Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™
Morbidity and Mortality Weekly Report (*MMWR*)

Scale-up of HIV Viral Load Monitoring — Seven Sub-Saharan African Countries

Weekly
November 27, 2015 / 64(46);1287-1290

Shirley Lecher, MD1; Dennis Ellenberger, PhD1; Andrea A. Kim, PhD1; Peter N. Fonjungo, PhD1; Simon Agolory, MD2; Marie Yolande Borget MS3; Laura Broyles, MD1; Sergio Carmona, MBBCh4; Geoffrey Chipungu, MBBS5; Kevin M. De Cock, MD6; Varough Deyde, PhD7; Marie Downer, MD6; Sundeep Gupta, MD5; Jonathan E. Kaplan, MD1; Charles Kiyaga, MPhil8; Nancy Knight, MD7; William MacLeod, Sc.D4; Boniface Makumbi9; Hellen Muttai, MBChB6; Christina Mwangi, MMed10; Jane W. Mwangi, MMed6; Michael Mwasekaga11; Lucy W. Ng'Ang'A, MBChB6; Yogan Pillay, PhD12; Abdoulaye Sarr, DSc5; Souleymane Sawadogo2; Daniel Singer, MD5; Wendy Stevens, MBBCh4; Christiane Adje Toure, PhD3; John Nkengasong, PhD1

To achieve global targets for universal treatment set forth by the Joint United Nations Programme on human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) (UNAIDS), viral load monitoring for HIV-infected persons receiving antiretroviral therapy (ART) must become the standard of care in low- and middle-income countries (LMIC) (*1*). CDC and other U.S. government agencies, as part of the President's Emergency Plan for AIDS Relief, are supporting multiple countries in sub-Saharan Africa to change from the use of CD4 cell counts for monitoring of clinical response to ART to the use of viral load monitoring, which is the standard of care in developed countries. Viral load monitoring is the preferred method for immunologic monitoring because it enables earlier and more accurate detection of treatment failure before immunologic decline. This report highlights the initial successes and challenges of viral load monitoring in seven countries that have chosen to scale up viral load testing as a national monitoring strategy for patients on ART in response to World Health Organization (WHO) recommendations. Countries initiating viral load scale-up in 2014 observed increases in coverage after scale-up, and countries initiating in 2015 are anticipating similar trends. However, in six of the seven countries, viral load testing coverage in 2015 remained below target levels. Inefficient specimen transport, need for training, delays in procurement and distribution, and limited financial resources to support scale-up hindered progress. Country commitment and effective partnerships are essential to address the financial, operational, technical, and policy challenges of the rising demand for viral load monitoring.

In 2014, UNAIDS launched "90-90-90" goals to increase to 90% by 2020 the proportion of persons living with HIV infection who know their status, the proportion of persons living with HIV infection receiving ART, and the proportion of persons living with HIV infection on ART who have achieved viral suppression (defined as HIV RNA concentration below the threshold needed for detection on a viral load assay) (*1*). Increasing viral load monitoring for ART patients will require lowering costs associated with viral load testing and improving access in LMIC. A global diagnostic access initiative was launched in 2014 by UNAIDS, which challenged the global community to work with manufacturers to provide reasonably priced viral load testing, reducing the price of test kits to as low as $10 per test (*2*).

By the first quarter in 2015, 15 million persons living with HIV infection were on ART globally (*3*). Recent results from the Strategic Timing of Anti-Retroviral Treatment trial demonstrated that early treatment reduced morbidity and mortality in persons with HIV infection (*4*). As a result, a greater demand for early ART initiation and viral load testing exists (*4*). In sub-Saharan Africa, where 11 million persons living with HIV infection are receiving ART (*3*), an estimated six million ART patients do not have access to viral load testing (*5*). Certain countries in sub-Saharan Africa have adopted the 2013 WHO recommendation to use routine viral load testing for monitoring treatment (*6*). This report highlights the initial successes and challenges of viral load monitoring as a national strategy in seven of these countries.

