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

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

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<tr>
<td>1. How will leadership and/or governance of routine viral load service roll-out be</td>
<td>• Viral load technical working group</td>
<td>• Ethiopia has a Viral Load Technical Working Group chaired by the Ethiopian Public Health Institute (EPHI)</td>
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<td>organized?</td>
<td>• Viral load roll-out coordinators</td>
<td>• Kenya national- and county-level HIV Care &amp; Treatment Technical Working Groups responsible for leading routine viral load service roll-out</td>
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<td>2. What monitoring and evaluation/laboratory information strategy will be implemented?</td>
<td>• Online dashboard</td>
<td>• Swaziland’s Ministry of Health provides technical guidance for viral load roll-out; a technical working group also supervises key decisions</td>
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<td></td>
<td>• Paper register/log book</td>
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<td>• Use of unique patient identifiers</td>
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<td>• Site readiness tool</td>
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<td><strong>Ethiopia uses a national level database among regional laboratories, and a standard viral load request form at the facility level (no other M&amp;E systems at the facility level)</strong></td>
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<td><strong>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</strong></td>
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<td><strong>Malawi has a national electronic medical record, which is strengthened by the use of log books to track all viral load specimens</strong></td>
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<td><strong>Swaziland is developing a national system to monitor the viral load cascade</strong></td>
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<td><strong>Tanzania utilizes an online, public database to track aggregate data</strong></td>
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<td>3. How and when will people living with HIV/AIDS be involved?</td>
<td>• Technical working group</td>
<td><strong>Ethiopia involves PLHIV via a national technical working group (NEP+)</strong></td>
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<td>• Coalition</td>
<td><strong>Kenya has civil society organizations led by the National Empowerment Network of PLHIV in Kenya (NEPHAK) and the Women Fighting AIDS in Kenya (WOFAK)</strong></td>
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<td>• Civil society organization</td>
<td><strong>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</strong></td>
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<td>4. Will the roll-out of routine viral load services be implemented using a phased or</td>
<td>• Prioritize populations, such as pregnant women or children</td>
<td><strong>Ethiopia used a global roll-out approach, with staggered installation of testing machines</strong></td>
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<td>global approach?</td>
<td>• Start with specific geographic regions</td>
<td><strong>Swaziland prioritizes women and children; they also prioritize roll-out based on facility readiness/capacity to implement viral load testing</strong></td>
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<td>• National roll-out</td>
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<td>5. What will be the standard viral load test frequency for the general population?</td>
<td>• WHO guidelines</td>
<td><strong>Ethiopia recommends routine viral load testing at six and 12 months after initiation of ART, and annually thereafter</strong></td>
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<td>• Recommended for ART monitoring and identification of treatment failure</td>
<td><strong>Kenya recommends viral load testing at six and 12 months after ART initiation, and every 12 months thereafter if test results remain &lt;1,000</strong></td>
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| 6. What will be the standard viral load test frequency for infants and children? | » Special guidelines  
» Same as general population | • 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? | » Special guidelines  
» Same as general population | • 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 ≥1,000 copies/mL, enhance adherence and repeat testing after one month; if test results are still ≥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? | » Plasma  
» DBS  
» Both | • 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? | » Purchase all machines  
» Rent all machines  
» Mix | • 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? | » Centralized  
» Decentralized  
» Both | • 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? | • Courier  
• National mail  
• Riders for Health                  | • 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? | • Physical (tangible) return of written results  
• SMS printer  
• Email message  
• Online database | • 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? | • Physical (tangible) return of written results  
• SMS printer  
• Email message  
• Phone  
• Online database | • 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? | • Central decision-making committee  
• Physicians only  
• Physicians and nurses  
• Facility team | • 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 |
### Key Strategic Decisions

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| 15. What will be the schedule for providing enhanced adherence counseling? | • Standardized frequency | • 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? | • Standardized content  
• Tailored content for priority patients | • 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? | • Technical working group  
• Coalition  
• Civil society organization | • 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? | • Technical working group  
• Training  
• Targeted messaging | • Ethiopia facilitates regional two-day trainings to review the Viral Load Sensitization Package (those trained are expected to pass along learnings to facility staff).  
• Kenya’s National AIDS & STI Control Program (NASCOP) 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? | • Mentorship  
• Quality assurance  
• High viral load register | • 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. |
<p>| 20. Who is responsible for forecasting for second line | • Supply chain management group | • Ethiopia’s national Pharmaceutical Fund &amp; Supply Agency is responsible for supply chain management and forecasting. |</p>
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<td>regimens?</td>
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<td>Kenya projects annually</td>
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| 21. How do you define treatment failure? | • Viral load >1,000 copies/mL  
• Viral load >400 copies/mL | • 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) |