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ARTICLE TITLE	THE POCKET LABORATORY IN PRACTICE: A SOCIO-TECHNICAL REVIEW OF SMARTPHONE-BASED POINT-OF-CARE DIAGNOSTICS IN LMICs: Implementation, Task Shifting, and Last-Mile Challenges in Infectious Diseases
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THE POCKET LABORATORY IN PRACTICE: A SOCIO-TECHNICAL REVIEW OF SMARTPHONE-BASED POINT-OF-CARE DIAGNOSTICS IN LMICs: *Implementation, Task Shifting, and Last-Mile Challenges in Infectious Diseases*

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ABSTRACT

Background: Infectious diseases remain a leading cause of mortality in low- and middle-income countries (LMICs), where nearly half the global population lacks adequate access to diagnostics. Smartphone-based point-of-care (POC) diagnostic technologies have emerged as a promising response to this gap, leveraging the rapid expansion of mobile phone ownership across resource-limited settings. However, a critical disconnect persists between the pace of technological innovation and the complex socio-technical realities of deploying such tools in resource-limited settings.

Objective: This narrative review synthesizes the literature on smartphone-based POC diagnostics for infectious diseases in LMICs, adopting a socio-technical systems perspective that extends beyond analytical performance to examine the human, organizational, and contextual determinants of implementation success.

Methods: A narrative review was conducted drawing on PubMed, Scopus, Web of Science, Google Scholar, and grey literature from WHO and partner agencies. The analysis was guided by a socio-technical systems framework and WHO's REASSURED criteria for evaluating point-of-care diagnostic readiness.

Results: The review identifies four principal technological approaches — imaging-based, sensor-based, molecular, and data-driven diagnostics — and evaluates them against the WHO REASSURED criteria. Three models of task shifting to community health workers are proposed, each carrying distinct implications for training, governance, and quality assurance. Five categories of last-mile barriers are documented: infrastructural, regulatory, socio-cultural, economic, and technological. While proof-of-concept evidence is abundant, real-world implementation data from scaled programs remain scarce. The persistent gap between technological capability and population-level health impact is attributable not to engineering deficits but to systemic implementation failures.

Conclusions: Transitioning from pilot projects to sustainable, nationally integrated diagnostic programs requires coordinated action across regulatory harmonization, workforce development, user-centered design, and domestic financing — a shift from technology-centric to socio-technical approaches.

KEYWORDS

Smartphone Diagnostics, Point-of-Care Testing, Low- and Middle-Income Countries, Task Shifting, Infectious Diseases, mHealth

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1. Introduction

Infectious diseases continue to exact a disproportionate toll on populations in low- and middle-income countries (LMICs). Malaria alone caused an estimated 597,000 deaths in 2023, with approximately 95% occurring in Sub-Saharan Africa (World Health Organization [WHO], 2024b). Tuberculosis (TB) remains the leading infectious cause of death globally, with the highest burden concentrated in South-East Asia and Africa (WHO, 2024a). Despite decades of investment, HIV/AIDS claimed approximately 630,000 lives in 2023, predominantly in LMICs (Joint United Nations Programme on HIV/AIDS [UNAIDS], 2024). Neglected tropical diseases (NTDs) affect over one billion people, almost exclusively in the poorest communities (WHO, 2023). The COVID-19 pandemic further exposed the fragility of health systems in resource-limited settings, amplifying pre-existing vulnerabilities in diagnostic capacity.

A central obstacle to effective disease control in these regions is the diagnostic gap. The 2021 Lancet Commission on Diagnostics documented that 47% of the global population has little or no access to diagnostics, with the most severe deficits found in LMICs (Fleming et al., 2021). Laboratory infrastructure in many Sub-Saharan African and South-East Asian countries remains sparse, unevenly distributed, and often confined to urban centers. Rural and periurban communities — where disease burden is frequently highest — are left with minimal laboratory coverage. This structural deficit leads to delayed or missed diagnoses, reliance on empirical treatment, the spread of antimicrobial resistance, and preventable mortality (Pai et al., 2012). Point-of-care

(POC) diagnostics, defined as tests performed at or near the site of patient care, have long been recognized as essential to closing this gap (Mabey et al., 2004).