Côte d'Ivoire, Kenya, Malawi, Namibia, South Africa, Tanzania, and Uganda are in various stages of scaling up viral load monitoring. Routine laboratory and clinical data were collected by the ministries of health and CDC personnel from each country's laboratory database on the total number of ART patients, the total number of viral load tests, the number of viral load tests with laboratory-confirmed viral suppression, and the established target number of viral load tests for 2015 and 2016. In addition, information was collected from the laboratory database on the time from sample collection to return of results to the referring clinic. The directors of the national reference laboratories and CDC laboratory liaisons were asked to report operational challenges and successes to viral load monitoring scale-up. The pre–scale-up period was defined as the year before each government scaled up routine viral load monitoring for their country and the post–scale-up period as the time from scaling up routine viral load monitoring until June 2015.

South Africa initiated viral load monitoring in 2004 and scale-up for routine viral load monitoring in 2014 on the basis of the 2013 WHO HIV treatment recommendations. In Kenya, Malawi, Namibia, and Uganda, the pre–scale-up period was 2013, and the post–scale-up period was 2014–2015. For comparison purposes, the pre–scale-up period for South Africa was defined as 2013 and the post–scale-up period as 2014–2015. For Côte d'Ivoire and Tanzania, the pre–scale-up period was 2014 and the post–scale-up period was 2015. In 2015, the number of ART patients was highest in South Africa (2,951,159) and lowest in Namibia (131,721) (Table 1). In 2015, the number of ART patients with one or more viral load test ranged from 3,687 (Côte d'Ivoire) to 2,119,890 (South Africa). Among countries initiating routine viral load monitoring scale-up in 2014, the proportion of ART patients with viral load tests in the pre– and post–scale-up period increased from 8% to 38% in Kenya, 6% to 11% in Malawi, 54% to 95% in Namibia, and 5% to 10% in Uganda (Table 1). A slight increase was seen in South Africa between the pre– and post–scale-up periods, from 72%–75%. In the countries where routine viral load monitoring scale-up occurred in 2015, the proportion of ART patients with viral load tests was low and unchanged between the pre– and post–scale-up periods in Tanzania (from 2% to 3%) and in Côte d'Ivoire (from 4% to 3%).

In 2015, the proportion of viral load tests with viral suppression in countries initiating routine viral load monitoring scale-up in 2014 was 78% in South Africa, 83% in Kenya, 84% in Malawi, 86% in Namibia, and 94% in Uganda (Table 1). Between the pre– and post–scale-up periods, viral suppression levels increased by 30% in Kenya and 16% in Namibia, and changed little in Malawi, South Africa, and Uganda. In comparison, suppression levels decreased in Tanzania (from 80% to 72%) and in Côte d'Ivoire (from 66% to 53%) in 2015 (Table 1).

During the post–scale-up period, the average time from specimen collection to return of results to the referring clinic varied, from 3 days in South Africa to 31 days in Kenya (Table 1). Turnaround times increased between the pre– and post–scale-up periods in Kenya and Malawi, remained unchanged in South Africa and Côte d'Ivoire, and decreased in Namibia, Tanzania, and Uganda. Laboratory results were returned to clinics using various methods, including short message service printers, laboratory information systems, courier services, email, and use of specimen transport networks to reduce turnaround times.

Difficulties in specimen transport and lack of trained laboratory personnel were among the most common challenges reported in viral load monitoring scale-up (Table 2). Five countries reported success with innovations in laboratory information management systems and use of high-throughput viral load platforms. Four countries reported that strong partnerships and use of specimen referral networks, such as networks for transporting specimens from health facilities to referral laboratories for early infant HIV diagnosis, were integral to success.

The majority of countries did not achieve the targets established by each government for routine viral load monitoring in 2015, highlighting the efforts needed in sub-Saharan Africa to improve viral load monitoring coverage rates to achieve the 90–90–90 objectives. The forecasted viral load testing gap for 2016 could be narrowed in some countries with implementation of strategies, including policies on laboratory service provision, use of automated high-throughput and polyvalent platforms, introduction of point-of-care viral load technologies, increasing work-flow efficiencies, and improving laboratory infrastructure.

