not adopted	2020	Adopted
	22	Tanzania	Yes, 2017	Not adopted	2021	Mostly adopte
	23	Uganda	Yes, 2016	Mostly adopted	2020	Mostly adopte
	24	Zambia	Yes, 2018	Not adopted	2020	Not adopted
	25	Zimbabwe	Yes, 2016	Adopted	2016	Adopted
	26	Botswana	Yes, 2016	Mostly adopted	2016	Not adopted
Couthown	27	eSwatini	Yes, 2018	Not adopted	2018	Not adopted
Southern	28	Lesotho	Yes, 2016	Adopted	2021	Mostly adopte
Africa	29	Namibia	Yes, 2016	No information	2018	Not adopted
	30	South Africa	Yes, 2016	Mostly adopted	2020	Not adopted
	31	Algeria	Yes, 2013	Adopted	2013	Not adopted
	32	Benin	No	_	2017	Not adopted
	33	Burkina Faso	Yes, 2008	Not adopted	2021	Mostly adopte
	34	Cabo Verde	No	_	_	_
	35	Ghana	Yes, 2014	Not adopted 🥁	2019	Mostly adopte
	36	Guinea	No	_	2019	Mostly adopte
	37	Guinea-Bissau	No	_	2021	Not adopted
Mastara	38	Ivory Coast	Yes, 2016	Not adopted	2016	Not adopted
Western	39	Liberia	Yes, 2015	Not adopted	2020	Mostly adopte
Africa	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 adopte
	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	Тодо	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)

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

AFRO					2010 11		1	ontinuati		Retestir		Universa		, 2014-2021
subregions	Pol	icies revie	ewed	Serial t	esting str	ategy	tieb	reaker* to	esting	to A	RT	3-test		No use of
(countries)								strategy	,	initia	tion	strategy	Centest**	Western Bl
Year	2014	2018	2021	2014	2018	2021	2014	2018	2021	2018	2021	2021 🗗	2021	2021
All	25	32	45	21	26	29	15	26	37	16	23	21 🖁	länö 21	35
(n=47)	(53%)	(68%)	(96%)	(84%)	(81%)	(64%)	(60%)	(81%)	(82%)	(50%)	(51%)	(47%)		(78%)
Western	6	9	16	5	7	9	4	5	9	1	5	8 an	uper 7	10
(n=17)	(35%)	(53%)	(94%)	(83%)	(78%)	(56%)	(67%)	(56%)	(56%)	(11%)	(31%)	(50%)	wnloaded buperieur Lur	(63%)
Central	4	5	8	4	5	7	3	4	7	1	5	2 01		6
(n=9)	(44%)	(56%)	(89%)	(100%)	(100%)	(88%)	(75%)	(80%)	(88%)	(20%)	(63%)	(38%)	BES) (25%)	(75%)
Eastern	11	13	16	10	10	12	5	12	16	9	9	9 9	• • •	14
(n=16)	(69%)	(81%)	(100%)	(91%)	(77%)	(75%)	(45%)	(92%)	(100%)	(69%)	(56%)	(56%) train		(88%)
Southern	4	5	5	2	4	1	3	5	5	5	4	1 9	en . 3	5
(n=5)	(80%)	(100%)	(100%)	(40%)	(80%)	(20%)	(75%)	(100%)	(100%)	(100%)	(80%)	(20%) and		(100%)
Use of a tl *Dual HIV												similar technologies.	om/ on June 11, 2025	
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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	
	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)	
2-assay	14	Uganda	Determine	StatPak	SD Bioline (for discordants)	
,	15	Nigeria	Determine Uni-Gold Stat-Pak Double Check Gold Sure Check HIV Quick Check	Determine Uni-Gold Stat-Pak Double Check Gold Sure Check HIV Quick Check	Determine Uni-Gold Stat-Pak Double Check Golc Sure Check HIV Quick Check (as tiebreaker)	
	16	Togo	Murex HIV Ag/Ab Apdia HIV Ag/Ab Determine Alere Combo Vikia HIV 1/2 Wanta Rapid Test ABON HIV 1/2/0 Standard Q Hexagon Genie Fast SD Bioline First Response SD Bioline HIV/Syphilis OraQuick HIV Self-Test	ABON HIV 1/2/0 Standard Q SD Bioline First Response HIV Tri-Dot	INNOLIA or Genius (as tiebreaker)	
	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	
3-assay	20	Guinea	Determine	SD Bioline	Multisure	
e assay	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	

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2					
2 3	26	Niger	Alere Combo	Wondfo One Step	SD Bioline
4	27	Senegal	Determine	SD Bioline	Multisure
5	28	Zimbabwe	Determine	Chembio	INSTI
6 7 8 9 10 11 12 13 14	29	Burkina Faso	3rd generation: Determine Double check Gold Ultra Onsite HIV1+2 Plus Combo VIKIA HIV 1/2 4th generation: Alere Ag/Ab Combo OnSite HIV Ab/Ag (CTK)	HIV TriDot ImmunoFlow OnSite HIV 1/2 Ab Plus (CTK) SD Bioline	Any of those not selected as A1 or A2
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