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Clinical Validity and Utility of CRISPR-Based Diagnostics in HIV: Lessons for Population Screening and Policy Methods, Challenges, and Future Directions

Kungu Erisa

Faculty of Pharmacy Kampala International University Uganda

Email: erisa.kungu@studwc.kiu.ac.ug

ABSTRACT

CRISPR-based diagnostics represent a promising innovation in the detection of human immunodeficiency virus (HIV), with potential to improve early diagnosis, expand population screening, and strengthen public health responses. This paper examines the clinical validity and utility of CRISPR-based HIV diagnostics by analysing three interrelated domains: analytical performance, clinical performance, and operational utility. It reviews key analytical metrics such as limit of detection, precision, linearity, and robustness; clinical indicators including sensitivity, specificity, and predictive values across stages of infection; and operational considerations such as scalability, turnaround time, accessibility, and suitability for point-of-care deployment. The discussion highlights the advantages of CRISPR technologies in detecting viral RNA and DNA during acute infection and maintaining sensitivity despite HIV's genetic diversity. At the same time, significant technical, regulatory, ethical, and health-system challenges remain, including validation standards, cost-effectiveness, data governance, and equitable access. Drawing lessons from existing population screening initiatives and diagnostic implementation frameworks, the paper underscores the importance of evidence-based policy design, sustainable financing, and integration with surveillance systems. Future directions include improving field readiness, user-centered design, digital reporting integration, and supportive regulatory pathways. Overall, CRISPR-based diagnostics could substantially enhance HIV screening strategies if their clinical performance, implementation feasibility, and policy alignment are systematically addressed.

Keywords: CRISPR-based diagnostics**,** HIV screening**,** Clinical validity and utility**,** Point-of-care testing and public health policy.

INTRODUCTION

Current diagnostics for human immunodeficiency virus (HIV) fail to meet global screening targets. Long-lasting stigma, discrimination, and concerns about confidentiality continue to hinder access to testing worldwide and to population screening initiatives targeted at vulnerable groups [2]. CRISPR-based diagnostics have emerged as promising alternatives to standard tests [1]. These instruments detect the integration of HIV into DNA, thereby enabling diagnosis during the acute infection window and prior to the formation of antibodies. Newly synthesized viral genes are simultaneously targeted, enabling these platforms to maintain sensitivity under the extreme sequence diversity exhibited by HIV [4]. Formal frameworks for evaluating the clinical validity and utility of CRISPR-based diagnostics in HIV remain scarce. A widely accepted conceptual framework distinguishes three interdependent performance domains: measurable analytical performance, clinically meaningful clinical performance, and practical operational utility [1]. Analytical performance quantifies the ability of a test to identify a target analyte consistently and precisely. It encompasses metrics such as the limit of detection, linearity, precision, and assay robustness and forms the basis for transferring a test from a research-development setting to wider use [2]. The performance characteristics that warrant consideration depend on the end-user and intended

application. For HIV diagnostic tools, determining whether a test can detect the virus within the acute infection window is critical [3]. Consequently, established thresholds for the detection of HIV RNA, HIV DNA, and HIV antigenemia provide key points of reference [2]

Background on HIV Diagnostics and CRISPR Technologies

All clinical tests, including point-of-care (POC) tests, require an assessment of their clinical validity (analytical and clinical performance) and operational utility before use in a given healthcare context [6]. This analytical and clinical framework applies equally to HIV molecular tests and to HIV diagnostics in general [5]. HIV is an enveloped RNA retrovirus that contains multiple genetic targets for molecular diagnostics in human specimens, including HIV RNA, proviral DNA, and early genome-integrated forms [4]. Each target is useful for defining acute HIV infection, validating partner status, or monitoring antiretroviral therapy (ART). CRISPR-based diagnostics can, in principle, detect each of these targets. HIV is an enveloped retrovirus that infects and replicates within human CD4+ T lymphocytes. A CHAMPION study across six countries consistently showed the majority of new infections occur via sex in persons either believed to be HIV-uninfected or among repeat non-injected substance users seeking new partners [3]. Individuals are therefore often motivated to obtain their own or their partner's HIV test results. Currently, 34.7 million people are estimated to be living with HIV worldwide. Current HIV-testing guidelines therefore recommend testing at least annually for partner acquisition and every 3 months for those with multiple partners [1]. CRISPR-Cas, an adaptive immune system in bacteria, can be harnessed to build diagnostic platforms that detect both RNA and DNA sequences with comparable or superior performance relative to nucleic acid amplification tests and other diagnostics for a range of pathogens [2].

