SUPPLEMENTARY MATERIAL FOR ISSUE BRIEF:

Achieving undetectable: what questions remain in scaling-up HIV virologic treatment monitoring?

Supplementary material includes national recommendations on infant diagnosis, CD4 and viral load testing, across 55 low- and middle-income countries, sourced from the UNAIDS database.

DECEMBER 2014

National recommendations: Guidelines on the use of infant diagnostic, CD4 and routine viral load testing across 55 low- and middle-income countries and the extent of implementation, where known

Data on guidelines was available from the UNAIDS database.

Routine viral load testing n = 39/52 (75%)	Targeted viral load testing n = 10/52 (19%)	Viral load testing not recommended n = 3/52 (6%)	No routine CD4 ART monitoring n = 4

	COUNTRY	Angola	Argentina	Benin	Botswana	Brazil	Burkina Faso	Burundi	Cambodia	Cameroon	Chile	China
	GUIDELINES	ART 2011 and 2013 update	ART 2012	ART 2012 and PMTCT	ART 2012	Adult ART 2013 and Paediatric ART 2009	ART 2009	ART 2010	Adult ART 2012 and Paediatric ART 2011	ART 2012	ART 2010	ART 2010 and PMTCT 2011
Infant diagnosis (using a virological test for HIV exposed infants <18 months of age)	When	4-6 weeks and, if negative, repeat at 6 months and 12 months; 9 months (serologic*) and, if positive, repeat every 3 months up to 18 months; 3 months post weaning (serologic) and, if positive, repeat every 3 months up to 18 months	Unknown	6 weeks; 6-8 weeks post weaning; 12 months (serologic) or if symptomatic; 18 months or 6 weeks post weaning (serologic)	4-6 weeks; 6 weeks post weaning; 18 months (double serological test) if infant is not breastfeeding	After 1 month; 2 months (if negative or discordant result); 12 months (serologic), if 2 negative HIV DNA PCR	6 weeks; 6 weeks post weaning	4-6 weeks	4-6 weeks; symptomatic; 6 weeks post weaning; 18 months (serologic)	6 weeks; 4 weeks after first test (if discordant result); 15 months (serologic); 4-6 weeks after weaning; 18 months (serologic)	Unknown	6 weeks; 3 months; 12 months (serologic); 18 months (serologic)
	Type of test	Virologic; serologic as HIV DNA PCR is limited	Unknown	HIV DNA PCR	HIV DNA PCR	RNA	HIV DNA PCR	HIV DNA or RNA	HIV DNA PCR; serological test if unknown HIV status of mother	HIV DNA PCR	Unknown	HIV DNA PCR
	Confirmation (type of test)	Recommended; test depends on availability	Unknown	HIV DNA PCR (if positive on first HIV DNA PCR at 6 weeks)	HIV DNA PCR	RNA (if positive on first HIV RNA test)	No	Unknown	HIV DNA PCR	HIV DNA PCR	Unknown	HIV DNA PCR (if positive on first HIV DNA test)
	Availability*	EID using HIV DNA PCR was piloted in 2009; in the capital there are four pilot units that perform PCR DNA; scale-up of EID at national level has progressed slowly	Unknown	Unknown	Plans to implement SMS technology in 2014 for mother and baby tracking and improve laboratory turn around time	In 2011, 80 of 305 (26%) health facilities provided EID services	In 2013, 68% (1745) health facilities provided PCR on site or from dried blood spot; but accessibility remains low because only six laboratories have the technical capacity to implement the PCR	Unknown	Availability of EID has increased as a result of Boosted Linked Response	A total of 167 (8%) of health facilities offering PMTCT services in 2012 offered EID services; reporting the results of PCR recipients takes 45 days on average	In 2012, EID was widely available; according to the national standard, the first diagnostic study sample of children born to HIV-positive mothers is within the first 48 hours after birth	Unknown
Infants born to HIV+ women receiving a virological test within 2 months of birth (%)	Year: 2011	8%	70%	33%	46%	35%	29%	Unknown	61%	56%	99%	22%
	Year: 2012	9%	70%	26%	39%	21%	40%	8%	33%	46%	97%	34%
	Year: 2013	17%	Unknown	18%	58%	Unknown	26%	17%	40%	24%	Unknown	Unknown
CD4 testing for treatment initiation and monitoring	ART Initiation criteria (cells/µL)	500	350, recommended for 350-500, consider >500	350	350	Irrespective of CD4 count	350	350	350	200	350	350
	Initiation irrespective of CD4 count	TB, WHO stage III or IV, pregnant women, hepatitis B, serodiscordant couples, high cardiovascular risk, people >55 years old, HIV-associated nephropathy	Symptomatic, HIV-associated nephropathy, hepatitis B, pregnant women, serodiscordant couples, recent infection, age >50 years, elevated red cell volume	TB, WHO stage III or IV, pregnant women, serodiscordant couples	TB, WHO stage III or IV, severe WHO stage II condition, CD4% <15%	For all people living with HIV (test and treat)	WHO stage III or IV	TB, WHO stage III or IV, hepatitis B	TB, WHO stage III or IV	WHO stage IV, WHO stage II or III if total lymphocyte count <1200	TB, CDC category C	TB, WHO stage III or IV
	Treatment monitoring	Every 3 to 6 months	Every 3 to 6 months	Every 6 months	3 months, 6 months and every 6 months thereafter	Every 6 months	3 months, 6 months, and every 6 months thereafter	Every 6 months	Every 6 months	Every 6 months	Every 4-6 months	Every 3 months for 1 year, then every 6 months
	Availability*	Unknown	Unknown	Unknown	Unknown	250 health services offering ANC perform CD4 counts at the same place or have a system for transportation of blood samples; there are 90 laboratories for CD4 count	In 2013, 38 ANC facilities were providing CD4 testing using fixed and mobile strategies. Also, in 2013, 30 CD4 units were acquired and 30,604 CD4 tests were conducted. But equipment failures persisted and biological testing is costly.	The immunological monitoring of patients is insufficient due to the problem of maintenance of equipment	Unknown	Limited availability; in 2011, 42 CD4 machines were acquired to facilitate implementation of new guidelines	Access to immunological monitoring is widely available	All provinces have the capacity; 406 laboratories carry out CD4 testing; the proportion of people receiving CD4 testing increased from 54.2% in 2009 to 71.1% in 2011
Viral load (HIV RNA) testing (for treatment monitoring)	ART Initiation criteria (copies/mL)	VL >100,000 irrespective of CD4 count	CD4 >500 and VL >100,000	NA	NA	CD4 >500 and VL >100,000	NA	NA	NA	NA	NA	CD4 350-500 if high VL
	Treatment monitoring	Every 6 months; If VL detectable, repeat after 1 month	4-6 weeks, then every 3-6 months	6 months, 12 months, then every 12 months	3 months, 6 months, every 6 months thereafter	2-3 months, then every 6 months	6 months, 12 months, then every 12 months	Every 6 months	24 months, then every 12 months or if treatment failure is suspected	Unknown	Every 4-6 months (or at least once a year)	6 months, 12 months, then every 12 months
	Virological failure threshold (copies/mL)	Detectable VL after 6 months on ART	VL >200 RNA (for automated methods) or VL >50 (by manual method) 24 weeks after starting ART	VL >1000	VL >400 after 6 months post ART or VL rebound to >400 after documented full suppression	Detectable VL 6 months after beginning or modification of ART or in individuals who maintained undetectable VL on ART	Persistence of detectable VL (>10,000) after 6 months of treatment	Detectable VL after 6 months on treatment or undetectable VL reverting detectable during ART	VL >5000	Unknown	Two consecutive VL >1000	VL >10,000
	Availability*	Unknown	11,436 people registered at least one viral load in 2011; Viral load was <50 in 63%, and between 51-400 in 13.5%, of people	Unknown	Widely available	Widely available - 80 viral load laboratories in 2013. As a result, in 2013, approximately 75% of individuals on ART had undetectable VL	In 2013, the ESTHERAID project started in Hauts-Basins, Boucle du Mouhoun, Cascades and Southwest, wherein blood samples were transported to the day hospital of Bobo-Dioulasso. In 2013, 10,526 VL tests were conducted.	The virological monitoring of patients is insufficient due to the problem of maintenance of equipment	Lack of equipment to check viral-load leads to lost follow-up	Limited availability - An agreement was signed to lower the cost of VL test from 16,000 to 10,000 CFA francs. A system for collecting samples in the northern part (Far North, North and Adamawa) was also organized to carry out the VL test at Centre Pasteur Annexe de Garoua	Access to virological monitoring is widely available	All provinces have the capacity; 101 laboratories can perform VL testing

