

Progress with Scale-Up of HIV Viral Load Monitoring — Seven Sub-Saharan African Countries, January 2015–June 2016

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The World Health Organization (WHO) recommends viral load testing as the preferred method for monitoring the clinical response of patients with human immunodeficiency virus (HIV) infection to antiretroviral therapy (ART) (1). Viral load monitoring of patients on ART helps ensure early diagnosis and confirmation of ART failure and enables clinicians to take an appropriate course of action for patient management. When viral suppression is achieved and maintained, HIV transmission is substantially decreased, as is HIV-associated morbidity and mortality (2). CDC and other U.S. government agencies and international partners are supporting multiple countries in sub-Saharan Africa to provide viral load testing of persons with HIV who are on ART. This report examines current capacity for viral load testing based on equipment provided by manufacturers and progress with viral load monitoring of patients on ART in seven sub-Saharan countries (Côte d'Ivoire, Kenya, Malawi, Namibia, South Africa, Tanzania, and Uganda) during January 2015–June 2016. By June 2016, based on the target numbers for viral load testing set by each country, adequate equipment capacity existed in all but one country. During 2015, two countries tested >85% of patients on ART (Namibia [91%] and South Africa [87%]); four countries tested <25% of patients on ART. In 2015, viral suppression was >80% among those patients who received a viral load test in all countries except Côte d'Ivoire. Sustained country commitment and a coordinated global effort is needed to reach the goal for viral load monitoring of all persons with HIV on ART.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) “90-90-90” goals are to increase to 90% by 2020 the proportions of 1) persons living with HIV infection who know their status, 2) persons living with HIV infection receiving ART, and 3) persons living with HIV infection on ART who have achieved viral suppression (3). Substantial progress has been made in initiating ART among HIV-infected persons. In 2015, an estimated 17 million persons with HIV accessed treatment compared with 7.5 million in 2010, with sub-Saharan Africa accounting for approximately two thirds (11.8 million) of the persons on ART (4). Despite progress in ART coverage, substantial challenges with access to viral load testing in resource-limited countries remain

(4,5). Unlike western countries, which have relied on viral load testing to monitor virologic response to ART, low- and middle-income countries have historically relied on CD4 cell counts (which monitor immunologic improvement for patients on ART) because of the higher cost of viral load testing.

Challenges to viral load testing scale-up have been identified, including weaknesses in sample transport and laboratory workflow; finance and procurement; human resources (i.e., staffing shortages); laboratory equipment maintenance; and laboratory-clinic interfaces (5,6). To address these barriers and increase access to viral load testing, the Diagnostic Access Initiative (which includes representatives from the U.S. President's Emergency Plan for AIDS Relief [PEPFAR], UNAIDS, WHO, and others), was launched to increase laboratory capacity and reduce pricing from manufacturers for better access to viral load testing (7). PEPFAR collaborates with manufacturers for procurement and viral loading testing reagents. CDC provides technical expertise in support of viral load testing, and the United States Agency for International Development (USAID) focuses on supply chain management, working with manufacturers for procurement and maintenance of viral load testing platforms. A previous evaluation found that countries were at various stages of implementation and that scale-up of viral load testing was feasible (6).

The seven sub-Saharan African countries were selected based on availability of data and agreements with ministries of health for January 2015–June 2016. Ministries of Health, CDC, and USAID program officers jointly collected information on viral load testing targets, viral load testing capacity, cumulative number of ART patients, number of ART patients with more than one viral load test, percentage of viral load tests indicating viral suppression (<1,000 virus copies/mL), test turnaround time, and number of CD4 tests. The WHO algorithm for viral load testing suggests starting viral load testing 6 months after ART initiation, followed by viral load testing at 12 months if viral suppression is achieved, and yearly thereafter (8). Each country set their viral load testing targets (i.e., the number of persons to receive viral load testing) based on several factors, including the number of persons with HIV on ART and the country's ability to increase viral load testing. Information

on the number of testing platforms and the overall testing capacity for each country was provided by the manufacturers, Roche and Abbott. Among the seven countries participating in the CDC HIV-1 Viral Load Proficiency Testing program, 62 laboratories were enrolled.