Discussion

The majority of countries in this report are in early stages of initiating viral load testing as a national monitoring strategy for patients on ART. Five countries reported high levels of viral load suppression, which has been previously reported (*7*). The increase in viral load testing for Kenya and Namibia was associated with an increase in viral suppression levels; however, minimal change in viral suppression occurred in Malawi, and there was a decrease in viral suppression in Côte d'Ivoire and Tanzania. One possible explanation for increases in viral load suppression following increases in viral load testing is that with scale-up in viral load testing, follow-up of patients is more frequent, which can reinforce ART adherence and lead to an overall improvement in viral load suppression. In other settings where a decrease in viral load suppression was noted, the increase in viral load testing might have overwhelmed constrained resources, leading to a backlog in performing viral load tests, and preventing the timely use of results for patient management, which might ultimately result in a decrease in viral load suppression.

Numerous health system challenges were encountered as viral load monitoring scale-up was initiated, including difficulties with specimen transport, equipment breakdown, personnel shortages, and weak laboratory information management systems and laboratory infrastructure. Similar challenges have been reported with the expansion of early infant diagnosis of HIV-infected children (*8*). Furthermore, even in programs with routine viral load monitoring, a substantial proportion of patients with confirmed virologic failure on first-line ART are not being appropriately switched to second-line ART (*9*). Therefore, as viral load monitoring is being scaled up, management of patient results should also be addressed. Novel approaches are needed, including alternative methods to improve the quality and efficiency of specimen transport, the use of electronic tools for transmission of results, and efficient use of human resources. Continuous quality improvement in laboratory systems is needed to meet the rising demand for viral load testing (*10*). Workforce development should be optimized through training of health care providers to use viral load results appropriately for patient management. Appropriate use of viral load results is important to the impact of increasing viral load testing. As scale-up progresses, a robust monitoring and evaluation system is needed to determine the effectiveness of viral load monitoring scale-up.

The findings in this report are subject to at least four limitations. First, because it was not possible to disaggregate results by patient and timing of test, the direct impact of viral load monitoring on patient management could not be assessed. Second, lower viral suppression rates observed during the pre–scale-up period might not be representative of all persons on ART but might reflect targeted testing of persons who were suspected to be failing treatment. Third, the results for pediatric and adult patients might differ; however, pediatric data were unavailable for six of the seven countries. Finally, specific patient information was not collected to inform the findings on the proportion of patients who achieved viral load suppression.

The initial experience of viral load scale-up in these seven sub-Saharan African countries provides evidence that routine viral load monitoring for ART patients in this region can be achieved. Considerable investments will be required to improve laboratory systems for service delivery and strengthen the overall health systems infrastructure. Effective partnerships and substantial financial, operational, technical, and political commitments are needed for successful scale-up. Routine viral load monitoring and usage of results to inform clinical decisions for ART patients in sub-Saharan Africa will lead to substantial improvements in health outcomes moving toward epidemic control of HIV.

1Center for Global Health, Division of Global HIV/AIDS, CDC, Atlanta, Georgia; 2Center for Global Health, Division of Global HIV/AIDS, CDC, Windhoek, Namibia; 3Center for Global Health, Division of Global HIV/AIDS, CDC, Abidjan, Côte d'Ivoire; 4Department of Molecular Medicine and Hematology, National Health Laboratory Service, Johannesburg, South Africa; 5Center for Global Health, Division of Global HIV/AIDS, CDC, Lilongwe, Malawi; 6Center for Global Health, Division of Global HIV/AIDS, CDC, Nairobi, Kenya; 7Center for Global Health, Division of Global HIV/AIDS, CDC, Pretoria, South Africa; 8Central Public Health Laboratories, Kampala, Uganda; 9Namibia Institute of Pathology, Windhoek, Namibia; 10Center for Global Health, Division of Global HIV/AIDS, CDC, Kampala, Uganda; 11Center for Global Health, Division of Global HIV/AIDS, CDC, Dar es Salaam, Tanzania; 12National Department of Health, Pretoria, South Africa.