	COUNTRY	Colombia	Cote d'Ivoire	Democratic Republic of Congo	Dominican Republic	Ecuador	Ethiopia	Ghana	Guatemala	Guinea	Haiti	India
	GUIDELINES	ART 2010	ART 2005	ART 2010	Adult ART 2013 and Paediatric ART 2013	ART 2013	ART 2008 and 2013 update	ART 2010	ART 2012	ART 2011	Adult ART 2011 and Paediatric ART 2006	ART 2013, ART 2013 update and PMTCT 2013
Infant diagnosis (using a virological test for HIV exposed infants <18 months of age)	When	Unknown	Non-breastfeeding infants: 2 tests at least one month apart after infant turns 4 weeks old; breastfeeding-infants: 2 tests at least one month apart 3 months post weaning	4-6 weeks; 9 months (serologic) or symptomatic	6 weeks, 6 months	Unknown	6 weeks symptomatic, 12 months, or 6 weeks after weaning (serologic)	6 weeks, 6 weeks post weaning, 18 months (serologic)	Unknown	6 weeks, symptomatic, 2 months post weaning (if first HIV DNA PCR is negative)	4 weeks, 6 weeks post weaning, 18 months (if virologic test is not available)	6 weeks or suspected HIV, 6 months, 12 months, 18 months (3 serological tests)
	Type of test	Unknown	HIV DNA PCR	HIV DNA PCR	HIV DNA PCR	HIV DNA or RNA PCR	HIV DNA PCR	HIV DNA PCR	Unknown	HIV DNA PCR	Virologic (if available)	HIV DNA PCR
	Confirmation (type of test)	Unknown	No	HIV PCR, serologic (6 weeks post weaning or at 18 months)	HIV DNA PCR	Unknown	No	Unknown	Unknown	No	Serological test at 18 months after virological test at 4 weeks; virological test if first test is a serological test	HIV DNA PCR using whole blood specimen after positive HIV DNA PCR
	Availability*	Improved access to diagnosis of children exposed in the first 17 months of life	There are two laboratories with PCR capabilities located in Abidjan	Only the National Reference Laboratory on HIV has PCR equipment and receives samples on filter paper from across the country for analysis	Compared to 2010, there was a decrease in the number of infants tested due to delays in the supply of inputs (filter paper and reagents)	Unknown	Limited access to and utilisation of EID services	Five institutions were equipped in 2009 with HIV DNA PCR machines; 250 service providers were trained to undertake EID using the dried blood spot method; in 2013, 8 PCR DNA machines were procured	Unknown	Two PMTCT sites (DREAM and MSF-Belgium) located in Conakry provide EID services	Unknown	EID was rolled out in March 2010 and is operational through 1157 integrated counselling and testing centres and 217 ART centres across 31 States; there are seven referral laboratories; 12,169 HIV-exposed infants <18 months old were tested in 2012
Infants born to HIV+ women receiving a virological test within 2 months of birth (%)	Year: 2011	48%	4%	2%	59%	90%	11%	18%	10%	12%	67%	Unknown
	Year: 2012	68%	15%	3%	44%	90%	19%	16%	14%	0%	70%	Unknown
	Year: 2013	Unknown	15%	10%	Unknown	24%	21%	30%	8%	5%	37%	4%
CD4 testing for treatment initiation and monitoring	ART Initiation criteria (cells/µL)	<250	200; 350 and CDC category B	350	350	350, recommended for 350-500	500	350	350	350 (consider for 350-500)	350	350
	Initiation irrespective of CD4 count	Symptomatic	CDC category B or WHO stage II, III or IV	TB, WHO stage III or IV	TB, WHO stage III or IV, pregnant women, hepatitis B, hepatitis C, age >55 years, high risk of cardiovascular disease, HIV-associated nephropathy	Cirrhosis, TB, symptomatic, age >55 years, high risk of cardiovascular disease, hepatitis B and C, pregnant women, HIV-associated nephropathy, serodiscordant couples	TB, WHO stage III or IV, pregnant women	TB, WHO stage III or IV	TB, symptomatic (CDC category C), pregnant women, hepatitis B	WHO stage III or IV	TB, WHO stage III or IV, hepatitis B, people >60 years old, HIV-associated nephropathy	TB, WHO stage III or IV, hepatitis B and C
	Treatment monitoring	Every 6 months	Every 6 months	Every 6 months	Every 4-6 months	Every 6 months	Every 6 months	6 months and yearly thereafter	Every 6 months	Every 6 months	Every 6 months	Every 6 months
	Availability*	Unknown	Unknown	CD4 diagnosis has expanded since 2009	Unknown	Unknown	Unknown	All district, regional, and teaching hospitals have CD4 count machines; but stock-outs of CD4 count reagents is a challenge	CD4 testing is done centrally where Regional Care Units send the samples to the national reference centers, which have the machines to run these tests; the purchase and acquisition of CD4 testing is centralized	CD4 devices were acquired from funds from GIZ; in 2012 and 2013, no new CD4 devices were acquired	More than 70% of the 131 locations providing HIV care have either manual or PIMA devices for CD4 testing offered by the CDC	There are 264 CD4 machines installed, serving 380 ART centres; about 975,725 CD4 tests have been performed in 2012
Viral load (HIV RNA) testing (for treatment monitoring)	ART Initiation criteria (copies/mL)	CD4 250-350 and VL >100,000	NA	NA	CD4 >350 and VL >85,000	CD4 >500 and VL >100,000	NA	NA	NA	CD4 350-500 and VL >100,000 on 2 separate tests	NA	NA
	Treatment monitoring	2 months; repeat after 6 months if optimal response at 2 months and every 6 months therafter if optimal response at 6 months; in case of suboptimal response and compliance or tolerance barriers, repeat 2 months after barriers are corrected; and in case of no barriers, repeat immediately	VL is not essential to initiate or monitor treatment	If performing VL is feasible, it should be used primarily to identify suspected treatment failure after CD4 decline after two successive measurements or the patient develops an OI on ART	Every 6 months	Every 6 months	Because of the limitation of resources, VL has not been considered as a standard benchmark for initiation or follow-up of ART	6 months and yearly thereafter; In a case of suspected failure, viral load must be done earlier	Every 6 months	Annually in reference centers; only in the case of immunological failure elsewhere	VL in cases of suspected treatment failure	VL monitoring is recommended for suspected clinical or immunological failure
	Virological failure threshold (copies/mL)	VL >400 after 6 months on ART; VL >1 log, 2 months after correction of compliance or tolerance barriers	Increase of VL by ≥1 log	VL >5000 after 6 months on treatment	Progressive increase in VL after undetectable VL (VL <60)	Detectable VL at 24 weeks after the start of ART on heightened adherence; detectable VL on two consecutive occassions at least four weeks apart after reaching undetectable	Plasma VL >10,000 after six months on ART	VL >5000 six months after initiating therapy in persons that are adherent to ART	VL >5000 after 12 months on ART; detectable VL >1000 on two measurements one month apart after an undetectable VL	Inability to reduce VL to undetectable levels (<50) after 6 months of ART; or VL becomes detectable after a long period of virologic success	VL >5000	VL >5000 after at least 6 months on ART
	Availability*	Unknown	Unknown	Limited availability	Unknown	Unknown	Limited availability	Unknown	VL testing is done centrally where Regional Care Units send the samples to the national reference centers, which have the machines to run these tests; the purchase and acquisition of VL testing is centralized	Limited availability	Only 4 sites offer targeted VL for 3,000 patients from a pilot project supported by the National Public Health Laboratory, NAP and the CDC	NACO piloted VL testing at 2 centres for 10 months from January 2008; currently there are nine laboratories and 4157 tests were performed in 2012

