ANNEX 2. An analysis of 48 national HIV testing and counselling policies.

Authors: Flynn D[1], Johnson C[2], Sands A[3], Wong V[4], Baggaley R[2]

2.1 Purpose

National HIV testing guidelines are critical to the success and expansion of HIV testing services. This report sought to analyse national HIV testing policies in WHO focal countries.

The focus of this review was two-fold:

1) To determine whether national HIV testing policies permit lay providers and nurses (working in community settings) to perform HIV rapid diagnostic testing and counselling services in their countries and;
2) Whether the national HIV testing strategies (outlined in HIV testing policies) aligned with WHO recommendations.

2.2 Introduction

HIV testing services (HTS) are the gateway to prevention, care and treatment of those with HIV. Despite achievements in the scale-up and expansion of HTS over the past three decades, it is estimated that only 45% of people with HIV are aware of their serostatus *(1)*. Furthermore, there are two million new infections annually, of which nearly half are among key populations *(2)*. In order to continue to effectively and efficiently expand HTS, the service should focus on reaching people with HIV who are undiagnosed and those who are HIV negative with an ongoing HIV risk who could benefit from prevention services.

Additional and more focused HTS approaches are critical to reach the UNAIDS "90-90-90" global targets, in which the first "90" aims for 90% of all people with HIV to know their serostatus by 2020 *(3)*. In order to reach the first 90, two critical issues need to be addressed: First, staff shortages which limit the expansion of HTS in low-resource settings *(4-6)*; and second, poor quality HIV testing—in particular, use of suboptimal testing strategies which can lead to significant rates of inaccurate test results and misdiagnosis of HIV infection *(7-11)*.

Lay providers

Due to the high burden and level of need, trained lay providers have been delivering HTS for decades *(12)* across the Americas *(13)*, Europe *(14, 15)*, sub-Saharan Africa *(16-22)* and Asia *(23)*. Task-sharing—the rational redistribution of tasks from "higher-level" cadres of health professionals to trained lay provider cadres[5]—can expand HTS more broadly, is acceptable and has been shown to increase uptake of HIV testing *(13, 17, 24)*. It has been shown to be of high quality with accurate HIV test results *(16, 23)*, and may also be lower in cost than services provided by health providers. In addition, evidence does suggest that key populations may particularly benefit from peer-based services, including the provision of community-based HIV testing *(25, 26)*. Several systematic reviews, from various domains of health care, support the general conclusion that good health outcomes can be achieved by devolving tasks to nurses and lay or community health workers *(27-30)*. WHO guidance supports the use of lay providers to perform some clinical services, including counselling and referrals, and particularly recommends such task-sharing in the delivery of HIV clinical services *(24, 31, 32)*. In this guidance, WHO has issued a **strong recommendation** for trained lay providers to perform HIV testing services using rapid diagnostic tests (RDTs) *(33)*.

[1] Griffith University School of Medicine, Queensland, Australia
[2] WHO, HIV/AIDS Department, Geneva, Switzerland
[3] WHO, Essential Medicines and Health Products, Geneva, Switzerland
[4] USAID, Global Health Bureau, Office of HIV/AIDS, Washington, DC
[5] Any person who performs functions related to health-care delivery and has been trained to deliver services but has received no formal professional or paraprofessional certificate or tertiary education degree.

Currently in many settings trained lay providers are not permitted to conduct HTS, including pre-test information, performing a HIV RDT (collecting specimen, performing the test, interpreting the result) and providing post-test counselling, referrals and support for the linkage to prevention, care and treatment *(34, 35)*. As a result, access to and uptake of HTS remains suboptimal in many settings, particularly from among key populations and other vulnerable groups *(36, 37)*.

Quality of HIV testing

HIV RDTs have been used in low-resource settings since the 1990s and are acceptable and feasible. HIV RDTs are highly accurate in diagnosing people with HIV and have been shown to be equivalent to laboratory-based testing when used within a WHO recommended testing strategy[6] *(38)*. HIV RDTs allow HIV testing services to be performed by lay providers and outside of health facilities, they do not require venepuncture and can provide same day test results and diagnosis *(37, 39, 40)*. However, most recently there have been a number of reports on poor quality HIV testing *(41)*.

Multiple sources have flagged the use of poor quality testing services and suboptimal quality assurance *(9-11, 41-43)*, some of which are due to health worker shortages, mistakes and errors *(9)*. In addition to human errors, a common error is implementation of inaccurate HIV testing strategies and testing algorithms. Most recently, several studies report that a testing strategy referred to as a "tie-breaker", where two discordant test results are resolved by a third assay whereby a HIV positive diagnosis was issued based on a reactive result for the third assay, leads to misclassifying people who are more likely to be truly HIV negative as HIV positive *(44-47)*.

Although the publication of these WHO testing guidelines have been available for several years, there is limited information in literature indicating the rate of uptake of the WHO testing strategies *(48)*. Anecdotal evidence suggests that sub optimal testing strategies, as set out in national HIV testing policies are a major contributor to high rates of misdiagnosis.

In order to investigate the uptake of WHO HTS recommendations globally, an analysis of national HIV testing policies from WHO Member States was undertaken. Data regarding whether lay providers and nurses could perform HIV testing with fingerstick blood-based and oral fluid-based RDTs was extracted as well as information regarding whether they were permitted to perform pre and post-test counselling. The national HIV testing strategy and testing algorithms of each country was also extracted and analysed to see if it aligned with WHO recommendations.

2.3 Methods

Data collection

Electronic searches for national HIV testing policies were conducted using Google, governmental and non-governmental websites, and WHO databases from 1st November 2014 to 21st December 2014. WHO and UNAIDS regional technical advisors, and key experts in the field were also contacted[7]. The most recent national HIV testing policies identified were then retained for analysis. Two reviewers assessed each policy. National HIV testing policies were included in this review. Standards and protocols developed by non-government organizations, donors or other technical agencies were excluded. There were no geographic or language restrictions on this analysis. However, English language versions of all policies were sought when available.

Policies were reviewed in full-text and analysed from 11 November 2014-22 January 2015. A data extraction tool was developed by: Vincent Wong[4], Charlene Brown[4], Anita Sands[3], Rachel Baggaley[2], Cheryl Johnson[2] and David Flynn[1].

[6] WHO recommends standardized testing strategies - at least two serial tests in high prevalence settings (HIV prevalence >5%), and three tests in lower prevalence settings (HIV prevalence <5%), where the positive and negative predictive values for the testing strategies are above 99%.

[7] See Table 2.1 and Table 2.2 for countries where this applies.

Using the extraction tool, one reviewer (DF) extracted data, which was then reviewed by RB and CJ. Any disagreement between reviewers was addressed and resolved through discussion and consensus by RB, CJ and DF.

Testing strategy evaluation

To align with WHO recommendations, the testing strategies must adhere to the guidelines put forward in *Service delivery approaches to HIV testing and counselling (HTC): A strategic policy framework (38)*.