Over the past decade, a parallel technological shift has created new possibilities. Smartphone adoption in LMICs has grown rapidly, with smartphones representing 51% of mobile connections in Sub-Saharan Africa by 2024, with projections of continued expansion (GSMA, 2024). Global internet connectivity has followed a similar trajectory (International Telecommunication Union [ITU], 2024). Modern smartphones carry high-resolution cameras, multi-axis sensors, substantial processing power, and broadband connectivity — all within a single, mass-produced, increasingly affordable device. These capabilities have positioned the smartphone as a candidate platform for POC diagnostics, giving rise to the concept of the "pocket laboratory" (Hernández-Neuta et al., 2019).

Researchers have exploited these features in diverse ways: coupling smartphone cameras with optical attachments for microscopy, using onboard processors to run machine learning algorithms for image classification, interfacing phones with external biosensors for electrochemical or fluorescence detection, and transmitting diagnostic data in real time for remote expert review (Hunt et al., 2021). In parallel, the WHO Special Programme for Research and Training in Tropical Diseases (TDR) updated its benchmark for evaluating POC diagnostics from the original ASSURED criteria (Mabey et al., 2004; Peeling et al., 2006) to the REASSURED framework, which added Real-time connectivity and Ease of specimen collection as essential attributes (Land et al., 2019). This expanded framework captures many of the specific affordances that smartphones bring to diagnostic design: connectivity, user-friendly interfaces, and the capacity for automated result interpretation.

Yet the trajectory from laboratory demonstration to routine clinical use has proven far from linear. A recurring pattern in global digital health is the phenomenon widely referred to in the mHealth community as "pilotitis" (Huang et al., 2017) — the proliferation of small-scale pilot projects that fail to transition into sustained, large-scale programs. Smartphone-based diagnostics are no exception. While proof-of-concept studies have multiplied, examples of nationally integrated, sustainably financed smartphone diagnostic programs in LMICs remain rare. The reasons for this disconnect are not primarily technological. They involve regulatory ambiguity, workforce constraints, infrastructure limitations, socio-cultural barriers, and fragmented financing — factors that operate at the intersection of technology and social systems (Greenhalgh et al., 2017).

Most existing reviews of smartphone-based diagnostics adopt a predominantly technical lens, cataloguing sensors, assays, and analytical performance metrics. Fewer examine the socio-technical conditions under which these technologies succeed or fail in practice. This gap matters because the determinants of real-world impact lie not only in the sensitivity and specificity of a device, but equally in the training of the health worker who operates it, the electricity supply that charges it, the regulatory pathway that authorises it, and the trust of the patient who accepts its result. Sittig and Singh (2010) proposed a socio-technical model for studying health information technology in complex adaptive systems, emphasizing the interdependence of technical, human, organizational, and environmental dimensions. This perspective is well suited to the challenge at hand.

The present review adopts such a socio-technical lens. Its aim is to synthesize and critically appraise the literature on smartphone-based POC diagnostics for infectious diseases in LMICs, with particular attention to the mechanisms and challenges of real-world implementation. The review addresses four research questions:

RQ1: What smartphone-based POC diagnostic technologies for infectious diseases have been implemented or piloted in LMICs?

RQ2: How does task shifting enable or constrain the deployment of these technologies by community health workers (CHWs)?

RQ3: What are the critical last-mile barriers limiting implementation and scale-up?

RQ4: What regulatory, ethical, and policy frameworks shape the implementation ecosystem?

By addressing these questions within an integrated socio-technical framework, this review seeks to move beyond the prevailing technology-centric perspective and contribute to a more nuanced understanding of what it takes for the pocket laboratory to deliver on its promise.

2. Methodology

2.1. Rationale for a Narrative Review

The questions guiding this review span several disciplines — biomedical engineering, public health, implementation science, health policy, and medical sociology. A systematic review with meta-analysis would require a narrowly defined intervention and a homogeneous outcome measure. Neither condition holds here. The technologies under consideration range from smartphone microscopy to CRISPR-based molecular assays. The outcomes of interest extend from analytical sensitivity to workforce acceptability, regulatory readiness, and cost-effectiveness. A narrative review is better suited to this breadth. It allows for the synthesis of heterogeneous evidence, the integration of qualitative and quantitative findings, and the identification of cross-cutting patterns that a rigid systematic protocol might obscure (Greenhalgh et al., 2017).

The objective is not to produce a pooled effect estimate but to map the current state of the field, identify recurring barriers and facilitators, and propose directions for future research and policy. The reporting of this review broadly follows the Scale for the Assessment of Narrative Review Articles (SANRA) (Baethge et al., 2019), which provides quality criteria for transparent narrative review reporting.

