**Point-of-care viral load testing and differentiated HIV care**

WHO recently approved the first quantitative point-of-care (POC) HIV viral load assay for use in resource-limited settings. The Xpert HIV-1 VL (Cepheid, Sunnyvale, US) requires 1 mL of plasma to measure viral load in 90 min on the GeneXpert platform. The assay has been validated in several clinical settings and detects virological failure (>1000 copies per mL) with 94% sensitivity and 99% specificity. Current costs seem similar to existing platforms available at US$17,000 and cartridges at $17 (excluding tax and shipping). Prequalification will allow the Xpert HIV-1 VL to be procured through WHO tender processes, facilitating expanded access at lower costs, particularly in low-income and middle-income countries. This could be an important milestone for HIV programmes, as POC viral load testing has potential to fill gaps in coverage and to change the way HIV care is provided, through more efficient client-centred services. As access to antiretroviral therapy (ART) increases, global demand for viral load monitoring is estimated to grow from 7 million tests in 2013 to 15–30 million in 2018. Scale-up is particularly challenging in southern Africa because of a paucity of trained laboratory personnel, high costs of centralised laboratory infrastructure, and challenges with specimen transport and return of results. POC viral load assays such as the Xpert HIV-1 VL may allow decentralised viral load testing that circumvents some of these problems. Automated systems allow operation by non-laboratory personnel, while near patient testing can eliminate the need for specimen transport. However, POC testing capacity will need to match numbers of patients with clinic flows adapted to minimise turn-around times. Technological advances to speed up sample processing will be important, as will fingerprick and dried blood spot testing, which are currently not available on Xpert HIV-1 VL. Several other quantitative POC viral load assays have been validated in decentralised clinics in southern Africa, including the SAMBA I/II semi-Q (Diagnostics for the Real World Ltd., Cambridge, UK), Alere Q NAT (Alere, Waltham, MA, US), and Liht HIV Quant (Roche Diagnostics, Basel, Switzerland). While the widespread availability of the GeneXpert platform for tuberculosis diagnostics might favour the introduction of the Xpert HIV-1 VL, most machines are situated within centralised laboratories, reflecting the remaining challenges of implementing POC molecular diagnostics within existing care models.

![Figure 1: Conceptual model of differentiated HIV care and integrated point-of-care viral load testing, adapted from STREAM](image)

of client visits. Integrating POC viral load testing into these services may further improve and expand access to differentiated HIV care in several ways.

First, rapid availability of POC results could allow quicker triage of patients into differentiated care pathways, while reducing the number of visits. Routine laboratory-based viral load testing requires two clinical contacts, one for blood draw and one to review results. In HIV services with frequent clinical visits, blood can be drawn at one visit and results reviewed at the next scheduled visit in 1–2 months. In differentiated care services, where stable clients may have clinical visits only every 6 months or 12 months, the interval between blood draw and review of results could be unacceptably long, unless extra visits are scheduled for viral load assessment or attempts are made to recall clients with abnormal results. Instead, POC testing could allow stable patients to have viral load measurements taken and reviewed in one clinical visit each year, with decentralised ART delivery in between (figure).

Resources could then be redirected to unstable clients, in whom POC testing may allow rapid identification of virological failure, earlier initiation of intensive adherence support, and ART regimen changes, if necessary. We are investigating a similar model of care in the STREAM study; a randomised trial of Xpert HIV-1 VL testing, with results expected in late 2018. Second, POC viral load testing may be particularly useful in differentiated care for specific hard-to-reach populations. The relative portability of POC systems allows use in community outreach services, such as for people who inject drugs or rural populations. For clients who can attend clinics only sporadically, because of migrant labour or being in conflict settings, the immediacy of POC results could empower clinicians and clients to manage ART appropriately, while minimising the need for frequent clinical contacts. Furthermore, in pregnant or breast-feeding women, faster identification and management of virological failure through POC testing may contribute to prevention of mother-to-child transmission.

POC viral load assays have potential to expand viral load coverage significantly and to improve differentiated care. However, successful integration into HIV services must take the following factors into account: client needs, clinic flows, staff training, quality control, supply chain management, and maintenance of equipment at decentralised sites. No strong evidence supports roll-out of POC viral load testing. Therefore, while prequalification of the Xpert HIV-1 viral load is welcome, high quality implementation research coupled with cost-effectiveness studies should be prioritised to determine whether POC testing can be successfully integrated into differentiated care.

“Jienchi Dorward, Paul K Drain, Nigel Garrett
Centre for the AIDS Programme of Research in South Africa (CAPRISA), University of KwaZulu-Natal, Durban, South Africa (JD, NG); Department of Global Health, Schools of Medicine and Public Health, University of Washington, Seattle, USA (PKD); Department of Medicine, School of Medicine, University of Washington, Seattle, USA (PKD); Department of Epidemiology, School of Public Health, University of Washington, Seattle, USA (PKD); Discipline of Public Health Medicine, School of Nursing and Public Health, University of KwaZulu-Natal, Durban, South Africa (NG) jienchi.dorward@gmail.com

The authors are investigators on the Simplified TREATment and Monitoring of HIV (STREAM) study, a randomised controlled trial of POC VL testing (using the Xpert HIV-1 VL) and task shifting to nurses. The STREAM study is funded by the US National Institute for Health (NIH) (AI24719-01). Cepheid Inc. loaned the GeneXpert® instruments for this study at no cost. NIH and Cepheid had no role in the conception, drafting or submission of this commentary.