The strategies must conform to the following guidelines, illustrated in section 7.1:

- The national testing strategy used must be in line with the HIV prevalence of the country as determined by the most up to date statistical data available from UNAIDS *(49)*. As per WHO guidelines), testing populations are divided into high prevalence (>5%) or low prevalence (<5%).
- The strategy must test specimens/individuals in a serial manner, meaning that the result of the -line assay is read and interpreted before the decision on if to proceed to the second-line assay, and so on.
- The strategy must not use the result of the third assay as a tiebreaker to rule in HIV infection, it may be used to rule out HIV infection.

Specifically for high prevalence settings (>5%):

- If the specimen is reactive on the first assay (A1), the specimen should be tested on another assay.
- If the specimen is reactive on the second assay (A2), the result should be reported as HIV-positive.
- If discrepant results are found between assay 1 and 2 (A1+, A2-), both assays should be repeated.
- If discrepant results are found upon repetition, a third assay should be undertaken. If the third assay is non-reactive (A1+, A2-, A3-), the patient is reported as HIV negative.
- If the third assay is HIV reactive (A1+, A2-, A3+), the patient is HIV-inconclusive and the individual should be retested with a new specimen after 14 days.

Specifically for low prevalence countries (<5%):

- If the specimen is reactive on the first assay (A1), the specimen should be tested on another assay.
- If the specimen is reactive on the second assay (A2), the specimen should be tested on another assay.
- If the specimen is reactive on the third assay (A3), the individual should be reported as HIV-positive.
- If the individual has discrepant results with A1 and A2 (A1+, A2-), the assays should be repeated. After repetition, if the assays are still discrepant the individual should be reported as HIV negative, if A1 is a 3rd or 2nd generation assay or HIV inconclusive with retesting recommended after 14 days, if 4th generation assays. If the assays are both non-reactive (A1-, A2-), the patient should be reported as HIV negative
- If the repeated assays are reactive (A1+, A2+), the specimen should be tested a third assay. If A3 is reactive, the individual is reported as HIV positive. If the assay is non-reactive (A1+, A2+, A3-), the individual is reported as HIV- inconclusive and retesting should be performed with a second specimen after 14 days.

2.4 Limitations

Only national HIV testing policies were reviewed. Therefore, it is possible that some information on lay provider HIV testing was included in other national guidelines, such as prevention of mother-to-child transmission or treatment guidelines.

No date restrictions were placed on this review. A number of policies were published from 2012 or earlier. Policies from 2012 or older were only included when a more recent policy was not identified. Additionally, some key experts that we contacted notified us that their country policies were currently being updated for 2015/2016.

The largest proportion of national HIV testing policies collected were from the WHO African (AFRO) region (n=25/48). Thus, regional analysis was only conducted for this region.

2.5 Results

A total of 48 policies were identified and included in this review: 25 policies from the WHO African Region (AFRO), 3 policies from the WHO American Region (AMRO), 9 from the WHO Eastern-Mediterranean Region (EMRO), 2 from the WHO European Region (EURO), 3 from the WHO Southeast Asia Region (SEARO), and 6 from the WHO Western Pacific Region (WPRO).

Across all 48 HIV testing policies, 42% permit lay providers to perform testing services using RDTs, and approximately one-third prohibit lay providers from performing such tasks. The remaining policies, however, did not specify the role of lay providers and if they were permitted, or not, to perform RDTs. Further analysis also showed that very few country policies explicitly permit lay providers to use oral fluid-based RDTs and the majority (65%) do not specify if oral fluid-based RDTs can be used or not (see Fig.2.1A).

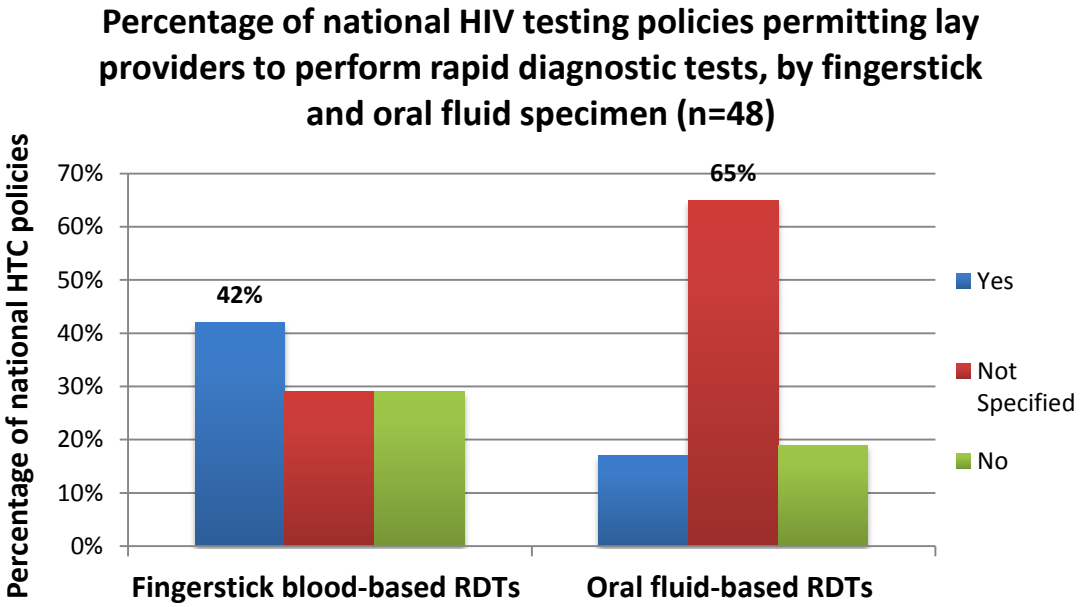
Table 2.1A: The role of lay providers and nurses in HIV Testing services (n=48).

General			Can lay providers perform			Can nurses perform		
WHO Region	Country	Document Reference	Fingerstick blood-based RDTs	Oral fluid-based RDTs	Pre and post- test counselling	Fingerstick blood- based RDTs	Oral fluid-based RDTs	Pre and post- test counselling
AFRO	Burundi	*(50)*	NS	NS	Y	NS	NS	Y
	Botswana	*(51)*	Y	NS	Y	Y	NS	Y
	Burkina Faso	*(52)*	Y	NS	Y	Y	NS	Y
	Cameroon	*(53)*	NS	NS	NS	NS	NS	NS
	Central African Republic	*(54)*	Y	NS	NS	Y	NS	NS
	Chad	*(55)*	NS	NS	N	NS	NS	Y
	Comoros	*(56)*	N	NS	Y	Y	NS	Y
	Cote d'Ivoire	*(57)*	N	N	Y	N	NS	Y
	Democratic Republic of Congo	*(58)*	Y	NS	Y	Y	NS	Y
	Ethiopia	*(59)*	Y	Y	Y	Y	Y	Y
	Ghana	*(60)*	Y	Y	Y	Y	NS	Y
	Kenya	*(61)*	Y	Y	Y	Y	Y	Y
	Liberia	*(62)*	NS	NS	N	N	NS	Y
	Malawi	*(63)*	Y	NS	Y	Y	NS	Y
	Mozambique	*(64)*	Y	NS	Y	Y	NS	Y
	Namibia	*(65)*	Y	Y	Y	Y	Y	Y
	Nigeria	*(66)*	Y	NS	Y	Y	NS	Y
	Rwanda	*(67)*	N	N	N	Y	NS	Y
	Sierra Leone	*(68)*	Y	NS	Y	Y	NS	Y
	South Africa	*(69)*	Y	NS	Y	Y	NS	Y
	Swaziland	*(70)*	Y	NS	Y	Y	NS	Y
	United Republic of Tanzania	*(71)*	NS	NS	Y	Y	NS	Y
	Uganda	*(72)*	N	N	Y	Y	Y	Y