Corresponding author: Shirley Lecher, slecher@cdc.gov, 404-639-6315.

References

1. Joint United Nations Programme on HIV/AIDS. 90-90-90: A transformative agenda to leave no one behind. Geneva, Switzerland: Joint United Nations programme on HIV/AIDS; 2014. Available at http://www.unaids.org/en/resources/presscentre/unaidsspeeches/2014/20141025_SP_EXD_Vietnam_launch_of_909090_en.pdf .
2. Joint United Nations Programme on HIV/AIDS. UNAIDS and partners launch initiative to improve HIV diagnostics. Geneva, Switzerland: Joint United Nations Programme on HIV/AIDS; 2014. Available at http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2014/july/20140723dai .

3. Joint United Nations Programme on HIV/AIDS. How AIDS changed everything. MDG6: 15 years, 15 lessons of hope from the AIDS response. Geneva, Switzerland: Joint United Nations Programme on HIV/AIDS; 2015. Available at http://www.unaids.org/sites/default/files/media_asset/MDG6Report_en.pdf .
4. Lundgren JD, Babiker AG, Gordin F, et al. Initiation of antiretroviral therapy in early asymptomatic HIV infection. N Engl J Med 2015;373:795–807.
5. Ford N, Roberts T, Calmy A. Viral load monitoring in resource-limited settings: a medical and public health priority. AIDS 2012;26:1719–20.
6. World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Recommendations for a public health approach. Geneva, Switzerland: World Health Organization. Available at http://apps.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf .
7. McMahon JH, Elliott JH, Bertagnolio S, Kubiak R, Jordan MR. Viral suppression after 12 months of antiretroviral therapy in low- and middle-income countries: a systematic review. Bull World Health Organ 2013;91:377–385E.
8. Chiduo MG, Mmbando BP, Theilgaard ZP, et al. Early infant diagnosis of HIV in three regions in Tanzania; successes and challenges. BMC Public Health 2013;13:910.
9. Haas AD, Keiser O, Balestre E, et al. Monitoring and switching of first-line antiretroviral therapy in sub-Saharan Africa: collaborative analysis of adult treatment cohorts. Lancet HIV 2015;2:e271–8.
10. Nguyen S, Ramos A, Chang J, et al. Monitoring the quality of HIV-1 viral load testing through a proficiency testing program using dried tube specimens in resource-limited settings. J Clin Microbiol 2015;53:1129–36.

Summary

What is already known on this topic?

The World Health Organization advocates viral load testing to monitor persons with human immunodeficiency virus (HIV) infection receiving antiretroviral therapy (ART) to enable earlier detection of treatment failure. Although viral load monitoring is the standard of care in the developed world, CD4 cell counts and clinical monitoring have been used to monitor ART response in sub-Saharan Africa. Low- and middle-income countries face political, financial, and operational challenges to scaling up viral load testing.

What is added by this report?

In seven sub-Saharan African countries, viral load testing as a national monitoring strategy was scaled up during 2014–2015. Difficulties with specimen transport was a common challenge. Strengthening collaborations between ministries of health, HIV programs, laboratory programs, and development partners contributed to success in most countries.

What are the implications for public health practice?

Viral load testing in sub-Saharan Africa, with the goal of complete viral load suppression, will improve the health status of persons living with HIV and decrease HIV transmission and the occurrence of HIV drug resistance, and is a necessary step toward the goal of epidemic control of HIV. Training of additional personnel to meet the requirement for skilled human resources and improved sample transport systems are needed.