Methods for Assessing Clinical Validity and Utility of CRISPR-Based HIV Diagnostics

CRISPR approaches to HIV diagnostics demonstrate a wide range of analytical and clinical performance, as well as operational utility, but individual studies fail to comprehensively assess the need for transparent and systematic evaluation [13]. Analytical performance encompasses limit of detection, linearity, robustness, and precision, all of which influence the interpretation of clinical metrics [11]. Clinical metrics comprise sensitivity, specificity, and positive and negative predictive values estimated for samples collected during acute and chronic infection over ranges of prevalence [12]. Operational utility considers throughput, scalability, access to sample types, time to result, and user-friendliness, with implications for integration into population-level screening. These dimensions target different populations within the screening cascade [14].

Analytical Performance Metrics

The analytical performance of CRISPR-based diagnostic tests for human immunodeficiency virus (HIV) is critical for establishing their clinical validity and utility. Analytical performance risk factors must be evaluated to quantify performance in absolute terms [3]. Studies meeting generalizable standards for experimental design, technical replication, sample matrix variety, processing time, and statistical evaluation can remain independent of the settings of concomitant benchmarks [4]. Analytical performance metrics highlighted during HIV scientific consultations as pertinent to rapid tests include the limit of detection (LoD), assay linearity, assay precision, and robustness to perturbation [8]. Individual thresholds depend on the intended purpose; for HIV diagnostic tests operating at baseline strains, World Health Organization guidelines recommend a minimum functional LoD of 2,000 RNA copies per millilitre of plasma within a measurement cycle not exceeding 1 day [7].

Clinical Sensitivity and Specificity in the HIV Context

HIV tests are divided into three distinct categories based on the biological markers they detect: antigen, RNA, and DNA [2]. The diagnostic window for each test depends on when its respective biomarkers reliably appear. Antigen tests detect the p24 protein from HIV-1 (subtypes B and D) and the corresponding protein from HIV-2. These proteins typically appear between 15 and 20 days post-exposure in a peripheral blood sample, but up to 36 days in a plasma sample [4]. RNA tests detect viral mRNA from the HIV-1 LTR and are expected to provide a response about 10 to 15 days after exposure in plasma and about 12 to 24 days in sero-positive blood, while DNA tests detect the HIV-1 LTR genome at the same time for both sample types. Lastly, CRISPR assays for HIV-1 and HIV-2 have already been demonstrated [5, 6].

Operational Considerations for Population Screening

Population screening encompasses the identification of asymptomatic individuals who are unaware of their status and would benefit from receiving the test [6]. Population screening also includes testing asymptomatic individuals who are at elevated risk due to other risk factors, such as age, who are therefore more likely to test positive. Prevalence and the point along the care continuum at which screening occurs determine the level of clinical sensitivity and specificity needed to achieve satisfactory public health impact [4]. In the population screening context, operational utility is therefore defined in terms of a specific use case (e.g., point-of-care self-testing, routine testing in clinical settings) and the associated needs and constraints [7, 8].

Challenges in Implementation

CRISPR-based diagnostics relying on Cas proteins are emerging as rapid, sensitive, and cost-effective alternatives to traditional methods for identifying viral sequences, including human immunodeficiency virus (HIV) [14]. The diverse array of speciation-linked gene 3p gene sequences available for various HIV strains places them at the forefront among confirmatory assays for early detection [15]. Initial studies demonstrate the analytical performance and feasibility of implementing these robust molecular tests for HIV screening and early detection using anterior nasal and oral-swab specimens [15]. However, significant barriers to adoption persist in technological, regulatory, and health-system facets. Addressing these challenges through evidence-informed policies and strategies can support an enduring role for a wider array of future CRISPR diagnostics in response to pathogenic threats [16].