General			Can lay providers perform			Can nurses perform		
WHO Region	Country	Document Reference	Fingerstick blood-based RDTs	Oral fluid-based RDTs	Pre and post- test counselling	Fingerstick blood- based RDTs	Oral fluid-based RDTs	Pre and post- test counselling
	Zambia	*(73)*	Y	NS	Y	Y	NS	Y
	Zimbabwe	*(74)*	Y	Y	Y	Y	Y	Y
AMRO	Brazil	*(75)*	NS	Y	NS	NS	Y	NS
	Canada	*(76)*	NS	NS	NS	NS	NS	NS
	Trinidad & Tobago	*(77)*	NS	NS	NS	Y	NS	Y
EMRO	Afghanistan	*(78)*	Y	Y	Y	Y	Y	Y
	Egypt	*(79)*	N	N	N	N	N	Y
	Libya*	*(80)*	N	NS	N	N	NS	Y
	Morocco*	*(81)*	N	N	N	Y	Y	Y
	Pakistan	*(82)*	NS	NS	Y	NS	NS	Y
	Somalia	*(83)*	NS	NS	N	Y	Y	Y
	Sudan	*(84)*	NS	NS	Y	NS	NS	Y
	Syria*	*(85)*	NS	NS	NS	NS	NS	NS
	Tunisia	*(86)*	Y	NS	Y	Y	NS	Y
EURO	Ukraine	*(87)*	N	NS	N	NS	NS	Y
	United Kingdom	*(88)*	N	N	NS	Y	Y	NS
SEARO	India	*(89)*	N	N	Y	N	N	Y
	Indonesia	*(90)*	N	NS	NS	Y	N	Y
	Nepal	*(91)*	N	N	Y	N	N	Y
WPRO	Australia	*(92)*	Y	Y	NS	Y	Y	NS
	Cambodia	*(93)*	Y	NS	Y	Y	NS	Y
	China	*(94)*	NS	NS	NS	NS	NS	NS
	Papua New Guinea	*(95)*	NS	NS	Y	NS	NS	Y
	Philippines	*(96)*	N	N	N	N	N	N
	Vietnam	*(97)*	N	NS	N	Y	NS	Y

Key		
	Y	Yes
	NS	Not Specified in policy
	N	No
	*	Regional technical advisors and key experts were contacted for this information.

Fig.2.1A: An analysis of national HIV testing= policies (n=48) showing whether lay providers are permitted to perform fingerstick blood-based and oral fluid-based RDTs.



An analysis of HIV testing policies from the WHO AFRO region (n=25) showed the majority of national HIV testing policies permitted lay providers to perform fingerstick blood-based HIV RDTs (64%). Further analysis on the use of oral-fluid based RDTs within the WHO AFRO region shows that only approximately one-fifth of countries permit lay providers to perform oral fluid-based RDTs while the vast majority of countries (68%) do not specify the information (see Figure 2.2A).

Over half of all policies analysed (n=48) stated lay providers are permitted to provide pre- and post- test counselling. However, one-fifth specifically stated that lay providers cannot perform these tasks and the other one-fifth does not specify the role of lay providers in administering these services. Within the WHO AFRO region (n=25), a much higher percent of countries (80%) permit lay providers to perform pre and post-test counselling (see Fig.2.3A).

Fig.2.2A: An analysis of WHO AFRO regional HIV testing policies (n=25) showing whether lay providers are permitted to perform finger stick RDTs.

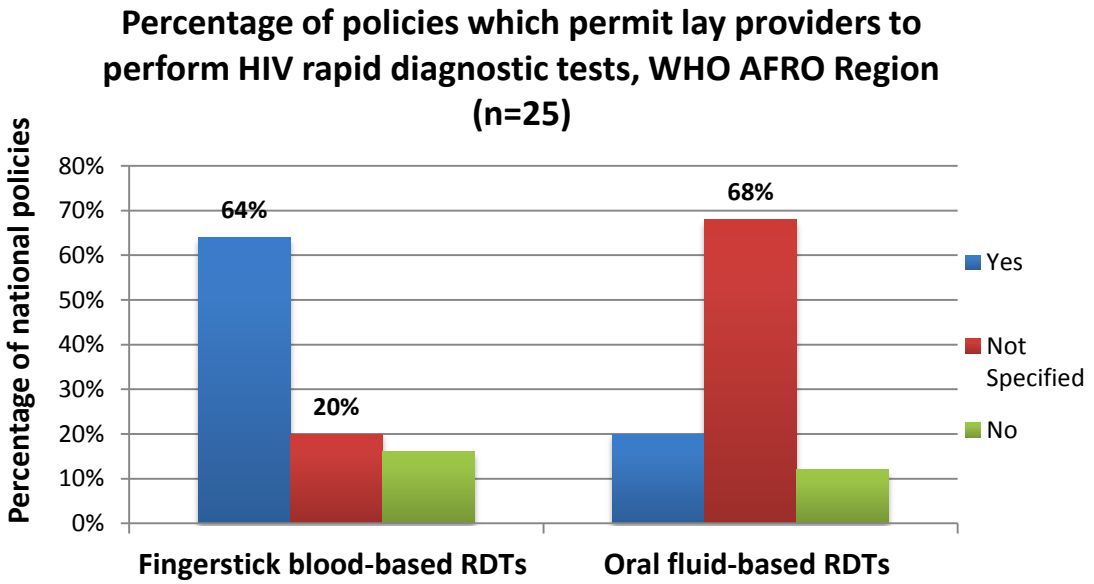


Fig.2.3A: An analysis of national HIV testing policies (n=48) and WHO AFRO regional policies (n=25) showing whether lay providers are permitted to perform pre and post-test counselling.

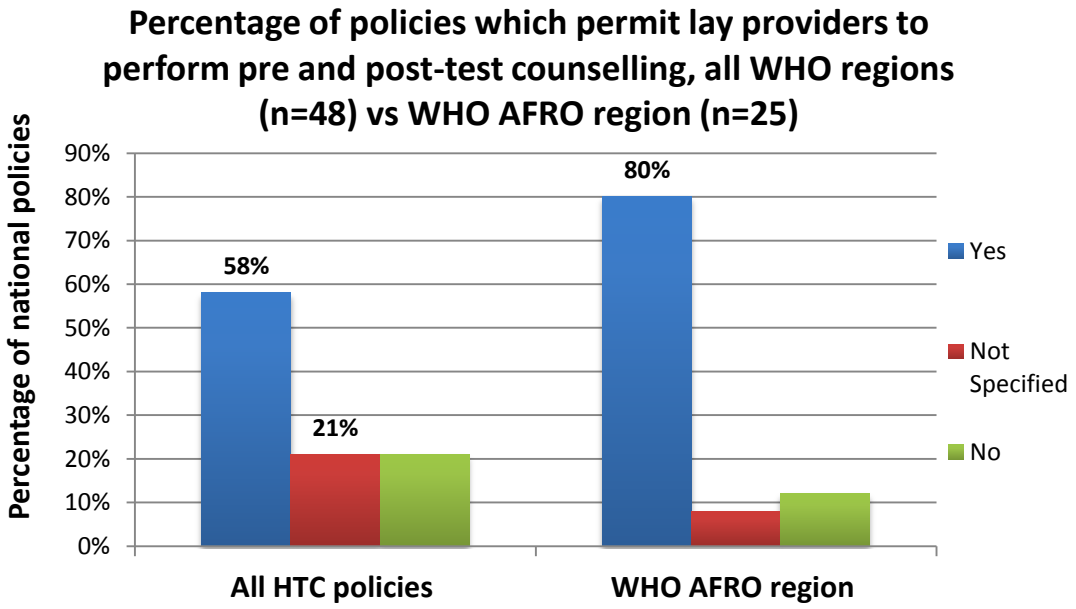


Table 2.2A. An overview of national HIV testing strategy type, their use of tiebreakers and their alignment to WHO recommendations.

