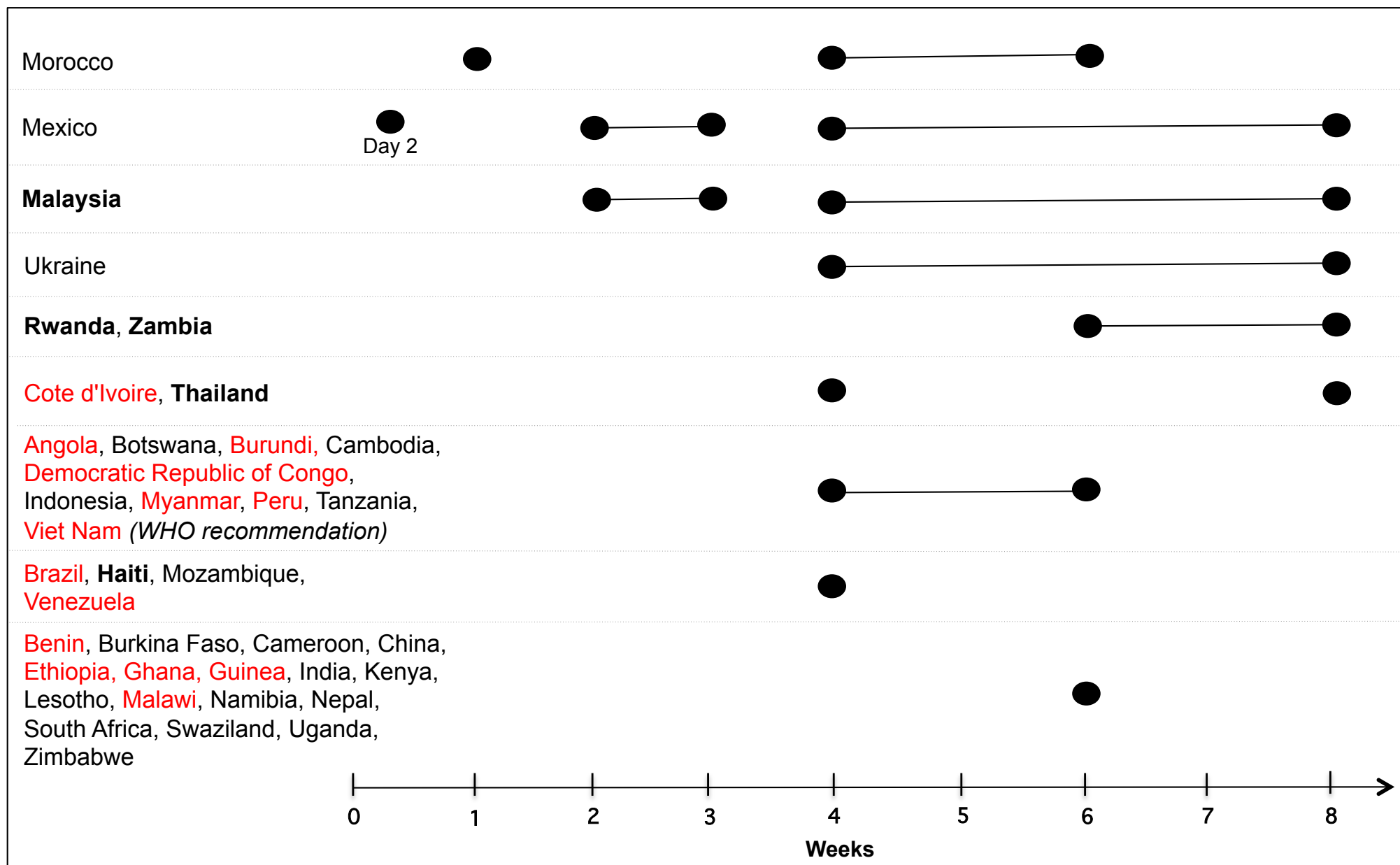


Survey results: The current state of provision of, and access to, infant diagnostic, CD4 and viral load testing across five countries