	COUNTRY	Indonesia	Kenya	Lesotho	Madagascar	Malawi	Mali	Malaysia	Mexico	Morocco	Mozambique	Myanmar
	GUIDELINES	ART 2011 and PMTCT 2013	ART 2014	ART 2014	ART 2013	ART 2014	ART 2013	Adult ART 2011 and Paediatric ART 2008	ART 2012	ART 2012 and HTC 2012	Adult ART 2010 and 2012 update, and Paediatric ART 2011	ART 2011
Infant diagnosis (using a virological test for HIV exposed infants <18 months of age)	When	4-6 weeks, 4 weeks after first test, 9-12 months (serologic or HIV RNA PCR)	6 weeks (serologic), 9 months or if symptomatic (serologic), 18 months or 6 weeks after weaning (serologic)	6 weeks (HIV DNA PCR, serological test if HIV status of mother is unknown), HIV DNA PCR at 14 weeks if breastfeeding or weaned <6 weeks, 9 months (serologic) if breastfeeding or weaned <6 weeks, rapid test 6 weeks post weaning,18 months (serologic) if never breastfed or weaned >6 weeks	Unknown	6 weeks, symptomatic (serologic)	4-6 weeks, one month after first test if on replacement feeding, 6 weeks after weaning, 9 months (serologic), 18 months (serologic)	14-21 days, 1-2 months, 4-6 months	48 hours, 2-3 weeks, 4-8 weeks; repeat after 4-6 months if negative; if child is at low risk, test at 48 hours, 3 months and 6 months	1 week, 4-6 weeks, 9 months, 18 months (serologic)	1 month, symptomatic, between 9-18 months (serologic), 18 months or 2 months after weaning (serologic)	4-6 weeks, 9 months (serologic) or symptomatic, 6 weeks after weaning
	Type of test	HIV DNA PCR	HIV serological test	HIV DNA PCR	Unknown	HIV DNA PCR if child is <12 months; serological test at 12-18 months old or if mother's status unknown	HIV DNA or RNA PCR	HIV DNA PCR	HIV DNA or RNA PCR	HIV DNA PCR	HIV DNA PCR if child is <9 months; serologic (Determine and Unigold RDTs) for 9-18 months old	Virological test
	Confirmation (type of test)	Serological test at 18 months if positive test result at 9-12 months	HIV DNA PCR (if result from serological testing is positive)	HIV DNA PCR	Unknown	HIV DNA PCR if serological test result is positive (for <12 months old) or negative (for >12 months old); confirmatory serological test at 12 and 24 months	HIV DNA or RNA PCR; confirmatory viralogic test if discrepency between first two test results	Serologic (at 12 months; if positive, repeat at 18 months)	HIV RNA PCR	HIV DNA PCR	HIV DNA PCR	Virological test
	Availability*	In 2011, EID services were available at 2 sites (both in Tanah Papua)	Infant diagnostic sites have increased from 434 in 2007 to 1500 in 2010; diagnostic laboratory services have been established at seven referral sites but availability is still limited	Volume of HIV DNA PCR tests processed has increased from 3600 in 2007 to 10,907 in 2010 and 11,437 in 2011	Unknown	In 2011, of the 544 PMTCT sites, 200 (37%) sites provided EID services but the median turn-around time from collection of DBS to dispatch of results was a considerable 19 days	Unknown	Unknown	In 2011, 100% of health facilities provided EID services	EID facilities are available in two support centers	The number of health facilities offering sampling for PCR increased from 597 in 2012 to 752 in 2013; there are four referral laboratories; provision and expansion of mobile printing technology for PCR DNA HIV results to 500 health units has decreased the turn-around time for test results	HIV DNA testing for EID started in June 2010; in 2011, 54 (9%) health facilities provided EID services; decentralisation of HIV testing, integrated in ANC settings nationwide, is planned
Infants born to HIV+ women receiving a virological test within 2 months of birth (%)	Year: 2011	Unknown	39%	72%	2%	Unknown	9%	100%	Unknown	13%	41%	5%
	Year: 2012	Unknown	39%	Unknown	0%	4%	14%	100%	Unknown	47%	35%	7%
	Year: 2013	2%	42%	36%	1%	15%	12%	68%	Unknown	41%	35%	6%
CD4 testing for treatment initiation and monitoring	ART Initiation criteria (cells/µL)	350	500	500	500	500	500	200 (consider for <350 and >350 but CD4% <14%)	350	350	350	350
	Initiation irrespective of CD4 count	TB, WHO stage III or IV, pregnant women, men who have sex with men, hepatitis B and C, female sex workers, injecting drug users, serodiscordant couples	TB, WHO stage III or IV, hepatitis B, pregnant women, serodiscordant couples, HIV-associated nephropathy	TB, WHO stage III or IV, hepatitis B, pregnant women, serodiscordant couples	TB, WHO stage III or IV, hepatitis B, pregnant women, serodiscordant couples	TB, WHO stage III or IV, pregnant women	TB, WHO stage III or IV, pregnant women, serodiscordant couples, hepatitis B, hepatitis C, HIV-associated nephropathy	Symptomatic, HIV–associated nephropathy, hepatitis B	WHO stage III or IV, hepatitis B, pregnant women, HIV-associated nephropathy, acute retroviral syndrome	Symptomatic, hepatitis B, HIV-associated nephropathy, severe thrombocytopenia	TB, WHO stage III or IV	MDR TB, WHO stage III or IV, hepatitis B
	Treatment monitoring	Every 6 months	Not recommended; CD4 monitoring every 6 months if VL monitoring is not available	Every 6 months	1 month, then every 3 months	Not recommended	Every 6 months but at least once a year	Every 3-4 months; once CD4 count is consistently >350, monitor every 6 months if the VL remains suppressed	Every 4-6 months	Unknown	Every 6 months	Every 6 months
	Availability*	CD4 testing services are limited	Unknown	Unknown	Unknown	In 2012, CD4 count machines (including point-of-care devices) were installed at 89 sites; many CD4 machines were broken or were running considerably below capacity	Unknown	Unknown	In 2011, 368 of 15,100 health facilities providing ANC services also provided CD4 testing; the health insurance covers the cost of ART, CD4 and VL testing	CD4 is operational within 2 Referral University Hospital Centres and 4 Referral Centres	Unknown	In 2011, 40 of 10,000 health facilities providing ANC services also provided CD4 testing; CD4 services were available onsite in 8 facilities
Viral load (HIV RNA) testing (for treatment monitoring)	ART Initiation criteria (copies/mL)	NA	NA	NA	NA	NA	VL >100,000 irrespective of CD4 count on two counts at least 3 months apart	NA	NA	NA	NA	NA
	Treatment monitoring	If resources permit, VL testing is recommended in cases of suspected treatment failure	Month 6, month 12 and then every 12 months	Month 6, month 12 and then every 12 months	6 months, then yearly	6 months, 2 years, and every 2 years thereafter	Every 6 months but at least once a year	4-6 months; when stable on treatment, consider VL every 6 months	Every 4-6 months or more frequently	6 months, repeat if treatment failure is suspected	6 months, then repeat if treatment failure (clinical or immunological) is suspected	Every 6 months; if availability is limited, use to confirm treatment failure; CD4 is used when VL is not available
	Virological failure threshold (copies/mL)	VL >5000 or VL detectable after previously being undetectable	VL >1000	VL >1000	VL >1000	VL >5000	VL >1000 after 24 weeks on ART documented by two measurements of VL at three months apart	VL >50 after 16-24 weeks on treatment; after virological suppression (VL <50), repeated detection of VL >400	VL >400 after 6 months on ART, or VL >50 after 12 months on ART, or VL is detectable after complete suppression (repeat VL before 8 weeks)	VL >5000	Detectable VL after 6 months or up to 1 log VL increase compared to previous VL, confirmed by repeated measures (30-45 days apart); or detectable VL >10,000, confirmed by 2 measures (30-45 days apart) despite good adherence, previously undetectable VL and no current vaccination or OI	VL >5000
	Availability*	Unknown	Limited availability; there are 7 referral facilities	Limited availability	Unknown	Roll-out in 2011, availability is limited	There are 8 laboratories and 2 reference laboratories for VL testing in Mali	Unknown	In 2013, 87% people on ART tested for VL had a suppressed VL and 90% people on ART tested for VL had VL level ≤1000 copies/mL after 12 months of therapy	Laboratory for viral load monitoring has been established in the city of Agadir	Limited availability - weak financing, human resources and institutional capacity are challenges delaying the introduction of VL	Limited availability