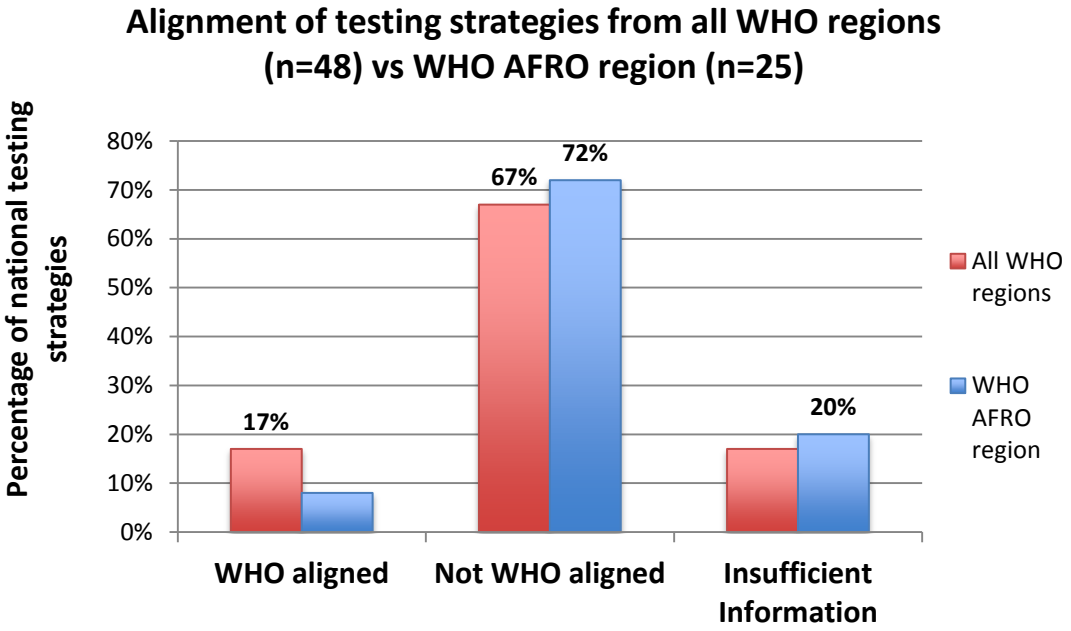
WHO Region	Country	Document Reference	Year of policy publication	Testing strategy used for diagnosis	Is a tie breaker used	Does the strategy align with WHO recommendations?
AFRO	Burundi	*(50)*	2004	S	N	N
	Botswana	*(51)*	2009	P	N	N
	Burkina Faso	*(52)*	2008	S	N	NS
	Cameroon	*(53)*	2014	S	Y	N
	Central African Republic	*(54)*	2010	S	NS	N
	Chad	*(55)*	2011	S	N	N
	Comoros	*(56)*	2007	S	NS	NS
	Cote d'Ivoire	*(57)*	2002	S	N	N
	Democratic Republic of Congo	*(58)*	2004	S	N	Y
	Ethiopia	*(59)*	2004	S	NS	NS
	Ghana	*(60)*	2008	S	NS	N
	Kenya	*(61)*	2010	S	Y	N
	Liberia	*(62)*	2007	S	Y	N
	Malawi	*(63)*	2013	S, P	N	N
	Mozambique	*(64)*	2008	S	N	Y
	Namibia	*(65)*	2011	P	NS	N
	Nigeria	*(66)*	2011	S	Y	N
	Rwanda	*(67)*	2013	S	Y	N
	Sierra Leone	*(68)*	2003	NS	NS	NS
	South Africa	*(69)*	2010	S	Y	N
	Swaziland	*(70)*	2012	S	NS	NS
	United Republic of Tanzania	*(71)*	2012	S	Y	N
	Uganda	*(72)*	2010	S	Y	N
	Zambia	*(73)*	2006	S	Y	N
	Zimbabwe	*(74)*	2014	S	Y	N
AMRO	Brazil	*(75)*	2014	S	N	N
	Canada	*(76)*	2013	NS	NS	NS
	Trinidad & Tobago	*(77)*	2012	P	Y	N
EMRO	Afghanistan	*(78)*	2013	S	N	Y
	Egypt	*(79)*	2004	S	N	N

WHO Region	Country	Document Reference	Year of policy publication	Testing strategy used for diagnosis	Is a tie breaker used	Does the strategy align with WHO recommendations?
	Libya*	*(80)*	2010	S	N	N
	Morocco*	*(81)*	2008	S	NS	N
	Pakistan	*(98)*	2013	S	N	Y
	Somalia	*(83)*	2011	S	N	N
	Sudan	*(84)*	2008	S, P	N	N
	Syria*	*(85)*	2014	S	N	N
	Tunisia	*(86)*	2014	S	N	N
EURO	Ukraine	*(87)*	2006	NS	NS	NS
	United Kingdom	*(88)*	2014	S	N	NS
SEARO	India	*(99)*	2013	S	Y	N
	Indonesia	*(90)*	2014	S	N	Y
	Nepal	*(91)*	2007	S	Y	N
WPRO	Australia	*(92)*	2014	S	N	NS
	Cambodia	*(93)*	2012	S	N	Y
	China	*(94)*	2009	S	Y	N
	Papua New Guinea	*(95)*	2010	S	N	N
	Philippines	*(96)*	2010	P	N	N
	Vietnam	*(100)*	2014	S	N	Y

Key		
	S, P	Serial strategy followed by parallel strategy
	S	Serial strategy
	P	Parallel strategy
	NS	Not Specified
	Y	Yes
	N	No
	*	Regional technical advisors and key experts were contacted for this information.

Analysis of national HIV testing policies from all WHO regions (n=48) showed that under a fifth (17%) of testing strategies aligned with WHO recommendations while almost two-thirds (67%) of the strategies did not align to the same recommendations. In policies from the WHO AFRO region (n=25), only 8% of the testing strategies aligned with WHO recommendations while 72% did not (see Fig.2.4A).

Fig.2.4A: An analysis of national HIV testing policies from all WHO regions (n=48) vs WHO AFRO region (n=25), showing whether testing strategies align with WHO recommendations.



