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Closing Diagnostic Gaps in Pediatric HIV: Innovations in Point-of-Care and Digital Monitoring, with an Asia–Pacific Implementation Lens

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ADMINISTRATIVE INFORMATION

Support - None.

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Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 November 2025 and was last updated on 19 November 2025.

INTRODUCTION

Review question / Objective To systematically evaluate the impact of point-of-care (POC) diagnostic technologies (early infant diagnosis and viral load monitoring) and digital monitoring tools on pediatric HIV outcomes, specifically diagnostic turnaround times, time to treatment initiation, and viral suppression. Review Question (PICOS):

Population: Infants, children, and adolescents (0–19 years) exposed to or living with HIV.

Intervention: Point-of-care (POC) nucleic-acid testing (e.g., Xpert, Alere q), near-patient viral load platforms (e.g., SAMBA II), and digital adherence tools (mHealth).

Comparator: Standard centralized laboratory-based PCR testing and standard clinical care pathways.

Outcome: Diagnostic accuracy, time-to-result, ART initiation rates (≤60 days), viral suppression, and implementation feasibility.

Setting: Global, with a specific focus on implementation gaps and strategies in the Asia–Pacific region.

Rationale Early virological diagnosis is critical for survival in infants with HIV, as mortality is high without immediate antiretroviral therapy (ART). However, global coverage of early infant diagnosis (EID) remains suboptimal (~59%). In the Asia–Pacific region, implementation is highly uneven; while some countries have eliminated mother-to-child transmission, others report EID coverage below 20%. Centralized laboratory networks often suffer from logistical delays (sample transport, batching), leading to high loss to follow-up. Innovations such as Point-of-Care (POC) diagnostics and digital monitoring tools offer solutions to close these gaps, but a synthesis of their effectiveness and specific implementation

challenges in the Asia–Pacific context is needed to guide policy and scale-up efforts.

Condition being studied Pediatric HIV infection, focusing on the diagnostic and monitoring cascade. This includes the need for molecular virological testing (nucleic acid testing) for infants under 18 months due to the persistence of maternal antibodies, as well as routine viral load monitoring for children and adolescents on ART to ensure viral suppression and prevent drug resistance.

METHODS

Search strategy We searched PubMed/MEDLINE, EMBASE, the Cochrane Library, and WHO Global Index Medicus for studies published between January 1, 2015, and [Current Date] 2025. Search Terms: Combinations of keywords including "pediatric HIV", "early infant diagnosis" (EID), "point-of-care" (POC), "viral load", "GeneXpert", "Alere q", "SAMBA", "digital adherence", "mHealth", and "Asia–Pacific". Additional Sources: We screened reference lists of included studies and reviewed programmatic reports from WHO, UNAIDS, and UNICEF to capture implementation data relevant to the region.

Participant or population Infants, children, and adolescents (aged 0–19 years) who are HIV-exposed or living with HIV.

Intervention POC Diagnostics: Decentralized nucleic-acid tests for Early Infant Diagnosis (e.g., Cepheid Xpert HIV-1 Qual, Abbott Alere q/m-PIMA) and viral load monitoring (e.g., Cepheid Xpert HIV-1 VL, SAMBA II).

Digital Tools: mHealth interventions including SMS reminders, mobile applications, and electronic dose-monitoring devices designed to support adherence and retention.

Comparator Standard centralized laboratory-based PCR testing (often using Dried Blood Spots transported to reference laboratories) and standard-of-care adherence support.

Study designs to be included Randomized Controlled Trials (RCTs), quasi-experimental studies, cohort studies, cross-sectional diagnostic accuracy evaluations, existing systematic reviews, and authoritative guidance/programmatic reports from international health organizations.

Eligibility criteria Studies published from 2015 to 2025.

Studies reporting on diagnostic accuracy, clinical impact (time-to-result, treatment initiation), or implementation outcomes of relevant technologies.

Data specific to the Asia–Pacific region were prioritized, though high-quality evidence from sub-Saharan Africa was included where regional data were sparse.

Information sources Electronic databases (PubMed/MEDLINE, EMBASE, Cochrane Library, WHO Global Index Medicus); Grey literature (programmatic reports from WHO, UNAIDS, UNICEF); Reference lists of eligible articles.

Main outcome(s) Time-to-Result: The interval between sample collection and result receipt by the clinician or caregiver.

ART Initiation: The proportion of HIV-infected infants initiating antiretroviral therapy within 60 days of sample collection.

Diagnostic Accuracy: Sensitivity and specificity of POC assays compared to the gold standard (central lab Roche/Abbott assays).

Quality assessment / Risk of bias analysis Diagnostic Accuracy Studies: Assessed using the QUADAS-2 tool (Quality Assessment of Diagnostic Accuracy Studies).

Intervention Studies (RCTs/Non-randomized): Assessed using the Cochrane Risk of Bias tool (RoB 2) for randomized trials and the Risk of Bias Assessment Tool for Non-randomized Studies (RoBANS) for observational studies.

Strategy of data synthesis A structured narrative synthesis is conducted, organizing findings by technology type (EID, VL, Digital Tools) and implementation theme. Due to the heterogeneity of study designs and the lack of sufficient extractable numerators/denominators specifically from Asia–Pacific studies, a de novo quantitative meta-analysis was not performed. Instead, the review references existing robust pooled estimates from global literature to contextualize regional findings.

Subgroup analysis Findings are synthesized and discussed across specific subgroups:

Geography: Specific implementation challenges in Asia–Pacific nations (e.g., archipelagos like Indonesia vs. mountainous regions like PNG).

Age: Neonates (birth testing) vs. Infants (6-week testing) vs. Adolescents (viral load/adherence).

Sensitivity analysis Not applicable, as no quantitative meta-analysis was performed.

Language restriction No language restrictions were imposed on the search, although retrieved literature was predominantly in English.

Country(ies) involved Taiwan.

Keywords pediatric HIV; early infant diagnosis; point-of-care testing; viral load; Asia–Pacific; implementation; PRISMA; INPLASY; mHealthAcute necrotizing encephalopathy; Pediatric neurology; Immunomodulatory therapy.

Contributions of each author

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