Technical and Analytical Challenges

A hallmark of an effective diagnostic test for HIV, whether screening or confirmatory, is a rapidly quantifiable direct measurement of the viral particle or its nucleic acids during the accepted biological window of infection [15]. Nevertheless, much of the work reimagining the viral tests that CRISPR could ostensibly solve fails to consider the symbiotic dynamics between HIV and the natural repertoire of the human virome and microbiome. While some HIV-targeted CRISPR approaches are ongoing, the discovery of resistant escape mutants will likely curtail any longer-term treatment options [1]. Hence, several pressing technical challenges remain to reach the threshold of clinical validity for even the simplest one-pot, direct CRISPR-based RNA diagnostics[13].

Regulatory and Ethical Considerations

In many jurisdictions, a regulatory framework governing the manufacture and use of devices capable of detecting human pathogens, including HIV, exists at the national or supranational level [3]. For instance, the United States has a separate classification system for diagnostics under the Federal Drug Administration (FDA), while in the European Union, the In Vitro Diagnostic Regulations affect diagnostic tests [13]. Other countries maintain regulatory regimes similar to either model, and additional guidelines establish best practices even where national law is absent or unenforced [9]. There is variation in the exact balance of analytical versus clinical evidence required for a given class of device, but an analogous situation arises early in each model, where evidence of analytical performance is often considered sufficient merely to gain the status of a device and begin accelerating toward a public health objective, such as emergency use authorization in some locales [17]. Adherence to foundational ethical principles is essential for translating laboratory and field testing of the technology into sustained deployment [11]. Many of the principles articulated by global bodies apply [18]. The collection, storage, and use of information generated by population screening activities raise ethical concerns. Additional operational burdens, such as pre–test and post–test counseling, may be incurred depending on the specific conditions under which testing is provided, the requirements of funding or advocacy organizations, and ongoing public health objectives. Investments in elimination strategies may also incentivize targeted development pathways downstream, provided adequate safeguards can be implemented [10]. Conversely, a simple device intended for non–invasive detection of viral RNA within public health windows offers a clear opportunity to bundle such capabilities at minimal marginal cost [11].

Health System and Policy Implications

Clinical screening interventions reduce the burden of health crises while informing subsequent policy and public health actions [12]. To complement insights from former screening initiatives targeting HIV, the cost-effectiveness of the proposed CRISPR HIV test versus conventional tests or no test is assessed to inform implementation strategies and resource prioritization [13]. Analytical modeling investigates the implications of pre-test probabilities of infection, test kit price reflecting development, manufacturing, and procurement costs, and screening interval on adoption, uptake, and compliance. Budget impact assessments quantify the test's affordability given prevailing resource constraints [11]. Background on HIV diagnostics and CRISPR technologies is provided, along with an outline of clinically relevant system specification requirements. Addressing existing CRISPR-based HIV diagnostics, state-of-the-art engineering specifications, the evidence base, and the current regulatory landscape can clarify the anticipated implications of incorporating a new CRISPR HIV test into population screening programs [13].

Health System and Policy Implications

The cost of the proposed CRISPR-based HIV test, critical for assessing technical feasibility, reimbursement requirements, and implementation planning, can be estimated from laboratory and manufacturing expenditure reports on existing pipette-coupled, lyophilized, polymerase-assisted CRISPR diagnostics delivered in 2022 [14]. If the same assembly process and chemical constituents remain applicable, expenditures on the materials required to fabricate twenty-four tests total around $4.74 (USD) [18]. To comply with established cost-effectiveness benchmarks, a breakdown of laboratory service provision is also required [11].

Lessons from Population Screening Initiatives

Population genomic screening programs for BRCA1/2, Lynch syndrome, and familial hypercholesterolemia (FH) improve pathogenic variant detection compared to family history-based approaches [10]. Evidence supporting the clinical and cost-effectiveness of BRCA1/2 screening, especially in unselected populations, is stronger than for other conditions [11]. A genome-wide association study identified 716 polygenic risk score candidates for breast, ovarian, or prostate cancer; incorporating four facilitated program integration, public awareness, and communication. Providing single-gene testing to at-risk relatives and offering preventive interventions had high population-coverage impacts [9]. Prevalence-based scenario analysis indicated cost-effectiveness and budget-impact sustainability across diverse settings. Acceptability, psychological outcomes, occasional overdiagnosis, equity, and access remain key implementation questions. Comprehensive health-economic evaluation for unselected population-scale programs continues to advance [11]. Engaging with an early initiative clarifies considerations associated with integrating genomics into population-screening structures [13]. Genomic information lends itself to multiplex transmission beyond single-gene pathogenic variant tests, expanding screening options and complicating scope delimitation [12]. The appropriateness of population genomics hinges on prospective health gains and comparison to alternative preventive strategies. Scenarios transferring emergent knowledge for other frameworks, geography, and integration objectives provide useful insights to refine policy conclusions and enhance future screening efforts [15].