An analysis of all national HIV testing policies (n=49) showed that approximately 80% used serial testing and a small percentage (10%) still used parallel testing. Less than 10% did not specify which type of strategic testing type they used. Throughout WHO AFRO regional policies, the results were quite similar with 84% using serial testing strategies and less than 10% using parallel strategies (see Fig.2.5A). NB: Those that were 'mixed' used a serial testing strategy followed by a parallel strategy.

Just over a quarter (27%) of all national testing strategies (n=48) used a tiebreaker for HIV diagnosis and over half did not. Within the WHO AFRO region, the use of tiebreakers increased to 40% of all strategies while those not using them decreased to 32% (see Fig.2.6A).

Fig.2.5A: An analysis of national HIV testing policies from all WHO regions (n=48) vs WHO AFRO region (n=25), showing the type of testing strategy (serial/parallel) used in diagnostic HIV testing. 'Mixed' refers to the use of serial followed by parallel.

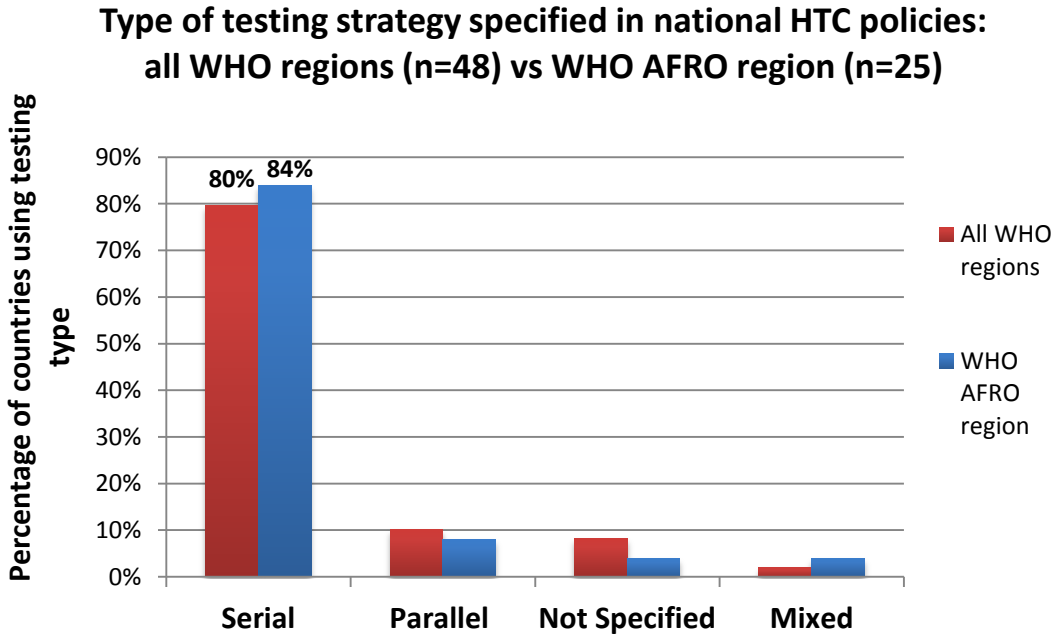
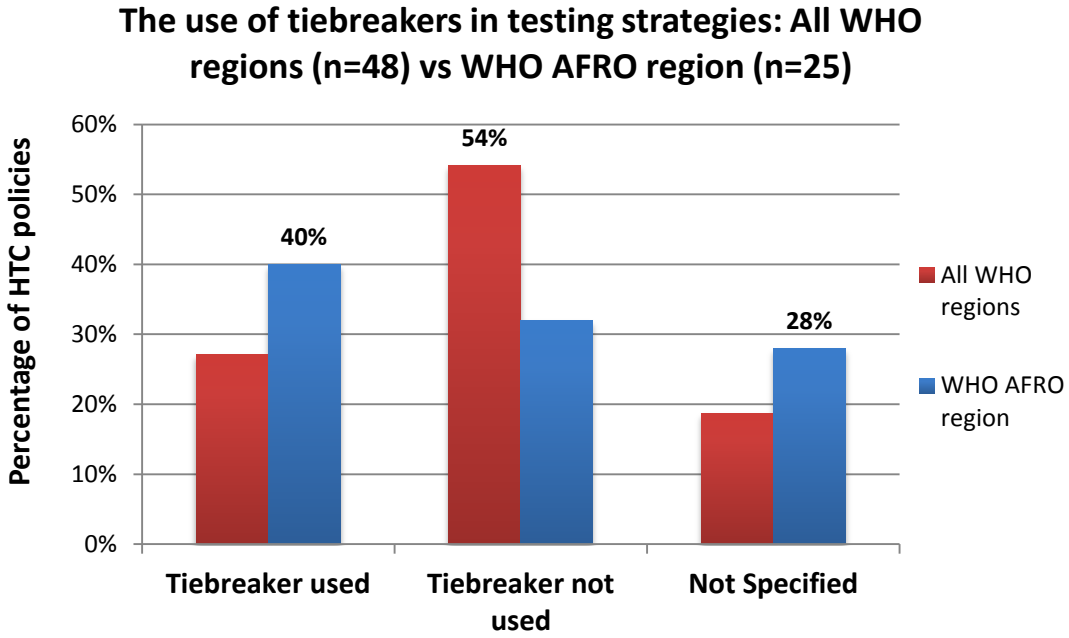


Fig.2.6A: An analysis of national HIV testing policies from all WHO regions (n=48) vs WHO AFRO region (n=25), showing the use of tiebreakers in HIV testing strategies.



2.6 Discussion

The data presented within this report shows that lay providers are most commonly used to administer fingerstick blood-based RDTs and perform pre and post-test counselling. This result is encouraging, given the well documented benefits of lay provider use in HIV service settings, including the increased access to and uptake of HIV testing *(18, 37)*.

Sub-analysis of national HIV testing policies from the WHO AFRO region suggests that there is a more supportive policy environment for lay provider testing services in this region, as demonstrated by their overall higher rates of lay provider utilisation. This may reflect the large volume of tests that are needed in countries with high prevalence and incidence, with countries recognising the utility of task sharing to increase access to testing more efficiently and effectively.

From these findings, national HIV testing polices reflect what was found in currently available national policies. Consideration should be given to updating polices to include trained lay providers to provide HTS to expand testing, especially in community settings and outreach programmes to populations who are currently not receiving testing.

Very few policies addressed if oral fluid-based HIV RDTs could be performed by lay providers. In most cases, these policies also do not address the use of oral fluid-based RDTs by health professionals. For countries seeking to scale-up lay provider use for HIV testing and increase outreach to key populations, oral fluid-based RDTs may be a useful technology to consider addressing in policies. Brazil *(75)*, Zimbabwe *(74)* and Afghanistan *(78)* are examples of countries which has adopted oral fluid-based RDTs as an option to increase uptake of HIV testing services.

Major drawbacks to the effectiveness of HIV testing, is the poor quality of testing strategies outlined in national HIV testing policies. As demonstrated from the extracted policy data, a significant proportion of testing strategies do not align with WHO recommendations. This low number of policies that align with WHO recommendations is lower in policies from the WHO AFRO region, which is concerning given the high volume of tests performed and higher prevalence rates in the region.