	India	Kenya	Malawi	South Africa	Zimbabwe
Number of people living with HIV/AIDS (ref: UNAIDS, year 2012)	2,085,008	1,646,012	1,129,768	6,070,751	1,368,128
Number of people on ART (ref: UNAIDS, year 2012)	750,000 (year 2014)	604,000	405,100	2,200,000	565,700
Viral load testing in national protocols to confirm treatment failure (after clinical or immunological failure) or offered routinely based on WHO 2013 guidelines (including adherence support)	confirm failure	confirm failure	routine and confirm failure (biennially, and 5000 copies/mL failure threshold due to use of DBS)	routine and confirm failure	confirm failure
Viral load testing available for this purpose in the public sector	limited	yes	limited	yes	limited
Number of viral load tests provided in 2013	6,000 - 7,000	53,000 (up from 15,000 in 2012; already 53,000 by May 2014)	37,000	2,400,000	30,000 - 48,000
CD4 threshold for treatment initiation (cells/μL)	350	350 (500 expected imminently)	500 (but most people started on ART based on clinical symptoms)	350	500
CD4 testing recommended for treatment monitoring	yes	yes	no	no, only one test 12 months post initiation	yes
Viral load monitoring to replace immunological treatment monitoring	not currently	not currently	not applicable (CD4 monitoring never recommended)	yes	yes, once routine viral load testing is fully implemented
Decision-maker responsible for switching to 2nd-line treatment	54 State AIDS Clinical Research Panels (SACEPs, formal committees)	doctors (increasingly using viral load to confirm failure)	doctors (decision often reviewed by Most officials and experienced doctors, especially when based on clinical signs alone)	clinicians (nurse-led care covers other services)	doctors (after consultation with a HIV/AIDS specialist or mentor)
Number of government laboratories offering viral load testing (number of instruments)	9 (20)	7 (15)	5 (6 Abbott)	17 (8 Abbott, 9 Roche)	1 (NMRL, Harare; 1 bioMérieux [supplied by MSF])
Number of government viral load testing instruments	20	about 15	6 Abbott	8 Abbott, 9 Roche	1 bioMérieux (supplied by MSF)
Manufacturers currently supplying viral load testing platforms and commodities	Abbott (being installed) and Roche	Roche and Abbott (about 50/50 split)	Abbott (government & NGOs), bioMérieux (MSF, Thyolo), DRW-SAMBA (MSF, Chiradzulu)	Abbott and Roche (50/50 volume split)	bioMérieux, Caviid (limited)
Manufacturers expected to supply laboratory-based viral load tests in the future (and reason)	Abbott and Roche (mainly due to technical support), possibly Caviid	Abbott and Roche (already established in-country; low \$10.50 price negotiated by CHAI) but others will be considered	Abbott (uniformity and simplicity; accuracy of results using DBS), possibly bioMérieux	dependent on tender (including quality, automation, integrated service and maintenance, renting equipment and price) 3 year duration	Roche (streamlining and familiarity), possibly bioMérieux and Caviid
Sample transport and results delivery	local facilities to towns; private courier from towns to lab	local facilities to towns; private courier from towns to lab (some access to web-based, SMS or SMS printers for results)	partially covered by Riders for Health (supported by EGPAP) otherwise informal government transportation systems	local facilities to towns; private courier from towns to lab (internet or SMS for results is possible)	local facilities to towns; private courier from towns to lab (FedEx)
Scale-up of viral load testing planned	yes, to approximately 30 laboratories	no official targets but aiming for 150,000 tests in 2014 (already achieved 54,000 = 20% of need)	2 new machines in 2014; no official targets but aiming for 300,000 tests annually by 2016 (80,000 in 2014 = 30% of need)	20% increase per year	5 instruments by end 2014 (= 54,000 tests or 7.7% coverage for routine testing); ultimately 2 instruments per each of the 10 provinces by end 2016
Priority groups during viral load testing scale-up	1) on ART >5 years 2) opportunistic infections 3) immunological decline	piggy-back on infant diagnostic testing using existing labs that could scale up capacity	piggy-back on infant diagnostic testing, beginning with high volume sites, prioritising high burden facilities (>5000 on ART) and district hospitals	not applicable (sufficient capacity)	those suspected of failing treatment
Access barriers to viral load testing and subsequent intervention	1) SACEPs as "gate-keepers" 2) cost 3) limited human resources 4) lack of procurement management (which is highly centralised) 5) poor awareness of importance 6) geography and distance (including sample collection & transport) 7) lab infrastructure and maintenance of equipment	1) funding 2) validation and acceptance of DBS 3) patient tracking 4) sample transport and results delivery 5) demand from doctors and other clinicians 6) logistics of full implementation 7) staffing at labs & clinics	1) funding 2) lack of lab staff and poor logistics 3) poor supply chain management 4) lack of training and staffing at clinics 5) poor record keeping and patient tracking 6) poor follow-up on results by healthcare workers and high loss to follow-up	1) access unequal between provinces and urban areas better serviced 2) training and capacity of healthcare workers 3) lack of initiative to request test or urgency to return results to patients or act on results 4) poor patient tracking and high loss to follow-up	1) funding 2) lack of existing lab capacity and instrument maintenance 3) poor supply chain management 4) poor sample transport and results delivery 5) lack of training and staffing at district level 6) lack of knowledge and testing demand from healthcare workers 7) weak adherence counselling
