

REACHING THE THIRD 90: IMPLEMENTING HIGH QUALITY VIRAL LOAD MONITORING AT SCALE

Key Strategic Decisions for Countries Designing & Scaling-Up Viral Load Services

	Key Strategic Decisions	Common Options	Country Examples
1.	How will leadership and/or governance of routine viral load service roll-out be organized?	<ul style="list-style-type: none"> • Viral load technical working group • Viral load roll-out coordinators 	<ul style="list-style-type: none"> • Ethiopia has a Viral Load Technical Working Group chaired by the Ethiopian Public Health Institute (EPHI) • Kenya national- and county-level HIV Care & Treatment Technical Working Groups responsible for leading routine viral load service roll-out • Swaziland's Ministry of Health provides technical guidance for viral load roll-out; a technical working group also supervises key decisions
2.	What monitoring and evaluation/laboratory information strategy will be implemented?	<ul style="list-style-type: none"> • Online dashboard • Paper register/log book • Use of unique patient identifiers • Site readiness tool 	<ul style="list-style-type: none"> • Ethiopia uses a national level database among regional laboratories, and a standard viral load request form at the facility level (no other M&E systems at the facility level) • Kenya relies on a national web-based system to monitor the viral load cascade; at the facility level, a standard viral load request form and log book are used • Malawi has a national electronic medical record, which is strengthened by the use of log books to track all viral load specimens • Swaziland is developing a national system to monitor the viral load cascade • Tanzania utilizes an online, public database to track aggregate data
3.	How and when will people living with HIV/AIDS be involved?	<ul style="list-style-type: none"> • Technical working group • Coalition • Civil society organization 	<ul style="list-style-type: none"> • Ethiopia involves PLHIV via a national technical working group (NEP+) • Kenya has civil society organizations led by the National Empowerment Network of PLHIV in Kenya (NEPHAK) and the Women Fighting AIDS in Kenya (WOFAK) • Swaziland's Viral Load Technical Working Group includes at least one expert client; the Swaziland National Network of People Living with HIV/AIDS (SWANNEPHA) assists with facility-based tasks
4.	Will the roll-out of routine viral load services be implemented using a phased or global approach?	<ul style="list-style-type: none"> • Prioritize populations, such as pregnant women or children • Start with specific geographic regions • National roll-out 	<ul style="list-style-type: none"> • Ethiopia used a global roll-out approach, with staggered installation of testing machines • Swaziland prioritizes women and children; they also prioritize roll-out based on facility readiness/capacity to implement viral load testing
5.	What will be the standard viral load test frequency for the general population?	<ul style="list-style-type: none"> • WHO guidelines • Recommended for ART monitoring and identification of treatment failure 	<ul style="list-style-type: none"> • Ethiopia recommends routine viral load testing at six and 12 months after initiation of ART, and annually thereafter • Kenya recommends viral load testing at six and 12 months after ART initiation, and every 12 months thereafter if test results remain <1,000

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		<ul style="list-style-type: none"> » Every 12 months » Every 24 months 	<ul style="list-style-type: none"> copies/mL • Swaziland adopted WHO guidelines
6.	What will be the standard viral load test frequency for infants and children?	<ul style="list-style-type: none"> • Special guidelines • Same as general population 	<ul style="list-style-type: none"> • Ethiopia recommends a baseline viral load test for HEIs six months after ART initiation and annually thereafter (no special recommendations for other children) • Kenya recommends baseline viral load test for HEIs following a positive PCR test; baseline viral load specimen can be drawn before or at the time of ART initiation (no special recommendations for other children) • Swaziland recommends baseline viral load test for infants and children six months after ART initiation and every six months thereafter
7.	What will be the standard viral load test frequency for pregnant and lactating mothers?	<ul style="list-style-type: none"> • Special guidelines • Same as general population 	<ul style="list-style-type: none"> • Ethiopia and Tanzania use standard viral load testing frequency for general population, including pregnant and lactating women • Kenya recommends viral load testing for pregnant and breastfeeding women six months after ART initiation. (1) If test results are $\geq 1,000$ copies/mL, enhance adherence and repeat testing after one month; if test results are still $\geq 1,000$ copies/mL, switch regimens. (2) If test results are $< 1,000$ copies/mL, repeat test every six months until end of breastfeeding • Swaziland recommends viral load testing for pregnant and breastfeeding women six months after ART initiation and every six months thereafter until end of breastfeeding
8.	Will plasma or dried blood spots be used for routine viral load testing?	<ul style="list-style-type: none"> • Plasma • DBS • Both 	<ul style="list-style-type: none"> • Ethiopia started with plasma only, but now utilizes plasma and DBS • Kenya utilized plasma and DBS specimens • Swaziland prefers plasma specimens; they use DBS specimens for children and in facilities without the capacity to manage plasma (no storage/centrifuge)
9.	Will machines to process specimens be purchased or rented?	<ul style="list-style-type: none"> • Purchase all machines • Rent all machines • Mix 	<ul style="list-style-type: none"> • Ethiopia rents all machines • Swaziland plans to purchase at least two machines and rent others, as needed
10.	Will the laboratory system be centralized or decentralized?	<ul style="list-style-type: none"> • Centralized • Decentralized • Both 	<ul style="list-style-type: none"> • Ethiopia has seven main decentralized laboratories • Kenya has seven decentralized laboratories • Swaziland has identified two laboratories for decentralization, but has yet to do so

