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Decentralizing HIV Viral Load Monitoring: Feasibility and Market Insights from the HIVQuant® Prototype Evaluation

Timely HIV viral load monitoring remains a major challenge in resource-limited settings, where reliance on centralized laboratories and fragile supply chains delays treatment decisions and worsens outcomes. Decentralized, point-of-care solutions are urgently needed to improve equity and access.

We evaluated the HIVQuant® prototype, a proposed low-cost, ambient-temperature molecular diagnostic platform, through a UKRI-IAA funded feasibility study at Zomba Central Hospital, Malawi. The study assessed feasibility, acceptability, and reproducibility under real-world conditions. In parallel, a UKRI ICURe-supported market discovery exercise engaged over 100 stakeholders across the global HIV diagnostic supply chain to identify implementation barriers and priorities.

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The prototype demonstrated moderate concordance with routine viral load testing (45.7%). Key operational challenges included reagent stability, extraction complexity, and reduced sensitivity. Air-dried reagents showed superior field stability compared to freeze-dried formulations, and plasma RNA extraction emerged as the most reliable quantification method.

Market insights revealed strong demand for decentralized diagnostics, particularly in rural and peri-urban clinics. Stakeholders emphasized simplified workflows, robust reagent formulations, and integration with existing health systems. Findings highlight both the promise and limitations of early-stage point-of-care viral load technologies. Technical refinements—such as improving reagent robustness and workflow simplicity—are critical for scale-up. Aligning innovation with health system realities and user needs will be essential to advance equitable HIV care.

Keywords
HIV, Point-of-Care, Diagnostics, PCR, Ambient-Temperature, Malawi

Biography
Dr Catherine N. Kibirige is the Intellectual Property Strategy Officer at Imperial College London, with over 20 years of experience in HIV-1 clinical research, diagnostics, and public health. She led an initiative to improve access to molecular diagnostics in resource-limited settings, including the development and field evaluation of the HIVQuant® prototype assay. Catherine holds a PhD in Molecular Microbiology and Immunology from Johns Hopkins Bloomberg School of Public Health and has participated in multiple commercialization accelerators. Her work bridges research, implementation science, and health equity, with a focus on translating laboratory innovation into sustainable, real-world solutions for global health.

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