By June 2016, 176 molecular testing platforms were in use within the seven countries; Roche accounted for 107 (61%) and Abbott 69 (39%). By June 2016, based on the target numbers for viral load testing set by each country, adequate equipment capacity resided in all but Uganda. However, three countries (Malawi, Tanzania, and Uganda) did not have the capacity to test all the persons with HIV currently on ART at least once per year (Table 1) (Table 2). Of the 62 laboratories enrolled in viral load proficiency testing, 92% passed proficiency testing; only a few laboratories in Malawi and one in Kenya did not pass (Table 1). During January–June 2016, the mean test turnaround time was ≤ 4 days in Namibia and South Africa, but was 28–50 days in all other countries (Table 1). During January 2015–June 2016, turnaround times decreased in Kenya and Uganda, but increased in Côte d'Ivoire, Malawi, and Tanzania.

During January 2015–June 2016, the number of patients on ART increased in all countries, with the greatest proportional

increase observed in Uganda (13%) and the lowest in Malawi (2%) and Tanzania (2%) (Table 2). The percentage of ART patients with one or more viral load tests during 2015 varied substantially across countries. Two countries tested $>85\%$ of patients on ART: Namibia (91%) and South Africa (87%). Four countries, tested $<25\%$ of ART patients: Côte d'Ivoire (10%), Malawi (19%), Tanzania (5%), and Uganda (23%) (Table 2). During January–June 2016, all countries reported testing $<50\%$ of patients. Viral suppression was $\geq 82\%$ in all countries except Côte d'Ivoire (66%) and Tanzania (72%). During January 2015–June 2016, viral suppression rates decreased by 12% in Côte d'Ivoire and 16% in Tanzania. CD4 test data were available for five countries. Overall, during January 2014–June 2016, four countries had declines in CD4 testing volume; Côte d'Ivoire had increases (Table 2).

Discussion

Global support from international agencies and collaboration with manufacturers has led to four of seven countries in sub-Saharan Africa having adequate capacity to perform viral load testing of all persons with HIV on ART per WHO guidance. All countries increased the number of patients receiving

TABLE 1. Human immunodeficiency virus viral load testing capacity and quality monitoring indicators, by country — seven sub-Saharan African countries, January 2015–June 2016

Country	Established target no. of tests		Equipment capacity 2015/2016	Molecular testing platforms		Laboratory proficiency testing		Mean turnaround time* (days)	
	2015	2016		Roche	Abbott	No. participated	No. passed	2015	Jan–Jun 2016
Côte d'Ivoire	0	102,967	399,168	22	0	3	3	17	50
Kenya	1,200,000	1,393,557	1,464,372	15	21	16	15	48	36
Malawi†	166,652	237,815	391,608	0	14	15	11	31	42
Namibia	190,382	211,394	309,960	6	2	0	0	5	4
South Africa	3,600,000	3,900,000	5,973,912	37	14	16	16	3	3
Tanzania	87,589	207,277	412,776	9	8	8	8	30	34
Uganda	200,000	800,000	739,368	18	10	4	4	43	28

* Mean turnaround time from whole blood draw to report sent from testing laboratory.

† Malawi guidelines recommend viral load testing every other year for persons on antiretroviral therapy.

TABLE 2. Human immunodeficiency virus treatment monitoring indicators, by country — seven sub-Saharan African countries, January 2015–June 2016

Country	Total no. of ART patients		No. of ART patients with ≥ 1 viral load test		% ART patients with ≥ 1 viral load test		% viral load tests with viral suppression*		No. CD4 tests		
	2015	2016	2015	2016	2015	2016	2015	2016	2014	2015	2016
Côte d'Ivoire	147,947	160,561	15,502	17,114	10	11	78	66	186,159	145,755	177,815
Kenya	860,297	923,000	650,645	456,756	76	49	83	84	ND	ND	ND
Malawi†	595,186	606,673 [§]	115,971	115,528	19	19	82	89	125,543	75,973	16,164
Namibia	143,805	148,940	130,367	63,732	91	43	87	87	50,091	23,424	8,048
South Africa	3,318,384	3,422,724	2,875,734	3,125,011	87	91	83	83	3,933,588	3,627,960	1,736,211
Tanzania	758,344	769,527	41,289	66,344	5	9	88	72	ND	ND	ND
Uganda	1,066,519	1,213,091	243,099	267,140	23	22	91	92	1,097,691	960,241	341,019

Abbreviations: ART = antiretroviral therapy; ND = data not available.