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11.	How will specimens be transported from testing facilities to laboratories for testing?	<ul style="list-style-type: none"> • Courier • National mail • Riders for Health 	<ul style="list-style-type: none"> • Ethiopia sends specimens to laboratories by courier with an agreement between EPHI and the Ethiopian Postal Enterprise Service • Kenya sends specimens to laboratories by courier • Swaziland utilizes refrigerated cars to support national sample transport, and is exploring back-up options (e.g. DHL courier)
12.	How will results be returned from the laboratory back to testing facilities?	<ul style="list-style-type: none"> • Physical (tangible) return of written results • SMS printer • Email message • Online database 	<ul style="list-style-type: none"> • Ethiopia uses SMS printers and courier • Kenya uses an online database (www.nascop.org) • Malawi's electronic medical record system is capable of receiving/recording test results directly from the laboratory; they also utilize a log book to track all specimens • Swaziland is considering two options for national roll-out: laboratory information strategy that allows for communication between laboratories and facilities, or result print-out (paper) and return • Zambia is developing a SMS platform specifically for EID test results
13.	How will results be shared with patients and/or caregivers?	<ul style="list-style-type: none"> • Physical (tangible) return of written results • SMS printer • Email message • Phone • Online database 	<ul style="list-style-type: none"> • South Africa is piloting an SMS platform to return test results to patients • Swaziland is considering two options for national roll-out: telephone or SMS to instruct patients to return to facility
14.	Who can authorize the switch to second line regimens?	<ul style="list-style-type: none"> • Central decision-making committee • Physicians only • Physicians and nurses • Facility team 	<ul style="list-style-type: none"> • Ethiopia uses physician-led multi-disciplinary teams at the facility level • Kenya trains clinicians on identifying first-line treatment failure and initiating second-line regimens; facility-based multi-disciplinary teams make the final decision to switch to second-line, in collaboration with trained clinicians • Kenya has a National HIV Clinical Support Center that records second-line treatment failure cases for review and approval of drug resistance testing; switch to third-line regimens is based on results of drug resistance testing • Mozambique uses a central committee that approves all switches • Swaziland uses multidisciplinary teams (physician, ART nurse, laboratory liaison, pharmacist and adherence counselor) at each facility to discuss and agree on when to switch to second-line regimens; genotyping prior to

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			switching to third-line regimens is done specifically for children
15.	What will be the schedule for providing enhanced adherence counseling?	<ul style="list-style-type: none"> Standardized frequency 	<ul style="list-style-type: none"> Kenya's National Toolkit on Adherence Support guides the provision of EAC Swaziland provides EAC to all patients with viral load results >1,000 copies/mL
16.	What content will be included in enhanced adherence counseling?	<ul style="list-style-type: none"> Standardized content Tailored content for priority patients 	<ul style="list-style-type: none"> Kenya's National Toolkit on Adherence Support guides the provision of EAC Swaziland employs Expert Clients to provide Stepped-Up Adherence Counseling (SUAC) to patients with viral load results >1,000 copies/mL until an improvement in adherence is observed Swaziland's Ministry of Health is developing SOPs for provision of EAC
17.	How will patients be involved in generating demand for routine viral load testing?	<ul style="list-style-type: none"> Technical working group Coalition Civil society organization 	<ul style="list-style-type: none"> Kenya has civil society organizations led by the National Empowerment Network of PLHIV in Kenya (NEPHAK) and the Women Fighting AIDS in Kenya (WOFAK); and uses patient education in the facility and community to foster demand Health Communication Capacity Collaborative (HC3) in Swaziland provides community-based programming to communities and high-risk groups to increase demand for viral load services
18.	How will clinicians be involved in generating demand for routine viral load testing?	<ul style="list-style-type: none"> Technical working group Training Targeted messaging 	<ul style="list-style-type: none"> Ethiopia facilitates regional two-day trainings to review the <i>Viral Load Sensitization Package</i> (those trained are expected to pass along learnings to facility staff) Kenya's National AIDS & STI Control Program (NAS COP) has an HIV-integrated curriculum for clinicians, which includes a case-based orientation package; CMEs, mentorship and Project ECHO are also used Malawi is building clinician prompts into their national electronic medical record to remind clinicians when a patient is due for viral load testing
19.	What policies, strategies and/or interventions will ensure that routine viral load test results are utilized by clinicians?	<ul style="list-style-type: none"> Mentorship Quality assurance High viral load register 	<ul style="list-style-type: none"> Ethiopia employs Clinical Mentors to ensure physicians properly follow-up on test results Kenya uses data-driven mentorship Swaziland utilizes SIMS findings and clinical mentorship to provide feedback to clinicians on their use of viral load test results; they also monitor progress along the cascade with a High Viral Load Register
20.	Who is responsible for forecasting for second line	<ul style="list-style-type: none"> Supply chain management group 	<ul style="list-style-type: none"> Ethiopia's national Pharmaceutical Fund & Supply Agency is responsible for supply chain management and forecasting

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	regimens?		<ul style="list-style-type: none"> • Kenya projects annually
21.	How do you define treatment failure?	<ul style="list-style-type: none"> • Viral load >1,000 copies/mL • Viral load >400 copies/mL 	<ul style="list-style-type: none"> • Kenya defines treatment failure as viral load test results at or above 1,000 copies/mL for two tests within a three month interval following at least six months of ART (with enhanced adherence counseling between measurements)