2.2. Search Strategy

The literature search was conducted across five databases: PubMed/MEDLINE, Scopus, Web of Science, Google Scholar, and the WHO Global Index Medicus. The latter was included specifically to capture publications from LMIC-based journals that are underrepresented in mainstream indexing services.

Search strings combined terms along three axes using Boolean operators. The first axis captured the technology: (smartphone OR mobile phone OR mHealth OR cell phone). The second captured the application: (point-of-care OR POC OR diagnostic* OR rapid test OR biosensor OR LAMP OR CRISPR). The third captured the setting: (LMIC OR low-income OR middle-income OR developing countr* OR Sub-Saharan Africa OR South-East Asia). These terms were adapted to the syntax requirements of each database.

The search was supplemented by manual screening of reference lists from key articles and by targeted retrieval of grey literature. Grey literature sources included technical reports and policy documents from the World Health Organization, the Foundation for Innovative New Diagnostics (FIND), UNITAID, PATH, UNAIDS, the GSMA, and the International Telecommunication Union. These sources were considered essential because much of the evidence on implementation, financing, and regulatory frameworks exists outside the peer-reviewed literature.

The review focused primarily on publications from 2015 onward, with foundational works from earlier periods retained where they established core concepts — such as the ASSURED criteria (Mabey et al., 2004; Peeling et al., 2006), the socio-technical model for health information technology (Sittig & Singh, 2010), and the WHO guidelines on task shifting (WHO, 2008). The search was restricted to English-language publications.

2.3. Inclusion and Exclusion Criteria

Studies were included if they met the following conditions: (a) the smartphone served as a platform or integral component of a POC diagnostic system, not merely as a data recording tool; (b) the diagnostic target was an infectious disease; (c) the study was situated in an LMIC context, as defined by the World Bank income classification; and (d) the publication type was an original research article, systematic or narrative review, pilot study, field evaluation, or policy analysis.

Studies were excluded if: (a) the diagnostic device was a dedicated, standalone instrument with no smartphone integration; (b) the primary focus was a non-communicable disease, unless the study addressed co-infections with an infectious pathology; (c) the work was limited to laboratory-based analytical validation without any field or clinical testing component; or (d) the publication was an editorial, letter, or commentary lacking empirical data.

No formal quality appraisal tool was applied, consistent with established practice for narrative reviews. However, preference was given to studies published in indexed, peer-reviewed journals and to reports issued by recognized international organizations.

2.4. Analytical Framework

The analysis was organised around two complementary frameworks. The first is the socio-technical systems (STS) model, as articulated by Sittig and Singh (2010) for health information technology. This model identifies eight interdependent dimensions: hardware and software, clinical content, human-computer interface, people, workflow and communication, organizational policies, external rules and regulations, and system measurement and monitoring. It provides a structured lens through which to examine why a technology that performs well on the laboratory bench may falter in the clinic or the community.

The second framework is the REASSURED criteria developed by WHO/TDR (Land et al., 2019), which serve as a standardized benchmark for evaluating the field-readiness of POC diagnostic tools. These criteria — Real-time connectivity, Ease of specimen collection, Affordable, Sensitive, Specific, User-friendly, Rapid and Robust, Equipment-free, and Deliverable to end-users — were used to assess the maturity and deployment readiness of the technologies identified in the review.

Findings were synthesized thematically, structured around the four research questions outlined in the Introduction. Emergent themes were identified through iterative reading and grouped into the categories that form the subsequent sections of this review: technological landscape, task shifting, last-mile barriers, and socio-technical integration.

3. Smartphone-Based POC Diagnostics: Technological Landscape

3.1. Taxonomy of Technological Approaches

The range of smartphone-based diagnostic technologies reported in the literature can be grouped into four broad categories: imaging-based, sensor-based, molecular, and data-driven approaches. These categories are not mutually exclusive — several platforms combine elements from more than one — but they reflect distinct design philosophies and technical requirements.

3.1.1. Imaging-based diagnostics

The most mature category exploits the smartphone camera as an optical detector. In its simplest form, a clip-on lens attachment converts the phone into a portable microscope capable of magnifying biological specimens — blood smears, sputum samples, stool preparations — to levels sufficient for parasite or pathogen identification (Hunt et al., 2021). More sophisticated implementations pair the optical hardware with machine learning algorithms, typically convolutional neural networks (CNNs), trained to classify images automatically. Yang et al. (2020) demonstrated deep learning models for detecting malaria parasites in thick blood smears via smartphone microscopy, reporting diagnostic accuracy approaching that of expert microscopists. Quinn et al. (2016) applied similar CNN architectures to both malaria and tuberculosis microscopy at the point of care. A systematic review by Aggarwal et al. (2021) confirmed that deep learning in medical imaging has reached clinically meaningful levels of diagnostic accuracy across multiple domains, though the authors cautioned that most validation has occurred in controlled rather than field settings.