	COUNTRY	Namibia	Nepal	Niger	Nigeria	Pakistan	Papua New Guinea	Peru	Rwanda	Senegal	Sierra Leone	South Africa
	GUIDELINES	ART 2014	ART 2012	ART 2009	ART 2010	ART 2005, PMTCT 2006 and HTC	ART 2012	Adult ART 2012 and Paediatric ART 2009	ART 2013	ART	ART 2006	ART 2013 and PMTCT 2013
Infant diagnosis (using a virological test for HIV exposed infants <18 months of age)	When	6 weeks, 9 months (serologic), 3 months post weaning (serologic)	6 weeks, 6 weeks post weaning, 9 months during the time of measles vaccination (serologic)	Unknown	<9 months at first encounter, 6 weeks after weaning (serologic), 9 months or if symptomatic (serologic), 18 months (serologic)	Unknown	6 weeks, 6 weeks after weaning, symptomatic (serologic), 18 months (serologic)	4-6 weeks	6-8 weeks, 9 months (serologic), 18 months (serologic)	Unknown	Unknown	6 weeks or symptomatic, 6 weeks post weaning, 18 months (serologic)
	Type of test	HIV DNA PCR	HIV DNA PCR	Unknown	HIV DNA PCR if child is <9 months, serological test for children 9-18 months old	Unknown	HIV DNA PCR	HIV DNA PCR	HIV DNA PCR	Unknown	HIV DNA or RNA PCR	HIV DNA PCR
	Confirmation (type of test)	HIV DNA PCR; confirmatory HIV DNA PCR if discrepency between first two test results	HIV DNA PCR; HIV serological test at 18 months	Unknown	HIV DNA PCR	Unknown	HIV DNA PCR	HIV DNA PCR	HIV DNA PCR; confirmatory HIV DNA PCR if discrepency between first two PCR tests	Unknown	Unknown	HIV RNA PCR; serological test at 18 months for confirmation
	Availability*	HIV DNA PCR testing was introduced in 2005 and by March 2011, 224 (66%) health facilities were submitting dried blood spot samples for DNA PCR	Only 5 health facilities provide EID services; dried blood spot samples are sent to Bangkok; in 2013, 76 babies were enrolled for EID from the sites; National Public Health Laboratory (NPHL) has initiated the process of in-country DNA PCR testing	Limited availability - challenges in providing EID include malfunctioning of the steering circuit samples for PCR	Very few health facilities (274) are providing EID services	Unknown	DNA PCR methods using dried blood spots are being implemented through a separate program and are available at 170 sites in 18 province; there are 2 EID testing laboratories	Unknown	In 2013, all health facilities (health center and hospitals), including some district hospitals, collected dried blood spot samples; to complement the Rwanda National Reference Laboratory (NRL), a second laboratory center was set up in the southern province	EID services have shown improvement due to formalization of the routing circuit and use of SMS text messages to communicate results; 7 PCR machines are available in the country	EID was piloted in 2011 at five sites; it has been scaled-up tremendously and is currently being provided in 19 district hospitals	Government scaled up its efforts to improve EID by increasing the capacity for PCR testing at primary health care facilities
Infants born to HIV+ women receiving a virological test within 2 months of birth (%)	Year: 2011	Unknown	2%	Unknown	4%	20%	31%	10%	Unknown	8%	Unknown	50%
	Year: 2012	Unknown	Unknown	Unknown	Unknown	0%	25%	17%	75%	10%	3%	Unknown
	Year: 2013	56%	5%	9%	4%	2%	79%	33%	Unknown	16%	41%	78%
CD4 testing for treatment initiation and monitoring	ART Initiation criteria (cells/µL)	500	350	350	350	200, 350 and WHO stage III	350	350	500	200, 350 and CDC category B	350	350
	Initiation irrespective of CD4 count	TB, WHO stage III or IV, hepatitis B, serodiscordant couples, HIV-positive concordant couples currently intending to conceive a child	TB, WHO stage III or IV, hepatitis B	WHO stage IV	TB, WHO stage III or IV, hepatitis B, serodiscordant couples (>350), HIV-associated nephropathy	WHO stage IV	TB, WHO stage III or IV, pregnant women, hepatitis B	TB, symptomatic (CDC category C), pregnant women, HIV-associated nepropathy, hepatitis B	TB, WHO stage III or IV, pregnant women, hepatitis B, serodiscordant couples, men who have sex with men, female sex workers	CDC category C, Karnofsky score >70	WHO stage III or IV	TB, WHO stage III or IV
	Treatment monitoring	Use in case of virological failure to assess immunological status and inform clinical management	Every 6 months	Every 6 months	3 months, every 6 months	Every 3 to 6 months	Every 6 months	Every 6 months	Every 6 months	Unknown	Every 3-4 months	At 12 months only
	Availability*	In 2012, planning for roll-out of point-of-care CD4 count machines began	There are 18 CD4 count machines across 18 different ART sites	Unknown	Unknown	Three lab-based CD4 machines are installed in Islamabad, Lahore and Karachi; USAID provided the kits for 2012-2013; PoC CD4 machines were introduced at secondary level of care (WHO pilot programme)	60% - 80% of primary health care facilities have access to CD4 point of care for testing their patients; POC CD4 is available on-site in 40 health facilities	Unknown	Unknown	All regions have CD4 machines; 86 machines were available in 2013; problems include stock-outs of reagents and a lack of resources for maintenance (21 of 86 devices were non-functional); efforts are being made to use mobile machines in areas of difficult access	Unknown	Widely available
Viral load (HIV RNA) testing (for treatment monitoring)	ART Initiation criteria (copies/mL)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	Treatment monitoring	Month 6, month 12 and then every 12 months (for adults)	6 months, then every 6 months (do at least one a year as availability is limited)	Every 6 months	Every 6 months	Every 3 to 6 months, if available	Every 6 months	At 3 months, 6 months and then every 6 months	Every 12 months	Unknown	3 months, every 6 months thereafter	6 months, 1 year, and then every 12 months
	Virological failure threshold (copies/mL)	VL >1000 after 6 months on ART or viral rebound to >1,000 on two consecutive measurements after a period of viral suppression	VL >5000 at 6 months after ART	VL is detectable after 6 months of effective ART	VL >400 after 6 months on ART, or VL >50 after 12 months on ART	Increasing VL from an undetectable level	VL >5000	VL >400 after 6 months on ART; VL >400 on two measurements with an interval of 4 weeks after an undetectable VL	VL >1000 on two consecutive measurements after 3 months with adherence support	Unknown	VL >400 after 24 weeks or VL >50 after 48 weeks	VL >1000
	Availability*	Limited availability - VL testing is only available in Windhoek and transporting specimens across long distances poses challenges and delays results	VL testing is limited to Kathmandu; there is a plan to procure additional machines through external funding for all 5 regions; from 2009-2013, 1,529 VL tests were conducted and 1,086 tests reported VL <1000	Low capacity and maintenance of VL machines; malfunctioning of delivery and processing of samples	Limited availability	Three VL machines are installed in Islamabad, Lahore and Karachi; USAID provided the kits for 2012-2013 for Provincial and National programmes	Limited availability; there is one lab where VL testing is performed	Unknown	Unknown	13 VL machines were available in 2013	Unknown	Widely available