TABLE 1. Selected treatment and monitoring indicators for viral load (VL) monitoring scale-up during pre– and post–scale-up periods, by country — sub-Saharan Africa, 2013–2015

Country	VL monitoring periods			Cumulative no. of ART patients		No. of ART patients with ≥1 VL test		ART patients with ≥1 VL test (%)		VL tests with viral suppression (%)*		Turnaround time†		Established target number of VL tests	
	Yr of scale-up	Pre–scale-up	Post–scale-up	Pre–scale-up	Post–scale-up	Pre–scale-up	Post–scale-up	Pre–scale-up	Post–scale-up	Pre–scale-up	Post–scale-up	Pre–scale-up	Post–scale-up	2015	2016
Côte d'Ivoire	2015	2014	2015	129,993	138,365	4,922	3,687	4	3	66	53	10	10	50,000	112,000
Kenya	2014	2013	2014–2015	631,503	798,188	53,012	280,645	8	38	64	83	18	31	1,200,000§	1,393,557
Malawi¶	2014	2013	2014–2015	472,865	536,438	28,315**	61,227**	6	11	86	84	18	29	132,275	212,598
Namibia	2014	2013	2014–2015	126,779	131,721	76,716**	138,604**	54	95	74	86	5	4	192,616	206,520
South Africa	2014	2013	2014–2015	2,609,275	2,951,159	1,878,927	2,119,890	72	75	75	78	3	3	3,600,000	3,900,000
Tanzania	2015	2014	2015	600,886	758,344	14,334	22,772	2	3	80	72	10	4	87,589	363,314
Uganda	2014	2013	2014–2015	507,663	757,703	25,000	79,207	5	10	90	94	18	6	250,000	800,000

Abbreviation: ART = antiretroviral therapy.

* The percentage of viral load tests with viral suppression might include multiple tests per patient. In Kenya, the viral load suppression rate for pediatrics is 63% and represents 13% of the cumulative number of ART patients.

† Average time from specimen collection to return of test results to referring facility (days).

§ Might represent more than one viral load test per person.

¶ In the post–scale-up period, viral load testing is conducted every 2 years in Malawi compared with every 6 months and 12 months for other countries.

** The number of viral load tests could not be disaggregated at the individual level for adult and pediatric patients in Malawi and Namibia. Therefore, the proportion of ART patients with one or more viral load test is overestimated for these two countries. In Namibia, pediatric patients account for approximately 10% of all ART patients and receive two viral load tests per year. Because of this, 10% of the number of ART patients with one or more viral load test were assumed to be duplicates and were subtracted from the final value reported.

TABLE 2. Common challenges and successes to viral load scale-up in seven countries — sub-Saharan Africa, 2013–2015*

Challenges/Successes	Côte d'Ivoire	Kenya	Malawi	Namibia	South Africa	Tanzania	Uganda
Challenges							
No operational budget to support scale-up	X	X				X	X
Difficulty transporting samples	X	X	X	X		X	
Delays in commodity procurement and distribution		X	X				X
Inadequate laboratory information systems		X					X
Insufficient trained human resources dedicated for viral load testing	X	X	X			X	X
Equipment breakdown, delay in equipment repair		X					X
Inadequate laboratory and storage space to accommodate sample volume		X					
Insufficient viral load testing results management (record keeping and use of results for patient management in health care facilities)					X		
Successes							
Strong collaboration within MOH programs (e.g., HIV and laboratory) and between MOH and development partners	√	√	√	√	√		
Use of dried blood spots for viral load testing		√	√				√
Use of sample referral networks	√	√	√			√	√
Introduction of high throughput automated platforms	√	√	√		√	√	√
Renovations to improve laboratory infrastructure	√						√
Development of standardized procedures and curriculum	√	√					√
Participation in viral load EQA program	√		√	√			√
Innovations in laboratory information management systems	√	√	√	√			√

Abbreviations: EQA = external quality assurance; HIV = human immunodeficiency virus; MOH = ministry of health.

* Challenges and successes were based on country self-report. If a country did not report a particular challenge or success, the respective box was left blank.

20402-9371; telephone: (202) 512-1800. Contact GPO for current prices.

**Questions or messages regarding errors in formatting should be addressed to mmwrq@cdc.gov.

Page last reviewed: November 27, 2015
Page last updated: November 27, 2015
Content source: Centers for Disease Control and Prevention

Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30329-4027, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348 - Contact CDC–INFO