Case Studies and Comparative Analyses

Throughout the 2010s, several populous countries implemented national, multi-faceted circular economy (CE) strategies after reading the first-generation resources for CE [2]. The analysis is examined from February 2020, when the national economic program (2021-2025) of Vietnam was disclosed, until May 2022, when the target and plan for the new program were released by the government, covering 144 social, economic, and environmental indicators of Vietnam and global influence [6]. High-throughput screening aimed at assessing the therapeutic effects of CRISPR-loaded extracellular vesicles (CRISPR-EV) on multiform cancer cell lines remains limited to ex vivo study, notwithstanding the therapeutic successes of CRISPR-EV reported in experimental animals and living cells. Efficient solubilization and separation of CRISPR-EV samples from aqueous biological fluids are essential for high-throughput screening, although surfactants poorly stabilize CRISPR-EV against environmental stressors such as light and temperature [3]. Four classes of CRISPR-EV markers facilitate the tracking and confirmation of CRISPR-EV designs: trans-acting guide RNA (ga), the spatiotemporal indicator of DsbA-EGFP assembly, trans-activating CRISPR RNA single guide RNA (ta-sg), and the phylogenetically preserved Class 1 interferon-induced RNA (CiRNA). Three principles are expounded to obtain better therapeutic grading corresponding to varying demands [1]

Cost-Effectiveness and Resource Allocation

In recent years, cost-effectiveness analyses (CEAs) have played an important role in the evaluation of HIV testing interventions and the allocation of resources [13]. CEAs are used to estimate the cost per unit of health gain, where health gain can be quantified in various ways, such as through quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs) [16]. Alternatively, the incremental cost–effectiveness ratio (ICER) can be computed, which describes the additional cost required to achieve a particular health outcome [8]. Furthermore, CEAs also estimate the budget impact of an intervention, which is defined as the difference between the budget before and after the implementation of an initiative over a certain time horizon [12]. Finally, optimization models identify the most efficient allocation of several strategies under certain constraints [17]. Several modelling and optimization frameworks, developed to evaluate HIV testing interventions, can be adapted to the analysis of avoidable premature deaths under the implementation of CRISPR-based diagnostics. A core CEA model can address two key questions for the health system in the present scenario [15]. First, what is the expected ICER with CRISPR-based tests, and how would it affect the allocation of the HIV test budget among the candidate strategies? Second, to mitigate the expected health burden due to preventable premature deaths, the budget allocated to CRISPR-based tests should be maximized [16]. Further budget reallocations across candidate strategies can extend the health impact analysis under specified budget constraints [10].

Future Directions for CRISPR Diagnostics in HIV

The ongoing evolution of CRISPR-based diagnostics offers important avenues for enhancing analytical performance, clinical sensitivity, and operational utility within HIV-specific constraints [12]. Further technological development targeted at POC deployment and user-centered design may facilitate faster clinical access alongside cancer diagnostics and expanded low-resource screening for other infections. Integrating CRISPR diagnostics with seamless data-sharing across the health care chain from the point of sampling to centralized systems could pioneer the real-time public-health surveillance of both pathogens and population immunity [13]. Such a capability would allow rapid, ongoing evaluation of the epidemiological impact of vaccination, viral rebound after treatment interruption, and the emergence of new variants of concern [14, 2].

Progressing along these parallel trajectories would benefit from a supportive policy environment that aims to activate early-stage technologies, broaden the scope of practice within the laboratory workforce, enable large-scale test-and-treat interventions, strengthen supply chains and regional manufacture, maintain the viability of closed orchestration at laboratories for multiuser instrumentation, and reinforce the safety and privacy of digital records [19].