	COUNTRY	South Sudan	Sudan	Swaziland	Thailand	Uganda	Ukraine	United Republic of Tanzania	Venezuela	Viet Nam	Zambia	Zimbabwe
	GUIDELINES	ART 2014	ART 2014	ART 2010	ART 2010 and draft ART 2013	ART 2012 and 2013 update	ART 2010 and Paediatric ART 2006	ART 2012 and PMTCT 2013	ART 2014	ART 2009 and 2011 update	ART 2013	ART 2013
Infant diagnosis (using a virological test for HIV exposed infants <18 months of age)	When	4-6 weeks, symptomatic 9 months (serologic) 18 months and/or 6 months after weaning (serologic)	First encounter, 9 months or symptomatic (serologic), 6 months after weaning or 18 months (serologic)	6 weeks, 6-8 weeks post weaning (serological test if 12-18 months old), 18 months (serologic)	1 month, 2 months, 18 months (serologic)	6 weeks (HIV DNA PCR, serological test if mother's HIV status is unknown), 6 weeks after weaning, 18 months (serologic)	1-2 months, 3-5 months	4-6 weeks, symptomatic (HIV DNA PCR, serologic if mother's HIV status is unknown), 6 weeks post weaning (serologic), 18 months (serologic)	4 weeks, after 1 month and 4-6 months (if not breastfeeding), 6 weeks post weaning	4-6 weeks, 6 weeks post weaning, symptomatic during follow-up (serologic), 18 months (serologic)	6-8 weeks (serological test in case of unknown HIV exposure), symptomatic (serologic), 6 months for breastfeeding infant, 12 months for breastfeeding infant (serologic), 18 months and/or 6 weeks after weaning (serologic)	6 weeks, 9 months (serologic), 6 weeks post weaning (serologic), 18 months (serologic), whenever child is symptomatic
	Type of test	Viralogical test	Viralogical test	HIV DNA PCR if <12 months old; serological test if 12-18 months old	HIV DNA PCR	HIV DNA PCR	HIV DNA PCR	HIV DNA PCR if <9 months old; serologic if 9-18 months old	HIV DNA or RNA PCR; Serological test (ELISA) after 6 months, if not breastfeeding	HIV DNA or RNA PCR if <9 months old, serologic if 9-18 months old	HIV DNA PCR or serological test	HIV DNA PCR if <9 months old; serologic if 9-18 months old
	Confirmation (type of test)	Viralogical test	Viralogical test	HIV DNA or RNA PCR	HIV DNA PCR	HIV DNA PCR if first test is serologic, second confirmatory HIV DNA PCR on day of ART initiation	Unknown	HIV DNA PCR (if result from serological testing is positive)	HIV DNA PCR; serological test (ELISA) at 12-18 months if negative HIV DNA PCR throughout or if ELISA is done	HIV DNA PCR	HIV DNA PCR if positive result on serological test	HIV DNA PCR (if result from serological testing is positive)
	Availability*	Unknown	PCR testing is currently unavailable; it is anticipated that early infant diagnosis will be implemented on a large scale in all states by the end of 2014	EID using HIV DNA PCR was introduced in 2007; between 2007-2010, the National Reference Laboratory developed the capacity to run this test; in 2011, 82% (127) of 154 health facilities offering child-welfare services offered DBS for DNA PCR	In 2011, 643 (66%) health facilities provided EID services using dried blood spots	A consolidated laboratory at the Central Public Health Laboratories was launched in 2011 with specimen referral hubs and sample transport system; by end of 2013, the number of hubs will be expanded from 19 to 78 to reach 1700 facilities	Weaknesses in the provision of virological labs with necessary test-kits to perform PCR testing; the need for use of dried blood spot method and decentralization of EID services is recognized	30% of health facilities provide EID services; there are frequent supply interruptions of kits for collecting dried blood spots and few PCR machines are available	EID is made through special PCR tests which are performed at the Institute of National Hygiene Rafael Rangel	EID services were introduced in 2009; in 2011, 54 (22.7%) health facilities provided EID services; laboratory services were available at 2 institutes	25% of 1784 facilities in 2010, provided virological testing services on site or from dried blood spots; Project Mwana was launched to improve EID services; in 2012, it covered 268 health facilities located in remote and hard to reach areas; this project has halved the turnaround time due to use of SMS	Though a rapid scale-up of EID has occurred, there are challenges in terms of long turn-around time of results
Infants born to HIV+ women receiving a virological test within 2 months of birth (%)	Year: 2011	Unknown	Unknown	69%	73%	32%	55%	29%	65%	26%	55%	29%
	Year: 2012	Unknown	Unknown	Unknown	77%	Unknown	Unknown	32%	26%	24%	74%	36%
	Year: 2013	Unknown	Unknown	89%	78%	36%	Unknown	26%	8%	95%	55%	50%
CD4 testing for treatment initiation and monitoring	ART Initiation criteria (cells/µL)	500	500	350	350 (consider at <500)	500	350	350	500	350	500	500
	Initiation irrespective of CD4 count	TB, WHO stage III or IV, hepatitis B, pregnant women, serodiscordant couples	TB, WHO stage III or IV, hepatitis B, pregnant women, serodiscordant couples	TB, WHO stage III or IV, hepatitis B, HIV-associated nephropathy	TB, WHO stage III or IV, serodiscordant couples, pregnant women with unknown serostatus of partner, hepatitis C, people >50 years, HIV-associated nephropathy	TB, WHO stage III or IV, hepatitis B, pregnant women, serodiscordant couples, sex workers, fishermen, truckers, children <15 years	TB, HIV-associated nephropathy, age >50 years	TB, WHO stage III or IV, pregnant women	TB, CDC category B/C, decrease in CD4 >100 per year, pregnant women, HIV-associated nephropathy, hepatitis B and C, serodiscordant couples, age >50 years, any related or non-neoplastic disease with HIV	TB, WHO stage III or IV	TB, children <15 years, WHO stage III or IV, pregnant women, HIV-positive partners of pregnant and breastfeeding women, serodiscordant couples, hepatitis B	TB, WHO stage III or IV, serodiscordant couples, hepatitis B, pregnant women
	Treatment monitoring	Every 6 months	Every 6 months	3 months, then every 6 months	Every 6 months	CD4 not recommended for routine monitoring of ART response	Every 3-6 months	Every 6 months	Every 6-12 months	Every 6 months	Every 6 months	Every 6 months
	Availability*	Frequent breakdowns of CD4 instruments	Unknown	Point-of-care CD4 devices were introduced in a phased manner in 2010 in high volume clinics	In 2011, 900 of 11,000 health facilities providing ANC services also provided CD4 testing; CD4 testing services were available onsite in 110 facilities	Unknown	In 2011, access to CD4 count services before initiation of treatment was limited due to insufficient numbers of CD4 tests kits procured	Inadequate and non-functional CD4 machines are major issues	31 public establishments perform immunologic and virology tests; challenges include few laboratories, insufficient purchase of reagents and waiting averages of 3-5 months in the appointment system for people living away from cities; efforts are being made for regionalisation of new laboratories and expansion of capacity of National Institute of Hygiene Rafael Rangel	In 2011, 226 of 12,300 health facilities providing ANC services also provided CD4 testing; CD4 services were available onsite in 34 facilities; 41 laboratories were capable of performing CD4 counts	Health facilities providing ANC that also provide CD4 testing on site equaled 60% of 1563 in 2008 and 67% of 1784 in 2010	Lack of point-of-care CD4 machines and constant breakdowns of laboratory-based machines are major challenges
Viral load (HIV RNA) testing (for treatment monitoring)	ART Initiation criteria (copies/mL)	NA	NA	NA	NA	NA	NA	NA	CD4 >500 and VL >100,000	NA	NA	NA
	Treatment monitoring	Targeted VL for suspected treament failure	6 months, 12 months, then yearly	VL is done in cases of suspected treatment failure or in cases of discrepency in clinical and immunological findings; initially, routine VL to be provided at 6 months; and at 3 months, 6 months and after every 6 months, when widely available	At 6 months, 12 months, then yearly (every 6 months preferred)	6 months, every 12 months thereafter	Unknown	It is not essential but may be considered for routine monitoring of patients on ART	Every 6 months; at 8 weeks after change of ART (including simplification)	Every 6 months, if available	6 months and then every 12 months	Due to non-availability, VL is not recommended as a routine test; rather targeted VL monitoring (for suspected clinical or immunological failure) is recommended
	Virological failure threshold (copies/mL)	VL >1000	VL >1000	VL >400 at 6 months; VL >50 at 48 weeks or VL >1000 on 2 consecutive measurements, 1-3 months apart after prior undetectable VL	VL >400 after 6 months on ART or VL >50 after 12 months on ART with good adherence	2 consecutive VL >5000 at least 6 months apart	Unknown	VL detectable after 6 months of ART, or when the VL is persistently >5,000	VL >50 after 24 weeks on ART; detectable VL after viral suppression	VL >5000 from two tests with at least 1 month interval	VL >1000 on 2 consecutive measurements 6 months after ART initiation	VL >1000
	Availability*	Limited availability	Initially, VL will be used only for patients with suspected treatment failure; later (2015 onwards), routine VL will be introduced for all patients	Limited availability	VL is the preferred monitoring approach and is free of cost; in 2013, 95% of people on ART tested for VL had a suppressed VL	Limited availability	VL tests are procured in limited amounts (about 35% of needed amounts) and are available only for people on ART	Capacity for VL is currently limited to zonal consultant hospitals	31 public establishments perform immunologic and virology tests; challenges include few laboratories, insufficient purchase of reagents and waiting averages of 3-5 months in the appointment system for people living away from cities; efforts are being made for regionalisation of new laboratories and expansion of capacity of National Institute of Hygiene Rafael Rangel	Unknown	Limited availability	Limited availability

Abbreviations: ART = antiretroviral therapy; EID = early infant diagnosis, HTC = HIV testing and counselling; NA - not applicable, PMTCT = prevention of mother to child transmission, VL = viral load

*Most serologic tests are performed by rapid diagnostic tests measuring antibodies to HIV

National recommendations: Change in national guidelines on the use of infant diagnostic, CD4 and routine viral load testing across 15 low- and middle-income countries between 2007 and 2014

Data on guidelines was available from the UNAIDS database. Analysis was performed until mid-October 2014.

Highlighted cells indicate changes between guideline versions.

	COUNTRY	Botswana		Brazil		Cameroon	
	GUIDELINES	ART 2012	ART 2008	Adult ART 2013	ART 2010 and Paediatric ART 2009	ART 2012	ART 2009
Infant diagnosis (using a virological test for HIV exposed infants <18 months of age)	When	4-6 weeks; 6 weeks post weaning; 18 months (double serological test) if infant is not breastfeeding	4-6 weeks; 6 weeks after weaning (test dependent on age) ; 18 months (serologic)	NA	After 1 month; 2 months (if negative or discordant result); 12 months (serologic), if 2 negative HIV DNA PCR	6 weeks; 4 weeks after first test (if discordant result); 15 months (serologic); 4-6 weeks after weaning; 18 months (serologic)	NA
	Type of test	HIV DNA PCR	HIV DNA PCR	NA	RNA	HIV DNA PCR	NA
	Confirmation (type of test)	HIV DNA PCR	HIV DNA PCR	NA	RNA (if positive on first HIV RNA test)	HIV DNA PCR	NA
CD4 testing for treatment initiation and monitoring	ART Initiation criteria (cells/μL)	350	250	Irrespective of CD4 count	350	200	200
	Initiation irrespective of CD4 count	TB, WHO stage III or IV, severe WHO stage II condition, CD4% <15%	TB, WHO stage III or IV	For all people living with HIV (test and treat)	TB, Oral candidíse, idiopathic thrombocytopenic purpura, cognitive changes (even minor), pregnant women	WHO stage IV, WHO stage II or III if total lymphocyte count <1200	WHO stage III or IV
	Treatment monitoring	3 months, 6 months and every 6 months thereafter	3 months, 6 months and every 6 months thereafter	**Every 6 months**	**NA**	**Every 6 months**	**Every 6 months for 2 years and then once a year**
Viral load (HIV RNA) testing (for treatment monitoring)	ART Initiation criteria (copies/mL)	NA	NA	CD4 >500 and VL >100,000	CD4 between 350-500 and VL >100,000	NA	NA
	Treatment monitoring	3 months, 6 months, every 6 months thereafter	3 months, 6 months, every 6 months thereafter	**2-3 months, then every 6 months**	**NA**	Unknown	Month 6, at least once a year
	Virological failure threshold (copies/mL)	VL >400 after 6 months post ART or VL rebound to >400 after documented full suppression	VL >400 after 6 months post ART or VL rebound to >400 after documented full suppression	Detectable VL 6 months after beginning or modification of ART or in individuals who maintained undetectable VL on ART	NA	Unknown	VL> 5000 after 6 months (or 12 months depending on time to balance monitoring) of correct treatment and well observed