Overall, very few national testing strategies recognised the need for different strategies in populations with low (<5%) and high (>5%) prevalence rates. This is likely to be a factor contributing to high false positive rates in low prevalence settings where the high prevalence testing strategy is used. The high use of tiebreakers is a potentially important reason for the high levels of misclassifications reported in many settings and countries. These factors were more frequently seen in testing policies from the WHO AFRO region, with higher uses of "tiebreakers" and parallel testing strategies. They may therefore have a particularly important role in contributing to misdiagnosis and is particularly concerning given the high volumes of testing and the reliance upon RDTs for HIV diagnosis in the region.

There are serious implications of misdiagnosis, both at the individual and public health level. On an individual level and from an ethical perspective, using a testing strategy which may have a high false-positivity rate (such as the "tie breaker") may result in misdiagnosis and unnecessary initiation of potentially life long anti-retroviral therapy (ART). From a public health and health systems perspective, poor quality testing strategies resulting in significant levels of misclassification will result in inappropriate health actions, wasted resources and undermine the credibility of the health services. As an immediate remedial step WHO has re-issued its guidance, recommending to retest patients diagnosed with HIV before they are initiated on ART *(101)*. However, if an inappropriate testing strategy or suboptimal testing algorithm is in place, retesting procedures may not result in identifying those who have been misdiagnosed. It is critical to utilize WHO recommended testing strategies and follow guidance on how to select an appropriate assay and validate a national testing algorithm.

There is a need for countries to be aware of WHO recommendations, as well as the reasoning behind such recommendations. National guidance should also be clear and be designed so that providers can apply testing strategies correctly, as well as other key standards such as: quality assurance systems, job aides to perform HIV RDTs, standard operating procedures to follow national testing algorithms correctly, and implement retesting procedures before ART is initiated. In particular, greater information regarding the specifics of the "tie-breaker" approach and why

this approach is not to be used should be included in national guidelines and in the training of providers performing HIV testing.

The exact reason for low uptake of WHO recommended testing strategies is unknown. However, anecdotal reports suggest technical experts are unaware of these recommendations, particularly that WHO discourages the use of a "tie-breaker" approach, or do not understand the recommendations and how to operationalise them. Further research into country knowledge and understanding of WHO recommendations is needed.

2.7 Conclusion

The utilisation of trained lay providers for HTS and improvement of national testing strategies are key aspects to improving expansion and accuracy of HIV testing services.

Trained lay providers have a key role to play in the scale-up of HTS in order to reach global targets. In order to achieve such goals, supportive and clear policies that permit lay providers to administer both HIV RDTs and pre- and post-test counselling are needed. Countries should also consider how different technologies could be leveraged to enable lay providers to expand services; such as guidance on how and in what settings oral fluid-based RDTS ought to be used.

Countries should also review their national testing strategies to ensure they are correct, adhere to WHO recommendations and are appropriate for their national and sub-national settings where HIV prevalence may vary. In order to provide a correct HIV test result, following WHO recommended testing strategies is of paramount importance.

References

1. The Gap Report. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS), 2014.
2. AIDS by the numbers. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS), 2013.
3. 90-90-90: An ambitious treatment target to help end the AIDS epidemic. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS), 2014.
4. Samb B, Celletti F, Holloway J, Van Damme W, De Cock K, Dybul M. Rapid expansion of the health workforce in response to the HIV epidemic. The New England Journal of Medicine. 2007;357(24):2510-4.
5. Zachariah R, Ford N, Philips M, Lynch S, Massaquoi M, Janssens V, et al. Task shifting in HIV/AIDS: opportunities, challenges and proposed actions for sub-Saharan Africa. Transactions of the Royal Society of Tropical Medicine and Hygiene. 2009;103(6):549-58.
6. Parekh B, Kalou M, Alemnji G, Ou C-Y, Gershy-Damet G-M, Nkengasong J. Scaling up HIV rapid testing in developing countries comprehensive approach for implementing quality assurance. American Journal of Clinical Pathology. 2010;134(4):573-84.
7. Shanks L, Siddiqui M, Kliescikova J, Pearce N, Ariti C, Muluneh L, et al. Evaluation of HIV testing algorithms in Ethiopia: the role of the tie-breaker algorithm and weakly reacting test lines in contributing to a high rate of false positive HIV diagnoses. BMC Infectious Diseases. 2015;15(1):39.
8. Klarkowski D, O'Brien D, Shanks L, Singh K. Causes of false-positive HIV rapid diagnostic test results. Expert Review of Anti-Infective Therapy. 2014;12(1):49-62.
9. Shanks L, Klarkowski D, O'Brien D. False positive HIV diagnoses in resource limited settings: operational lessons learned for HIV programmes. PloS One. 2013;8(3):e59906.
10. Klarkowski D, Wazome J, Lokuge K, Shanks L, Mills C, O'Brien D. The evaluation of a rapid in situ HIV confirmation test in a programme with a high failure rate of the WHO HIV two-test diagnostic algorithm. PLoS ONE. 2009;4(2):e4351.
11. Baveewo S, Kaamya M, Mayanja-Kizza H, Fatch R, Bangsberg D, Coates T. Potential for false positive HIV test results with the serial rapid HIV testing algorithm. BMC Research Notes. 2012;5(1):154.
12. Walsh A, Ndubani P, Simbaya J, Dicker P, Brugha R. Task sharing in Zambia: HIV service scale-up compounds the human resource crisis. BMC Health Services Research. 2010;10(1):272.
13. Walensky R, Reichmann W, Arbelaez C, Wright E, Katz J, Seage I, et al. Counselor-versus provider-based HIV screening in the emergency department: Results from the universal screening for HIV Infection in the Emergency Room (USHER) randomized controlled trial. Annals of Emergency Medicine. 2011;58(1):126-32.
14. Champenois K, Le Gall J, Jacquemin C, Jean S, Martin C, Rios L, et al. ANRS-COM'TEST: description of a community-based HIV testing intervention in non-medical settings for men who have sex with men. BMJ Open. 2012;2(2):693.
15. Lorente N, Preau M, Vernay-Vaisse C, Mora M, Blanche J, Otis J. Expanding access to non-medicalized community-based rapid testing to men who have sex with men: an urgent HIV prevention intervention (the ANRS-DRAG study). PLoS ONE. 2013;8(4): e61225.
16. Molesworth A, Ndhlovu R, Banda E, Ngwira B, Glynn J, Crampin A, et al. High accuracy of home-based community rapid HIV testing in rural Malawi. Journal of Aquired Immune Deficiency Syndromes. 2010;55(5):625-30.
17. Bemelmans M, Van den Akker T, Ford N, Philips M, Zachariah R, Harries A, et al. Providing universal access to antiretroviral therapy in Thyolo, Malawi through task shifting and decentralization of HIV/AIDS care. Tropical Medicine and International Health. 2010;15(12):1413-20.
18. Jackson D, Naik R, Tabana H, Pillay M, Madurai S, Zembe W, et al. Quality of home-based rapid HIV testing by community lay counsellors in a rural district of South Africa. Journal of the International AIDS Society. 2013;16(1):18744.
19. Fylkesnes K, Sandoy I, Jurgensen M, Chipimo P, Mwangala S, Michelo C. Strong effects of home-based voluntary HIV counselling and testing on acceptance and equity: A cluster randomised trial in Zambia. Social Science and Medicine. 2013;86:9-16.
20. Iwu E, Holzemer W. Task shifting of HIV management from doctors to nurses in Africa: Clinical outcomes and evidence on nurse self-efficacy and job satisfaction. AIDS care. 2014;26(1):42-52.
21. Jurgensen M, Sandoy I, Michelo C, Fylkesnes K. Effects of home-based Voluntary Counselling and Testing on HIV-related stigma: Findings from a cluster-randomized trial in Zambia. Social Science and Medicine. 2013;81:18-25.