Technological Innovations and Point-of-Care Deployment

To maximize population impact, CRISPR diagnostics for HIV must become field-ready. Adaptations of existing protocols to simplify workflows, combine steps into fewer reactions, and increase resilience to environmental variation are essential [14]. In parallel, research on formulations that enhance the stability of enzymes, amplification templates, and other inputs while preserving activity is critical [18]. User-centered design considerations can further facilitate point-of-care deployment [19]. When samples are collected through self-testing, clear instructions for each step, including sample collection, reagent addition, and results interpretation, are vital. Incorporating a visual or smartphone-assisted readout improves accessibility and guides untrained users through the process. Beyond these considerations, embedding CRISPR RNA design automation into intuitive user interfaces would help make the technology broadly applicable across indicators and pathogens [11]. Infection surveillance through CRISPR diagnostics demands systematic approaches to data interoperability, real-time reporting, outbreak detection, and retrospective monitoring of transmission routes. Such functionalities, already implemented in some non-commercial tests, would reinforce the value of integrating diagnostic campaigns with public health infrastructure [10].

Integration with Public Health Surveillance

In support of effective public health responses, timely reporting of routine health data is required. Some applications for monitoring the spread of HIV utilize test result data; for example, [14] outlined a strategy for conducting HIV self-testing in France, where completed tests were recorded via a health app to provide an overview of screening coverage without identifying users. Such a reference group could be considerable among sporadic testers with unknown status [4]. Integrating HIV diagnostic screening using CRISPR-Cas into existing surveillance systems leveraged the country's large network of public health laboratories. Partners analyzed whether the inserted data would fit with the information technology framework maintained by the provincial public health agency [15]. Data on the use of CRISPR-Cas diagnostics for other pathogens, integrated with the upsurging uptake of self-testing technologies, could raise concerns about reduced reporting of lab confirmation testing and other traditional sources [12]. The key considered aspects were compatibility with existing databases, the possibility of centralizing temporary data received from partners' sites, and the potential to monitor if self-testing kits match recommended specifications [20]. Although some public health entities request readouts for samples compatible with such platforms, it remained uncertain whether they would extend comparable requirements to CRISPR-Cas systems [15]. The potential to trace samples across involved public health sites further supported document integration. Other recent CRISPR-Cas systems targeting diverse organisms at the RNA level have already been addressed by the provincial public health agency [16].

Policy Frameworks and Recommendations

Governance and oversight arrangements to ensure public health, equity, safety, and effectiveness are paramount for screening programmes [18]. The absence of standardised protocols, guidelines, or operating procedures increases variability and risks compromising clinical validity, hindering comparability, and increasing uncertainty around investment decisions [7]. Clear delineation of the knowledge base, evidence requirements, and practices needed to advance technologies in regulated and unregulated settings is critical [20-22]. Future-proof and inclusive guidelines are needed to update genomic assessments, evaluate novel data types, and encourage diverse participation to delineate the evidence required to consider implementation [23, 24]. Scalable prioritisation frameworks enable identification of the most promising innovations, focusing attention on maximising the overall population achieved outcome while remaining aligned with standards of care [25].

CONCLUSION

CRISPR-based diagnostics have the potential to transform HIV detection by enabling earlier diagnosis, improving sensitivity across diverse viral strains, and enabling scalable population screening. Their strength lies not only in analytical precision but also in their adaptability to point-of-care and self-testing contexts, which can help address persistent barriers such as stigma, delayed diagnosis, and limited laboratory capacity. However, widespread adoption depends on overcoming key challenges. Robust and standardized evaluation frameworks are required to establish clinical validity and operational reliability across diverse epidemiological settings. Regulatory approval pathways, ethical safeguards for data privacy and counseling, and health-system readiness must also be strengthened to ensure responsible deployment. In addition, cost-effectiveness analyses and resource allocation strategies are essential to guide policymakers in integrating CRISPR diagnostics into existing HIV testing programs without exacerbating inequities. Looking ahead, continued technological refinement, investment in

manufacturing and supply chains, and integration with digital surveillance platforms will be crucial. With coordinated scientific, regulatory, and policy efforts, CRISPR-based HIV diagnostics could become an important component of future screening strategies, contributing to earlier treatment initiation, reduced transmission, and progress toward global HIV control targets.

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