	COUNTRY	India		Kenya		Lesotho		Malawi	
	GUIDELINES	ART 2013, ART 2013 update and PMTCT 2013	Adult ART 2007 and ART 2011 update	ART 2014	ART 2011	ART 2014	ART 2010	ART 2014	ART 2011
Infant diagnosis (using a virological test for HIV exposed infants <18 months of age)	When	6 weeks or suspected HIV, 6 months, 12 months, 18 months (3 serological tests)	NA	6 weeks (serologic), 9 months or if symptomatic (serologic), 18 months or 6 weeks after weaning (serologic)	6 weeks (serologic), 9 months or if symptomatic (serologic), 18 months or 6 weeks after weaning (serologic)	6 weeks (HIV DNA PCR, serological test if HIV status of mother is unknown), HIV DNA PCR at 14 weeks if breastfeeding or weaned <6 weeks, 9 months (serologic) if breastfeeding or weaned <6 weeks, rapid test 6 weeks post weaning,18 months (serologic) if never breastfed or weaned >6 weeks	6 weeks (HIV DNA PCR, serological test if HIV status of mother is unknown), 9 months (serologic), 6 weeks post weaning	6 weeks, symptomatic (serologic)	6 weeks, symptomatic (serologic)
	Type of test	HIV DNA PCR	NA	HIV serological test	HIV serological test	HIV DNA PCR	HIV DNA PCR	HIV DNA PCR if child is <12 months; serological test at 12-18 months old or if mother's status unknown	HIV DNA PCR if child is <12 months; serological test at 12-18 months old
	Confirmation (type of test)	HIV DNA PCR using whole blood specimen after positive HIV DNA PCR	NA	HIV DNA PCR (if result from serological testing is positive)	HIV DNA PCR (if result from serological testing is positive)	HIV DNA PCR	HIV DNA PCR, serologic (at 18 months and when child is symptomatic despite earlier negative serological test)	HIV DNA PCR if serological test result is positive (for <12 months old) or negative (for >12 months old); confirmatory serological test at 12 and 24 months	HIV DNA PCR if serological test result is positive (for <12 months old) or negative (for >12 months old); confirmatory serological test at 12 and 24 months
CD4 testing for treatment initiation and monitoring	ART Initiation criteria (cells/μL)	350	350	500	350	500	350	500	350
	Initiation irrespective of CD4 count	TB, WHO stage III or IV, hepatitis B and C	TB, WHO stage III or IV	TB, WHO stage III or IV, hepatitis B, pregnant women, serodiscordant couples, HIV-associated nephropathy	TB, WHO stage III or IV, hepatitis B, HIV-associated nephropathy	TB, WHO stage III or IV, hepatitis B, pregnant women, serodiscordant couples	TB, WHO stage III or IV, hepatitis B	TB, WHO stage III or IV, pregnant women	TB, WHO stage III or IV, pregnant women
	Treatment monitoring	Every 6 months	Every 6 months	**Not recommended; CD4 monitoring every 6 months if VL monitoring is not available**	**Every 6 months**	Every 6 months	Every 6 months	**Not recommended**	**Every 6 months**
Viral load (HIV RNA) testing (for treatment monitoring)	ART Initiation criteria (copies/mL)	NA	NA	NA	NA	NA	NA	NA	NA
	Treatment monitoring	VL monitoring (for suspected clinical or immunological failure)	VL may be considered for diagnosis of early treatment failure or to assess discordant clinical and CD4 findings in patients in whom failure of ART is suspected	**Month 6, month 12 and then every 12 months**	**VL is recommended for suspected treatment failure and before substituting d4T in cases of toxicity where d4T has been used for more than 6 months**	**Month 6, month 12 and then every 12 months**	**Every 6 months, ideally, but it is not recommended for routine monitoring in resource-limiting setting**	6 months, 2 years, and every 2 years thereafter	6 months, 2 years, and every 2 years thereafter
	Virological failure threshold (copies/mL)	VL >5000 after at least 6 months on ART	VL >10,000	VL >1000	VL >1000	VL >1000	VL >5000 after 6 months on treatment	VL >5000	VL >5000

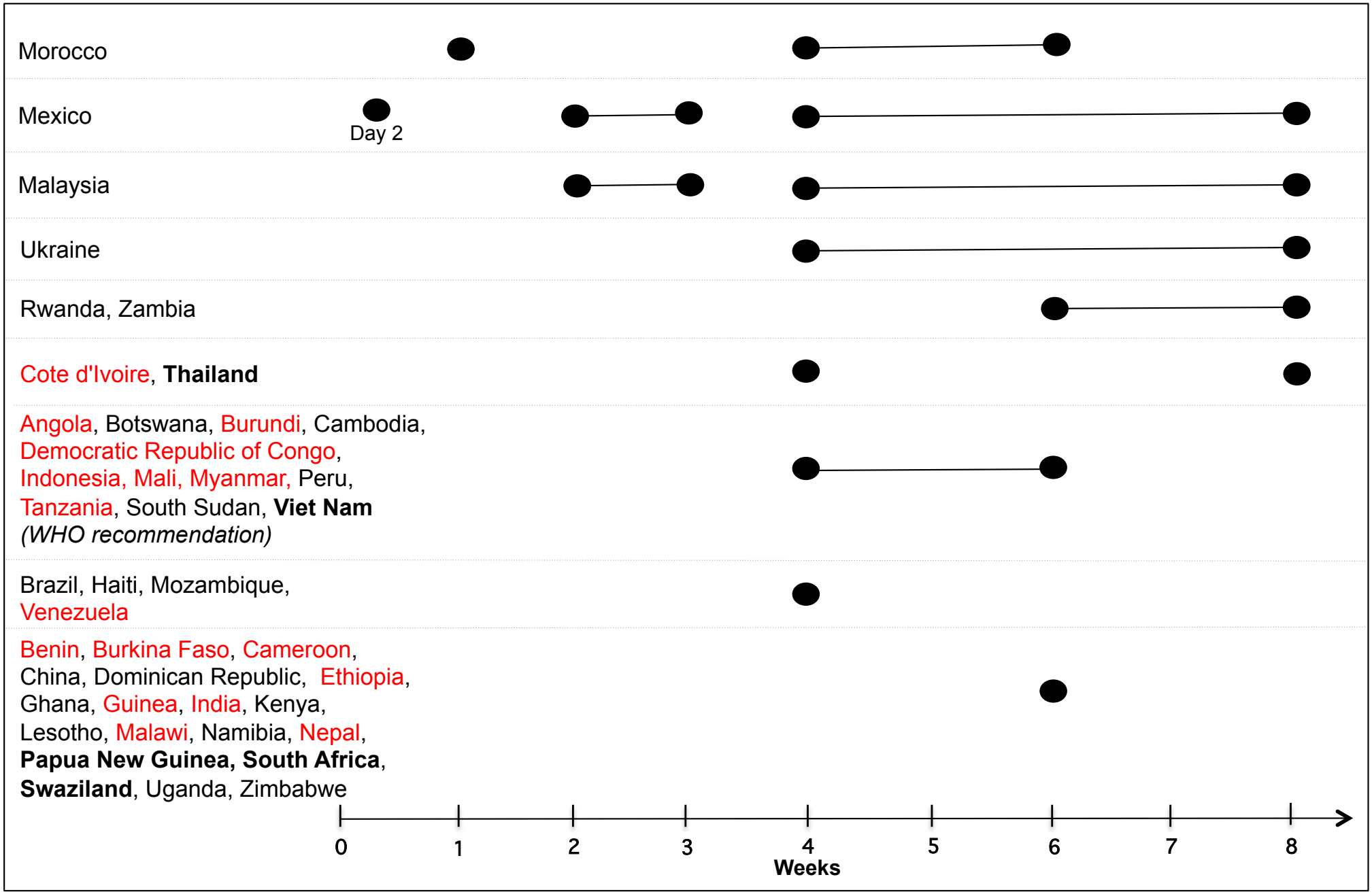
	COUNTRY	Myanmar		Namibia		Nigeria		South Africa	
	GUIDELINES	ART 2011	ART 2007	ART 2014	ART 2010	ART 2010	ART 2007	ART 2013 and PMTCT 2013	ART 2010 and PMTCT 2010
Infant diagnosis (using a virological test for HIV exposed infants <18 months of age)	When	**4-6 weeks, 9 months (serologic) or symptomatic, 6 weeks after weaning**	**6 weeks**	6 weeks, 9 months (serologic), 3 months post weaning (serologic)	6 weeks, 9 months (serologic), 3 months post weaning (serologic)	<9 months at first encounter, 6 weeks after weaning (serologic), 9 months or if symptomatic (serologic), 18 months (serologic)	NA	6 weeks or symptomatic, 6 weeks post weaning, 18 months (serologic)	6 weeks or symptomatic, 6 weeks post weaning, 18 months (serologic)
	Type of test	Virological test	HIV DNA PCR	HIV DNA PCR	HIV DNA PCR for <9 months; serologic or ELISA for 9-17 months	HIV DNA PCR if child is <9 months, serological test for children 9-18 months old	NA	HIV DNA PCR	HIV DNA PCR
	Confirmation (type of test)	Virological test	NA	HIV DNA PCR; confirmatory HIV DNA PCR if discrepency between first two test results	HIV DNA PCR; confirmatory HIV DNA PCR if discrepency between first two test results	HIV DNA PCR	NA	HIV RNA PCR; serological test at 18 months for confirmation	HIV RNA PCR
CD4 testing for treatment initiation and monitoring	ART Initiation criteria (cells/μL)	350	200	500	350	350	200 (consider for <350)	350	200
	Initiation irrespective of CD4 count	MDR TB, WHO stage III or IV, hepatitis B	WHO stage IV	TB, WHO stage III or IV, hepatitis B, serodiscordant couples, HIV-positive concordant couples currently intending to conceive a child	TB, WHO stage III or IV, hepatitis B	TB, WHO stage III or IV, hepatitis B, serodiscordant couples (>350), HIV-associated nephropathy	WHO stage IV	TB, WHO stage III or IV	WHO stage IV
	Treatment monitoring	Every 6 months	Every 6 months	**Use in case of virological failure to assess immunological status and inform clinical management**	**Month 12, every 6 months thereafter**	Month 3, every 6 months	Month 3, every 6 months	**At 12 months only**	**6 months, 1 year, and then every 12 months**
Viral load (HIV RNA) testing (for treatment monitoring)	ART Initiation criteria (copies/mL)	NA	NA	NA	NA	NA	NA	NA	NA
	Treatment monitoring	**Every 6 months; if availability is limited, use to confirm treatment failure; CD4 is used when VL is not available**	**As needed; It may be considered to diagnose treatment failure earlier or to assess discordant clinical and CD4 findings in patients suspected of failing ART**	**Month 6, month 12 and then every 12 months (for adults)**	**Viral load at 6 months. Repeat VL as clinically indicated**	**Every 6 months**	**Not recommended**	6 months, 1 year, and then every 12 months	6 months, 1 year, and then every 12 months
	Virological failure threshold (copies/mL)	VL >5000	VL >10,000 after at least 6 months on ART	VL >1000 after 6 months on ART or viral rebound to >1,000 on two consecutive measurements after a period of viral suppression	VL >1000 after 6 months on ART or viral rebound to >1,000 on two consecutive measurements after a period of viral suppression	VL >400 after 6 months on ART, or VL >50 after 12 months on ART	Failure to reduce VL by at least 2 to 2.5 log 10 in HIV RNA level after 24 weeks on ART	VL >1000	VL >1000