22. Leon N, Naidoo P, Mathews C, Lewin S, Lombard C. The impact of provider-initiated (opt-out) HIV testing and counseling of patients with sexually transmitted infection in Cape Town, South Africa: a controlled trial. Implementation Science. 2010;5(8):11.
23. Kanal K, Chou T, Sovann L, Morikawa Y, Mukoyama Y, Kakimoto K. Evaluation of the proficiency of trained non-laboratory health staff and laboratory technicians using a rapid and simple HIV antibody test. AIDS Research and Therapy. 2005;2(1):5.
24. Global recommendations and guidelines on task shifting. Geneva: World Health Organization, 2007.
25. Mathews R, Johnson C, Verster A, Baggaley R. Review of community-based HIV testing and counselling among key populations. 2015.
26. *HIV diagnosis, prevention and treatment among key populations* Geneva: World Health Organization; 2014.
27. Lehmann U, D S. *What do we Know About Them? The State of Evidence on Programmes, Activities, Costs and Impact on Health Outcomes of Using Community Health Workers*. Geneva: World Health Organization; 2007.
28. Lewin S, Dick J, Pond P, Zwarenstein M, Aja G, van Wyk B, et al. Lay Health Workers in Primary and Community Health Care. Cochrane Database of Systematic Reviews. 2005;1.
29. Laurent M, Reeves D, Hermens R, Braspenning J, Grol R, Sibbald B. Substitution of Doctors by Nurses in Primary Care. Cochrane Database of Systematic Reviews. 2005.
30. Callaghan M, Ford N, Schneider H. A systematic review of task- shifting for HIV treatment and care in Africa. Human Resource Health. 2010;8(8).
31. *WHO information Note: Reminder to retest all newly diagnosed HIV-positive individuals in accordance with WHO recommendations*. Geneva: World Health Organization; 2014.
32. *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach*. Geneva: World Health Organization; 2013.
33. *Consolidated guidelines on HIV testing services*. Geneva: World Health Organization; 2015.
34. Matovu J, Makumbi F. Expanding access to voluntary HIV counselling and testing in sub-Saharan Africa: alternative approaches for improving uptake, 2001–2007. Tropical Medicine & International Health. 2007;12(11):1315-22.
35. UNAIDS. *Global AIDS response programme reporting*. Geneva: UNAIDS; 2014.
36. Sherr K, Pfeiffer J, Mussa A, Vio F, Gimbel S, Micek M, et al. The role of nonphysician clinicians in the rapid expansion of HIV care in Mozambique. Journal of Acquired Immune Deficiency Syndromes. 2009;52:20-3.
37. Ledikwe J, Kejelepula M, Maupo K, Sebetso S, Thekiso M, Smith M, et al. Evaluation of a well-established task-shifting initiative: the lay counselor cadre in Botswana. PLoS One. 2013;8(4):e61601.
38. Service delivery approaches to HIV testing and counselling (HTC): A strategic policy framework: World Health Organization; 2012.
39. Bemelmans M, Van Den Akker T, Ford N, Zachariah R, Harries A, Schouten E, et al. Providing universal access to antiretroviral therapy in Thyolo, Malawi through task shifting and decentralization of HIV/AIDS care. Tropical Medicine & International Health. 2010;15(12):1413-20.
40. Baiden F, Akanlu G, Hodgson A, Akweongo P, Debpuur C, Binka F. Using lay counsellors to promote community-based voluntary counselling and HIV testing in rural northern Ghana: a baseline survey on community acceptance and stigma. Journal of Biosocial Science. 2007;39(05):721-33.
41. Johnson C, Sands A, Fonner V, Tsui S, Wong WJ, Obermeyer C, et al. Are We Delivering the Wrong Results?: Examining Misclassification of HIV Status and False Positive Test Results. African Society for Laboratory Medicine; 30 Nov - 5 Dec; Cape Town, South Africa 2014.
42. Wolpaw B, Mathews C, Chopra M, Hardie D, de Azevedo V, Jennings K, et al. The failure of routine rapid HIV testing: a case study of improving low sensitivity in the field. BMC Health Services Research. 2010;10(1):73.
43. Shanks L, Siddiqui M, Kliescikova J, Pearce N, Ariti C, Muluneh L, et al. Evaluation of HIV testing algorithms in Ethiopia: the role of the tie-breaker algorithm and weakly reacting test lines in contributing to a high rate of false positive HIV diagnoses. BMC Infectious Diseases. 2015;15(39).
44. Baveewo S, Kamya M, Mayanja-Kizza H, Fatch R, Bangsberg D, Coates T, et al. Potential for false positive HIV test results with the serial rapid HIV testing algorithm. BMC Research Notes. 2012;5(1):154.
45. Gray R, Makumbi F, Serwadda D, Lutalo T, Nalugoda F, Opendi P, et al. Limitations of rapid HIV-1 tests during screening for trials in Uganda: diagnostic test accuracy study. British Medical Journal. 2007;335(7612):188.