Third-line available	not yet, in process this year	extremely limited (and for about 100 people in next Global Fund budget)	no	yes (several hundred people switched)	no (future possibility through Global Fund)
Laboratory capacity for viral load testing	some	some	some	sufficient (even for CD4 threshold of 500 with increased staff and shift work)	some
Sample collection and transport capacity	some, needs improvement	some, needs improvement	some, needs improvement	yes	some, needs improvement
Point-of-care tests currently available	none (20 Alere PIMA CD4 devices ordered)	about 100 Alere PIMA CD4 devices (not currently in operation)	about 125 Alere PIMA CD4 devices (meeting about 30% of need)	limited number of Alere PIMA CD4 devices (Free State province)	>250 Alere PIMA CD4 devices (mostly used for treatment initiation)
Interest in virological point-of-care testing	not currently, not prior to validation, only limited to augment lab system, depending on cost	not currently, although SAMBA is being evaluated by KEMRI; waiting for tests to become commercially available to gauge performance, usability and price	not currently (except for implementation of SAMBA by MSF); concerns about underuse, incorrect use and capacity for nurses to perform tests	not currently, although some products have been evaluated by the NHLS; possibly for infant diagnosis	not currently, although some products may be validated at the NMRL, and substantial interest to overcome lack of lab and sample transport capacity, and result delivery, including for infant diagnosis
Interest in CD4 point-of-care testing	yes, in specifically targeted areas only, based on difficulty of terrain and overlaid on ART centres, only limited to augment lab system	unsure	unsure, not if CD4 testing is phased out altogether	not currently (awaiting results from evaluation of Free State pilot)	yes, mainly due to quick turn around time and guaranteed results delivery
Cost of viral load test at government lab	test: \$29; with lab overheads: \$35	test: \$10.50; with lab overheads: about \$20 (estimate)	test: \$15; with lab overheads about \$22 (estimate) (ref. CHAI)	test: \$10; with lab overheads (subsidised): \$29	test: \$23 (ref. MSF); with lab overheads: \$35
Cost of CD4 test at government lab	test: \$8	test: \$7-8 (ref. CHAI)	unknown	test with lab overheads (subsidised): \$5	unknown
Funding source for HIV	Global Fund and domestic	PEPFAR, DFID, Unitaid	Global Fund, Unitaid, World Bank, MSF	Global Fund and 70% domestic	Global Fund, Unitaid, MSF
Projected future funding for HIV	domestic	PEPFAR and Global Fund (primarily)	Global Fund (primarily)	domestic	Global Fund (primarily)
Stock-outs of lab commodities	yes, mainly due to poor supply chain	not reported	yes	not reported	yes
Perspective of, and recommendations from, civil society	1) support routine viral load testing 2) improve supply chain to prevent stock-outs 3) improve counselling at ART centres 4) educate people with HIV/AIDS and care-givers about viral load	1) raising awareness for people with HIV/AIDS and care-givers about viral load 2) improving access to testing 3) timely results delivery and correct follow-up intervention	unknown	1) support routine viral load testing 2) decrease drug stock-outs 3) educate people with HIV/AIDS and care-givers about viral load	advocate more for quality of care
Infant diagnostic testing in national protocols as per WHO 2013 guidelines	yes	yes	yes	yes	yes
Infant diagnostic testing available for this purpose	yes	yes	yes	yes	yes
Number of government laboratories offering infant diagnostic testing	7	7	5 (Abbott)	9 (Roche)	1 (NMRL), using 2 instruments (Roche)
Infant diagnostic test turn around time	sample transport: ≥3 days lab processing: 6 days result delivery: email to ART centre	2-4 weeks (>1 month in rural areas); some access to web-based results; SMS or SMS printers but mostly paper-based	3 weeks - 2 months; some access to SMS and SMS printers but mostly paper-based	1-10 weeks depending on geography; internet-based results possible otherwise SMS printers or hard copies	1-4 months
Use of DBS as a sample type (in addition to plasma)	only for infant diagnosis; needs validation for viral load use	yes, for infant diagnosis and viral load - although viral load is still controversial and requires further validation due to accuracy issues	yes, for infant diagnosis and, from 2014, for viral load (with a subsequent validation at 1,000 copies/ml)	only for infant diagnosis	yes, for both infant diagnosis and viral load