* Suppression = $<1,000$ copies/mL.

† Malawi guidelines recommend viral load testing every other year for persons on ART.

§ These numbers reflect reported numbers from January–March 2016.

ART, thus creating a greater demand for viral load testing. This increase is expected to continue as countries strive to reach the goal of initiating ART for all persons with HIV. Although the number of patients who have received viral load testing has increased, the percentage of patients on ART with at least one viral load test was $\leq 25\%$ for four of the seven countries. In contrast, Namibia, Kenya, and South Africa tested $>75\%$ of patients on ART. Among the seven countries, Namibia is closest to reaching the third “90” UNAIDS goal (to increase to 90% the proportion of persons with HIV infection on ART who have achieved viral suppression), followed by South Africa and Kenya. The remaining countries will need to make substantial progress to meet this goal.

Since 2014, the landscape for HIV patient monitoring has changed. CD4 testing is declining and viral load testing is increasing. This change is expected to continue as countries with limited resources prioritize monitoring efficacy of ART to reach viral suppression goals.

During January–June 2016, the turnaround time from specimen collection to return of results was 28–50 days in five countries, compared with ≤ 4 days in two countries (Namibia and South Africa). Optimally, turnaround time would be ≤ 2 weeks. Reasons for long turnaround time included equipment breakdown, reagent stock depletion, inefficient systems for specimen transport, and personnel shortages. Prolonged turnaround times can delay the prompt use of results for patient management, such as intense adherence counseling or switching to second-line ART, both of which improve viral load suppression. Substantially decreasing turnaround time is a factor that needs more focused attention in many countries.

The findings in this report are subject to at least three limitations. First, capacity for viral load testing was calculated using the optimal number of specimens that could be run on a machine based on guidance from manufacturers. Second, field conditions such as staffing shortages and power outages might decrease actual capacity. Finally, low viral load suppression rates might be the result of targeted testing for suspected treatment failure rather than unbiased testing of all persons with HIV on ART.

Successful scale-up of HIV viral load testing requires a global response. Because of coordinated efforts, millions of persons with HIV receive viral load testing despite limited resources. PEPFAR works directly with ministries of health and implementing partners to support viral load scale-up through establishing and optimizing systems. CDC, USAID, and other U.S. agencies provide complementary activities in molecular diagnostics, management of supply chain, and building human capacity. WHO has developed guidelines for viral load testing. The Clinton HIV/AIDS Initiative supports

Summary

What is already known about this topic?

Persons with human immunodeficiency virus (HIV) who have viral suppression have improved health outcomes and a lower risk for transmitting HIV infection to others. Thus, viral load testing is recommended for monitoring patients with HIV receiving antiretroviral therapy (ART). Increasing and monitoring the capacity for viral load testing are important measures for global control of HIV, particularly in sub-Saharan Africa, which has the highest prevalence of HIV worldwide.

What is added by this report?

During 2015–2016, among the seven sub-Saharan African countries evaluated, the number of patients with HIV receiving ART increased. Four countries now have the capacity to perform viral load testing for all patients currently on HIV treatment. All seven countries increased testing capacity. However, the percentage of patients on HIV treatment who received viral load testing was $<25\%$ for four countries.

What are the implications for public health practice?

Continued international collaborative initiatives are needed to increase capacity for viral load testing, as well as access of these services among patients on HIV treatment in sub-Saharan Africa.

creation of electronic dashboards for data management. Continued coordination and effective partnerships are necessary to provide a harmonized, comprehensive approach that can maximize efficiencies and strengthen health systems for effective viral load scale-up.

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