	COUNTRY	Uganda			United Republic of		Zambia		Zimbabwe	
	GUIDELINES	ART 2013 update	ART 2012	ART 2009	ART 2012 and PMTCT 2013	ART 2009	ART 2013	ART 2010	ART 2013	ART 2010
Infant diagnosis (using a virological test for HIV exposed infants <18 months of age)	When	NA	**6 weeks (HIV DNA PCR, serological test if mother's HIV status is unknown), 6 weeks after weaning, 18 months (serologic)**	**4-6 weeks, 9-18 months (serologic), 3 months after weaning and aged 9-18 months (serologic)**	4-6 weeks, symptomatic (HIV DNA PCR, serologic if mother's HIV status is unknown), 6 weeks post weaning (serologic), 18 months (serologic)	4-6 weeks, symptomatic, 6 weeks post weaning (serologic),18 months (serologic)	**6-8 weeks (serological test in case of unknown HIV exposure), symptomatic (serologic), 6 months for breastfeeding infant, 12 months for breastfeeding infant (serologic), 18 months and/or 6 weeks after weaning (serologic)**	**6 weeks**	6 weeks, 9 months (serologic), 6 weeks post weaning (serologic), 18 months (serologic), whenever child is symptomatic	6 weeks, 9 months (serologic), 6 weeks post weaning (serologic),
	Type of test	NA	HIV DNA PCR	HIV DNA PCR	HIV DNA PCR if <9 months old; serologic if 9-18 months old	HIV DNA PCR	HIV DNA PCR or serological test	HIV DNA PCR	HIV DNA PCR if <9 months old; serologic if 9-18 months old	HIV DNA PCR
	Confirmation (type of test)	NA	HIV DNA PCR if first test is serologic, second confirmatory HIV DNA PCR on day of ART initiation	Serological test at 18 months	HIV DNA PCR (if result from serological testing is positive)	HIV DNA PCR, second confirmatory HIV DNA PCR if discordant results on first two tests	HIV DNA PCR if positive result on serological test	Unknown	HIV DNA PCR (if result from serological testing is positive)	HIV DNA PCR (if result from serological testing at <9 months is positive), Serologic test at 18 months
CD4 testing for treatment initiation and monitoring	ART Initiation criteria (cells/μL)	500	350	250	350	200	500	350	500	350
	Initiation irrespective of CD4 count	TB, WHO stage III or IV, hepatitis B, pregnant women, serodiscordant couples, sex workers, fishermen, truckers, children <15 years	TB, WHO stage III or IV, hepatitis B	WHO stage IV	TB, WHO stage III or IV, pregnant women	WHO stage IV	TB, children <15 years, WHO stage III or IV, pregnant women, HIV-positive partners of pregnant and breastfeeding women, serodiscordant couples, hepatitis B	TB, WHO stage III or IV, serodiscordant couples, hepatitis B	TB, WHO stage III or IV, serodiscordant couples, hepatitis B, pregnant women	TB, WHO stage III or IV
	Treatment monitoring	**CD4 not recommended for routine monitoring of ART response**	**NA**	**Every 6 months**	Every 6 months	Every 6 months	**Every 6 months**	**6 months, every year**	Every 6 months	Every 6 months
Viral load (HIV RNA) testing (for treatment monitoring)	ART Initiation criteria (copies/mL)	NA	NA	NA	NA	NA	NA	NA	NA	NA
	Treatment monitoring	**6 months, every 12 months thereafter**	**NA**	**Every 12 months or when suspect failure (optional test)**	**It is not essential but may be considered for routine monitoring of patients on ART**	**VL maybe considered to diagnose treatment failure earlier or to access discordant clinical and immunologic findings in patients in whom ART failure is suspected**	**6 months and then every 12 months**	**Every year, if available**	**Due to non-availability, VL is not recommended as a routine test; rather targeted VL monitoring (for suspected clinical or immunological failure) is recommended**	**Not recommended**
	Virological failure threshold (copies/mL)	2 consecutive VL >5000 at least 6 months apart	NA	VL >1000	VL detectable after 6 months of ART, or when the VL is persistently >5,000	A less than 10 fold drop in VL after 6-8 weeks of therapy, or VL >10,000	VL >1000 on 2 consecutive measurements 6 months after ART initiation	VL >50 after 6 months on ART on 2 consecutive measurements 3 months apart	VL >1000	VL >5000

Abbreviations: ART = antiretroviral therapy; EID = early infant diagnosis, HTC = HIV testing and counselling; NA - not applicable, PMTCT = prevention of mother to child transmission, VL = viral load

*Most serologic tests are performed by rapid diagnostic tests measuring antibodies to HIV

