

HIV: Closing the Access Gap in Viral Load, Early Infant Diagnosis, and Advanced Disease Identification

Human Immunodeficiency Virus (HIV) remains a major public health priority in many low- and middle-income countries (LMICs), with persistent gaps in viral suppression and advanced HIV disease (AHD) contributing to ongoing morbidity and mortality. In 2024, an estimated 40.8 million people were living with HIV globally and only 73% were virally suppressed.¹ While HIV infection is widely diagnosed through established serologic rapid-test algorithms, persistent access gaps lie in timely HIV viral load (VL) monitoring, early infant diagnosis (EID), and identification of advanced HIV disease (AHD).

Routine HIV VL monitoring is the World Health Organization (WHO)-recommended standard for assessing antiretroviral therapy (ART) effectiveness and diagnosing treatment failure. Persistent viremia $\geq 1,000$ copies/mL defines virologic failure and should trigger enhanced adherence counseling and possible regimen change.² Viral load testing is also central to transmission prevention, as individuals with sustained viral loads < 200 copies/mL do not sexually transmit HIV (U=U).³ Despite global scale-up, HIV VL testing in many LMICs remains centralized. Delays in specimen transport, plasma separation, batching, and result return can extend turnaround times to weeks or months, undermining timely clinical action.⁴ Near-point-of-care (near-POC) VL testing has been shown to significantly shorten time to results and clinical decision-making compared with centralized laboratory pathways.⁵

WHO guidance emphasizes quantitative VL measurement across clinically relevant ranges, including low-level viremia (< 200 copies/mL) and accurate identification of virologic failure ($\geq 1,000$ copies/mL).² Emerging implementation evidence suggests that decentralized VL platforms capable of operating on whole blood or minimally processed specimens, with time-to-result ≤ 60 minutes, can support same-visit decision-making in primary-care settings.^{5,6} Connectivity for automated reporting and integration into national surveillance systems further strengthen programmatic impact.⁷ Cost and specimen requirements remain critical barriers. Plasma-based workflows that require centrifugation limit decentralization. WHO and implementation partners have highlighted the importance of simplified sample collection, including capillary or whole-blood-compatible platforms, to enable VL testing closer to the patient.^{6,8}

Early infant diagnosis (EID) similarly relies on virological testing, as maternal antibodies render serologic assays unreliable in infants under 18 months. The WHO's 2021 guidance emphasizes the need for point-of-care (POC) EID to address delays in diagnosis and linkage to treatment for HIV-exposed infants.⁹ WHO has published a target product profile (TPP) for POC tests to diagnose HIV infection in children younger than 18 months, defining performance and operational requirements for decentralized use.¹⁰ Randomized trials demonstrate that POC EID reduces time to result and accelerates antiretroviral therapy (ART) initiation compared with conventional centralized laboratory pathways, improving early treatment coverage and outcomes.¹¹

Despite global scale-up of HIV VL monitoring, AHD remains a major contributor to AIDS-related mortality in LMICs. WHO recommends CD4 testing at ART initiation or re-entry into care to identify individuals with CD4 < 200 cells/ μ L who require the AHD package of care, including screening and prophylaxis for opportunistic infections such as tuberculosis and cryptococcal disease.¹² WHO has also published a TPP for POC CD4 tests to enable same-day identification of individuals with advanced immunosuppression.¹³ However, near-POC CD4 capacity has declined in many settings as platforms reach end-of-life and manufacturers exit the market, creating operational gaps in identifying patients at highest risk of mortality.¹⁴⁻¹⁵ Centralized CD4 testing remains available in some contexts but is frequently limited by turnaround time and access barriers. Sustained, affordable, decentralized CD4 solutions remain programmatically important to maintain AHD identification and delivery of life-saving interventions.^{12,15}

Across VL, EID, and AHD use cases, sustained impact will depend on decentralized tools that meet WHO performance standards, quantify viral load within clinically meaningful thresholds, operate on minimally processed specimens, integrate with surveillance systems, and achieve affordability compatible with high-burden LMIC settings.

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