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

#### 1. How will leadership and/or governance of routine viral load service roll-out be organized?

**Common Options**
- Viral load technical working group
- Viral load roll-out coordinators

**Country Examples**
- 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?

**Common Options**
- Online dashboard
- Paper register/log book
- Use of unique patient identifiers
- Site readiness tool

**Country Examples**
- 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?

**Common Options**
- Technical working group
- Coalition
- Civil society organization

**Country Examples**
- 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?

**Common Options**
- Prioritize populations, such as pregnant women or children
- Start with specific geographic regions
- National roll-out

**Country Examples**
- 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?

**Common Options**
- WHO guidelines
- Recommended for ART monitoring and identification of treatment failure

**Country Examples**
- 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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| **6.** What will be the standard viral load test frequency for infants and children? | » Every 12 months  
» Every 24 months | copies/mL  
Swaziland adopted WHO guidelines  
• 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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<td>11. How will specimens be transported from testing facilities to laboratories for testing?</td>
<td>• Courier • National mail • Riders for Health</td>
<td>• 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)</td>
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<td>12. How will results be returned from the laboratory back to testing facilities?</td>
<td>• Physical (tangible) return of written results • SMS printer • Email message • Online database</td>
<td>• Ethiopia uses SMS printers and courier • Kenya uses an online database (<a href="http://www.nascop.org">www.nascop.org</a>) • 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</td>
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<td>13. How will results be shared with patients and/or caregivers?</td>
<td>• Physical (tangible) return of written results • SMS printer • Email message • Phone • Online database</td>
<td>• 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</td>
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<td>14. Who can authorize the switch to second line regimens?</td>
<td>• Central decision-making committee • Physicians only • Physicians and nurses • Facility team</td>
<td>• 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</td>
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<td>switching to third-line regimens is done specifically for children</td>
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<td>15. What will be the schedule for providing enhanced adherence counseling?</td>
<td>• Standardized frequency</td>
<td>• Kenya’s National Toolkit on Adherence Support guides the provision of EAC</td>
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<td>• Swaziland provides EAC to all patients with viral load results &gt;1,000 copies/mL</td>
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<td>16. What content will be included in enhanced adherence counseling?</td>
<td>• Standardized content • Tailored content for priority patients</td>
<td>• Kenya’s National Toolkit on Adherence Support guides the provision of EAC</td>
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<td>• Swaziland employs Expert Clients to provide Stepped-Up Adherence Counseling (SUAC) to patients with viral load results &gt;1,000 copies/mL until an improvement in adherence is observed</td>
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<td>• Swaziland’s Ministry of Health is developing SOPs for provision of EAC</td>
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<td>17. How will patients be involved in generating demand for routine viral load testing?</td>
<td>• Technical working group • Coalition • Civil society organization</td>
<td>• 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</td>
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<td>• Health Communication Capacity Collaborative (HC3) in Swaziland provides community-based programming to communities and high-risk groups to increase demand for viral load services</td>
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<td>18. How will clinicians be involved in generating demand for routine viral load testing?</td>
<td>• Technical working group • Training • Targeted messaging</td>
<td>• Ethiopia facilitates regional two-day trainings to review the Viral Load Sensitization Package (those trained are expected to pass along learnings to facility staff)</td>
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<td>• Kenya’s National AIDS &amp; 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</td>
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<td>• Malawi is building clinician prompts into their national electronic medical record to remind clinicians when a patient is due for viral load testing</td>
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<td>19. What policies, strategies and/or interventions will ensure that routine viral load test results are utilized by clinicians?</td>
<td>• Mentorship • Quality assurance • High viral load register</td>
<td>• Ethiopia employs Clinical Mentors to ensure physicians properly follow-up on test results</td>
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<td>• Kenya uses data-driven mentorship</td>
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<td>• 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</td>
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<td>20. Who is responsible for forecasting for second line</td>
<td>• Supply chain management group</td>
<td>• Ethiopia’s national Pharmaceutical Fund &amp; Supply Agency is responsible for supply chain management and forecasting</td>
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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). |