46. Crucitti T, Taylor D, Beelaert G, Fransen K, Van Damme L. Performance of a rapid and simple HIV testing algorithm in a multicenter phase III microbicide clinical trial. Clinical and Vaccine Immunology. 2011;18(9):1480-5.
47. da Costa Ferreira Junior O, Ferreira C, Riedel M, Visinoni W, Sasazawa I, Westman S, et al. Field evaluation of an HIV rapid test algorithm for the rapid diagnosis of HIV infection in Brazil. HIV Pathogenesis, Treatment and Prevention; Sydney, Australia 2007.
48. Bateganya M, Abdulwadud OA, Kiene SM. Home-based HIV voluntary counselling and testing (VCT) for improving uptake of HIV testing. Cochrane Datase System Review. 2010;17(2).
49. AIDSinfo. Joint United Nations Programme on HIV/AIDS (UNAIDS). 2015. Available from: http://www.unaids.org/en/dataanalysis/datatools/aidsinfo.
50. *Guide de Conseil en Matiere de VIH/SIDA/IST*. Bujumbura, Burundi: Gouvernement de la Republique du Burundi: Ministère de la Santé Publique du Burundi; 2004.
51. *National Guidelines: HIV Testing and Counselling*. Republic of Botswana: Ministry of Health; 2009.
52. *Normes et Directives Nationales de Conseil Depistage de L'infection a VIH au Burkina Faso*. Gouvernement de Burkina Faso Government: Ministere de la Sante; 2008.
53. *Directives Nationales de prevention et de prise en charge du VIH au Cameroun*. Gouvernement de la République du Cameroun: Ministere de Sante Publique; 2014.
54. *Guide du depistage et conseil du VIH a l'initiative du prestataire*. Gouvernement de la Republic Centrafricaine: Ministere de la Sante Publique; 2010.
55. *Manuel de Formation en Counseling VIH/SIDA/IST*. Republic du Tchad: Ministere de la Sante Publique; 2011.
56. *Guide de prise en charge de l'infection à VIH Aux Comores*. Union des Comores: Ministère de la Santé, Programme National de lutte contre le SIDA; 2007.
57. *Document de Normes et Directives Nationales du Conseil et Depistage Volontaire du VIH en Cote D'Ivoire*. Abidjan, Republic de Cote D'Ivoire: Le gouvernement de Cote D'Ivoire: Ministere de la Solidarite, de la Sante et de la Securite Sociale; 2002.
58. *Normes et directives en conseil et depistage volontaire du VIH/SIDA*. Gouvernement de la République démocratique du Congo: Ministere de la Santé/ Programme national de lutte contre le SIDA et les IST; 2004.
59. *Guidelines for HIV Counselling and Testing in Ethiopia*. Government of the Federal Democratic Republic of Ethiopia: Federal Ministry of Health, Federal HIV/AIDS Prevention and Control Office; 2007.
60. *National guidelines for the implementation of HIV counseling and testing in Ghana*. Government of the Republic of Ghana; 2008.
61. *National Guidelines for HIV Testing and Counselling in Kenya*. Government of Kenya: Ministry of Public Health and Sanitation; 2010.
62. *Integrated Guidelines for Prevention, Testing, Care and Treatment of HIV/AIDS in Liberia*. Government of the Republic of Liberia: Ministry of Health and Social Welfare & National AIDS and STI Control Program; 2007.
63. *Malawi Comprehensive HIV Testing and Counselling training*. Government of Malawi: Ministry of Health; 2013.
64. *Guião Estratégico-Operacional para Implementação das Unidades de Aconselhamento e Testagem em Saúde (UATS)*. República de Moçambique: Ministério da Saúde; 2008.
65. *National Guidelines for HIV Counselling and Testing in Namibia*. Government of the Republic of Namibia: Ministry of Health and Social Services; 2011.
66. *National Guidelines for HIV Counselling and Testing*. Government of Nigeria: Federal Ministry of Health; 2011.
67. *National Guidelines for Prevention and Management of HIV, STIs & Other Blood Borne Infections*. Government of the Republic of Rwanda: Ministry of Health; 2013.
68. *Guidelines For Voluntary Confidential Counselling and Testing In Sierra Leone*. Government of the Republic of Sierra Leone: Ministry of Health and Sanitation; 2003.
69. *HIV Counselling and Testing (HCT) Policy Guidelines*. Government of the Republic of South Africa: Department of Health; 2011.
70. *HTC Program Annual Report 2012*. Swaziland: Kingdom of Swaziland: Ministry of Health; 2012.
71. *National guidelines for the management of HIV and AIDS*. The government of the United Republic of Tanzania: Ministry of Health and Social Welfare; 2012.

72. *National Implementation Guidelines for HIV Counselling and Testing in Uganda*. Government of the Republic of Uganda: Ministry of Health; 2010.
73. *National Guidelines for HIV Counselling & Testing*. Government of the Republic of Zambia: Ministry of Health 2006.
74. *National Guidelines on HIV Testing and Counselling*. Government of the Republic of Zimbabwe: Ministry for Health and Child Care; 2014.
75. *Manual Técnico Para O Diagnóstico Da Infecção Pelo HIV*. Government of Brazil: Department of Health; 2014.
76. *Human Immunodeficiency Virus: HIV Screening and Testing Guide*. Ottowa, Canada: Centre for Communicable Diseases and Infection Control, Public Health Agency of Canada; 2012.
77. *National HIV testing and Counselling Policy*. Government of the Republic of Trinidad and Tobago: Ministry of Health; 2012.
78. *National Guidelines of HIV Testing and Counseling Services*. Government of the Islamic Republic of Afghanistan: Depatment of Public Health; 2013.
79. *National Guidelines for Voluntary HIV Counseling and Testing*. Arab Republic of Egypt: Ministry of Health and Population/ National AIDS Program; 2004.
80. El-Gueneidy M, Bahaa T. HIV Voluntary Counseling and Testing Services: A Guidelines for Service Providers (Libya). 2010.
81. M K. *Morocco HTC Information provided by Dr Mehdi Karkouri* 2014.
82. *HIV Voluntary Counselling and testing (VCT) Guidelines for Pakistan*. Government of Pakistan; 2010.
83. *HIV Testing and Counseling in Health Care Settings*. Government of the Federal Republic of Somalia; 2011.
84. *Guidelines for Voluntary Counselling and Testing (VCT)* Government of the Republic of Sudan: Ministry of Health; 2008.
85. *Syria HIV testing information provided by WHO EMRO contact Joumanna Hermez.* . 2014.
86. *Stratégie nationale de dépistage de l'infection à VIH*. Government of the Tunisian Republic: Ministry of Health; 2014.
87. *Protocol of Voluntary HIV Counseling and Testing*. Government of Ukraine: Ministry of Health (Decree #415); 2005.
88. *UK Standards for Microbiology Investigations: Anti-HIV Screening*. Standards Unit, Microbiology Services, Public Health England; 2014.
89. *Guidelines on HIV Testing*. Republic of India: Ministry of Health and Family Welfare/ National AIDS Control Organisation 2007.
90. *Pedoman Pelaksanaan Konseling Dan Tes HIV*. Peraturan Menteri Kesehatan Republik Indonesia; 2014.
91. *National Guidelines for Voluntary HIV/AIDS Counseling and Testing*. Government of Nepal: Ministry of Health and Population; 2007.
92. *2014 National HIV Testing Policy*. Australian Government: Department of Health and Ageing; 2014.
93. *Standard Operating Procedures for HIV Testing and Counseling (HTC)*. Kingdom of Cambodia: Ministry of Health/ National Center for HIV/AIDS, Dermatology and STDs; 2012.
94. *National Guidelines for Detection of HIV/AIDS*. Chinese Center for Disease Control and Prevention; 2009.
95. *National Guidelines for HIV Counselling and Testing in Papua New Guinea*. Government of Papua New Guinea: Department of Health; 2010.
96. *Administrative Order: 2010- 0028. Policies and Guidelines in the conduct of Human Immunodeficiency Virus (HIV) Counseling and Testing in Community and Health Facility Settings.* . Government of the Republic of the Philippines: Department of Health; 2010.
97. *Decision on Promulgation of Voluntary HIV Counseling and Testing (VCT) Guidelines*Government of the Socialist Republic of Vietnam: Ministry of Health. ; 2007.
98. *Pakistan Country Strategy for HIV Testing & Counselling*. Government of the Islamic Republic of Pakistan; 2013.
99. *Antiretroviral Therapy Guidelines for HIV-Infected Adults and Adolescents*. Government of India: Ministry of Health and Family Welfare, National AIDS Control Organisation; 2013.
100. *Phương cách xét nghiệm chẩn đoán hiv quốc gia năm 2014*. Government of the Socialist Republic of Vietnam: Ministry of Health; 2014.

101. WHO reminds national programmes to retest all newly diagnosed people with HIV. Geneva: World Health Organization; 2014.