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



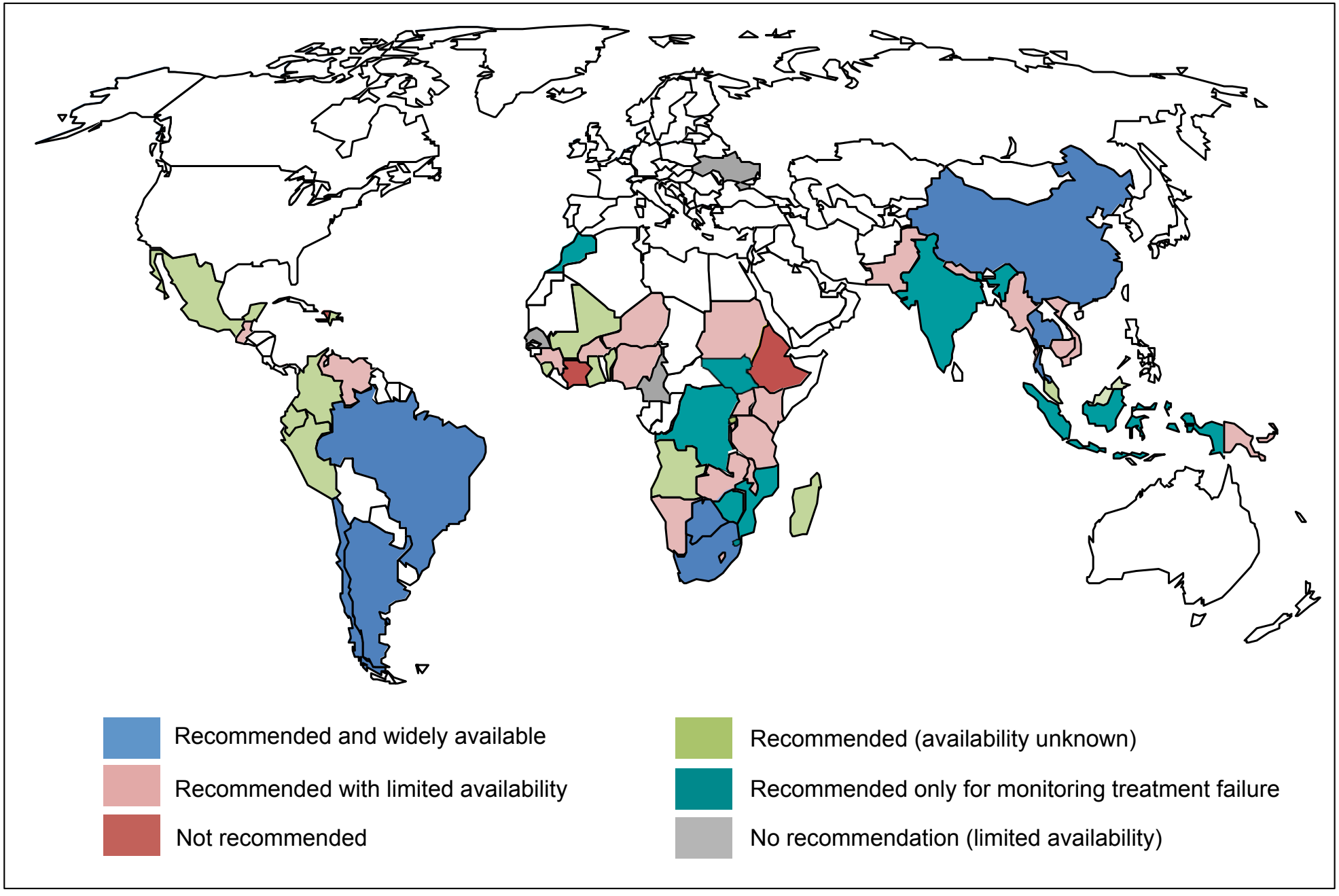
- In 2013, the percentage of HIV-exposed infants receiving a virological test within 2 months of birth was <30% in countries in red and >70% in **countries in bold** (source: UNAIDS GARPR 2014).
- Eleven countries without recommendations and two countries (Nigeria and Sudan) recommending EID at first encounter are not shown.

Frequency of CD4 Testing after ART Initiation from 55 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	4	Angola, Argentina, 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	3	Chile, Dominican Republic, Mexico
6-monthly *(WHO recommendation)*	31	Benin, Brazil, Burundi, Cambodia, Cameroon, Colombia, Cote d'Ivoire, Democratic Republic of Congo, Ecuador, Ethiopia, Guatemala, Guinea, Haiti, India, Indonesia, Lesotho, Mali, Mozambique, Myanmar, Nepal, Niger, Papua New Guinea, Peru, Rwanda, South Sudan, Sudan, Tanzania, Thailand, Viet Nam, Zambia, Zimbabwe
Every 6-12 months	1	Venezuela
Month 6; yearly thereafter	1	Ghana
In case of virologic failure	1	Namibia
Month 12	1	South Africa
Not recommended	3	Kenya, Malawi, Uganda
Recommendation not available	2	Morocco, Senegal

Note: Availability of CD4 testing services is limited in at least 18 countries in red.

Recommendation on Use of Viral Load Testing for ART Monitoring and its Availability (Source: UNAIDS)



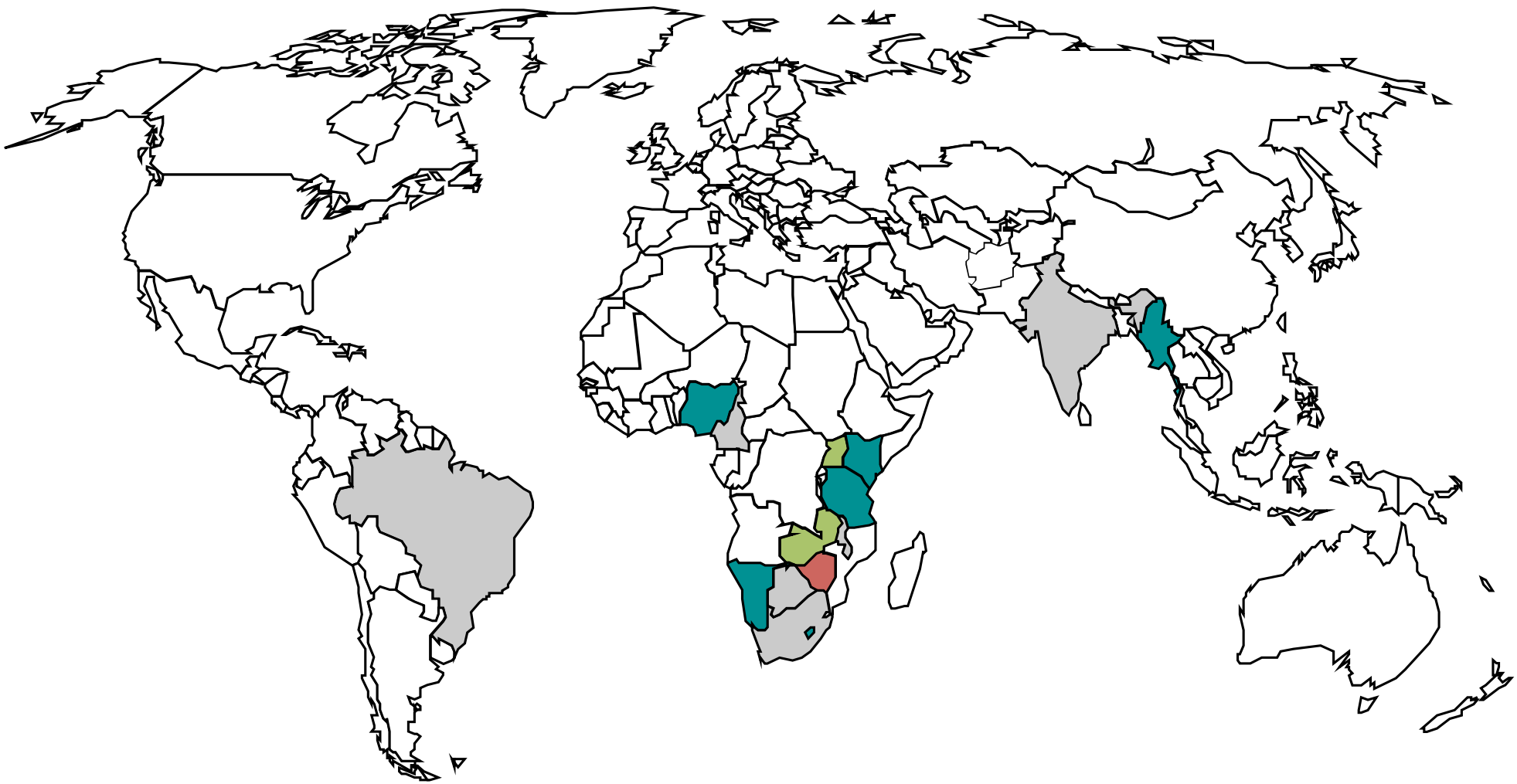
Note: Tanzania recommends routine VL for monitoring but it is not essential

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*, Dominican Republic, Ecuador, Guatemala, Malaysia*, Mali, Mexico*, Myanmar, Nepal, Niger, Nigeria, Pakistan*, Papua New Guinea, Venezuela, Viet Nam			✔		✔		✔		✔	6-monthly
Colombia	✔		✔		✔		✔		✔	6-monthly
Botswana, Peru		✔	✔		✔		✔		✔	6-monthly
Brazil, Sierra Leone		✔		✔		✔		✔		6-monthly
Benin, Kenya, Lesotho, Namibia, South Africa, Sudan, Thailand *(WHO recommendation)*			✔		✔				✔	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.
The frequency of VL testing is not available for Tanzania.

Changes in the recommendation on the use of viral load for monitoring of people on ART in 15 high-burden countries



Guidelines changed to recommend routine VL monitoring

Change in frequency of routine VL monitoring

Guidelines changed to recommend targeted VL monitoring

No change or unknown