Disclaimer: The data is cross-sectional and refers only to government programmes and facilities, unless otherwise indicated. Data collection occurred from March to mid-May 2014. Figures are in US\$. The information and observations provided in this document are based on notes taken during in-person discussions with respondents and (in a handful of cases) responses provided by email. No fact-checking, validation or verification has taken place. In some cases, different respondents provided conflicting data or gave different assumptions, observations and impressions. No effort was made to resolve such variances; where relevant, such differences in opinion and/or details are noted.

Timing of Early Infant Diagnosis (EID) for HIV-Exposed Infants within 2 Months of Birth (Source: UNAIDS)



- In 2012, the percentage of HIV-exposed infants receiving a virological test within 2 months of birth was <30% in **countries in red** and >70% in **countries in bold** (source: UNAIDS Global Report, 2013).
- Eleven countries without recommendations and Nigeria, which recommends EID at first encounter, are not shown.

Frequency of CD4 Testing after ART Initiation from 51 Low- and Middle-Income Countries (Source: UNAIDS)

FREQUENCY	NO. OF COUNTRIES	COUNTRIES
Month 1; 3-monthly thereafter	1	Madagascar
3-monthly	1	China
Every 3-4 months	2	Malaysia, Sierra Leone
Every 3-6 months	5	Angola, Argentina, Dominican Republic, Pakistan, Ukraine
Month 3 and 6; 6-monthly thereafter	2	Botswana, Burkina Faso
Month 3; 6-monthly thereafter	2	Nigeria, Swaziland
Every 4-6 months	2	Chile, Mexico
6-monthly (<i>WHO recommendation</i>)	28	Benin, Brazil, Burundi , Cambodia, Cameroon, Colombia, Cote d'Ivoire, Democratic Republic of Congo, Ecuador, Ethiopia, Guatemala , Guinea, Haiti, India, Indonesia , Kenya, Lesotho, Mozambique, Myanmar, Nepal , Niger, Peru, Rwanda, Tanzania, Thailand, Viet Nam , Zambia, Zimbabwe
Every 6-12 months	1	Venezuela
Month 6; yearly thereafter	1	Ghana
In the case of virologic failure	1	Namibia
Month 12	1	South Africa
Not recommended	2	Malawi , Uganda
Recommendation not available	2	Morocco , Senegal

Note: Availability of CD4 testing services is limited in at least **16 countries in red**.

Recommendations on the Frequency of Viral Load Testing for ART Monitoring (Source: UNAIDS)

MONTH AFTER ART INITIATION	Month 2	Month 3	Month 6	Month 9	Month 12	Month 15	Month 18	Month 21	Month 24	Post the last VL test
Angola, Burundi, Chile*, Ecuador, Guatemala, Malaysia*, Mexico*, Myanmar, Nepal, Niger, Nigeria, Pakistan*, Venezuela, Viet Nam			✓		✓		✓		✓	6-monthly
Colombia	✓		✓		✓		✓		✓	6-monthly
Botswana, Dominican Republic, Peru		✓	✓		✓		✓		✓	6-monthly
Brazil, Sierra Leone		✓		✓		✓		✓		6-monthly
Benin, Namibia, South Africa, Thailand <i>(WHO recommendation)</i>			✓		✓				✓	Yearly
Burkina Faso, China, Ghana, Madagascar, Uganda, Zambia			✓				✓			Yearly
Guinea, Rwanda					✓				✓	Yearly
Malawi			✓						✓	Biennially
Cambodia									✓	Yearly

Note: This table does not include Argentina, which recommends viral load monitoring at 4-6 weeks and then every 3-6 months.

*While Chile, Malaysia and Mexico recommend viral load monitoring every 4-6 months, Pakistan recommends it every 3-6 months.