The appeal of imaging-based approaches lies in their relative simplicity. The consumable cost is low — often limited to glass slides and staining reagents — and the smartphone itself requires no permanent modification. The principal limitation is optical: image quality depends on the phone model, ambient lighting, and the precision of the lens attachment, introducing variability that is difficult to standardize across heterogeneous device ecosystems.

3.1.2. Sensor-based diagnostics

A second category interfaces the smartphone with external biosensors. These may be optical — colorimetric, fluorescence-based, or surface plasmon resonance — or electrochemical, connected to the phone via Bluetooth, USB, or the audio jack. Baker et al. (2025) provided a comprehensive review of the smartphone as a molecular analysis platform, cataloguing the optical and electrochemical modalities that have been coupled with mobile devices. Xiao et al. (2022) surveyed the specific application of such sensors to virus detection, tracing the progression from laboratory-grade instruments to smartphone-compatible formats.

A particularly active subfield involves smartphone-based readers for lateral flow assays (LFAs). Rapid diagnostic tests for malaria, HIV, and COVID-19 rely on LFA strips that produce colored lines interpreted visually. Visual interpretation, however, is subjective. It suffers from inter-reader variability, especially under poor lighting conditions. Smartphone-based readers address this by capturing an image of the test strip and applying algorithmic interpretation, yielding semi-quantitative or binary results with reduced operator dependence. Laksanasopin et al. (2015) demonstrated an early and influential example: a smartphone dongle that performed multiplexed immunoassays for HIV and syphilis from a finger-prick blood sample in under fifteen minutes, validated in a field trial in Rwanda. More recently, Kanakasabapathy et al. (2017) developed a smartphone-compatible microfluidic chip for label-free CD4 cell counting using just 30 microlitres of whole blood, targeting HIV disease staging in resource-limited settings.

3.1.3. Molecular diagnostics

Molecular detection — the identification of pathogen nucleic acids — has traditionally required thermocycling equipment, stable electricity, and trained laboratory technicians. Isothermal amplification methods, which operate at a single temperature, have lowered these barriers substantially. Loop-mediated isothermal amplification (LAMP) is the most widely adapted for smartphone integration. García-Bernalt Diego et al. (2022) developed SMART-LAMP, a handheld, Bluetooth-controlled device that performs real-time colorimetric LAMP reactions with smartphone readout, validated against SARS-CoV-2, *Schistosoma*, and *Strongyloides* targets. Heithoff et al. (2022) evaluated a smartphone-based LAMP assay for SARS-CoV-2 and influenza in a community cohort, reporting concordance with RT-qPCR testing.

CRISPR-based diagnostics represent a newer frontier. Fozouni et al. (2021) achieved amplification-free detection of SARS-CoV-2 using CRISPR-Cas13a combined with mobile phone fluorescence microscopy, reaching clinically relevant sensitivity without a separate amplification step. De Puig et al. (2021) developed miSHERLOCK, a minimally instrumented CRISPR platform that processes unextracted saliva and delivers results via a smartphone-readable fluorescent output within one hour. Both platforms were designed with point-of-care deployment in mind, though field validation in LMIC settings remains limited.

The convergence of isothermal amplification, CRISPR-based detection, and microfluidic sample preparation with smartphone readout represents a technically compelling trajectory. Yet the consumable costs, cold-chain requirements for reagents, and the need for quality-controlled nucleic acid extraction continue to constrain field deployment. Lee et al. (2023) addressed some of these challenges with a sample-to-answer platform for COVID-19 that integrated sample preparation, deep learning-assisted analysis, and smartphone-based readout into a single workflow, but acknowledged that scalability outside controlled study conditions had not yet been demonstrated.

3.1.4. Data-driven diagnostics

A fourth, less hardware-dependent category uses the smartphone primarily as a computational and communication platform. Clinical decision support applications guide health workers through structured diagnostic algorithms, integrating symptom data, vital signs, and — where available — rapid test results to generate pre-screening or triage recommendations. These tools do not perform a diagnostic assay in the biochemical sense, but they extend the diagnostic reach of frontline workers by embedding clinical reasoning into the device interface. Their relevance to this review lies in their role as complements to the POC technologies described above, particularly in task-shifting models discussed in Section 4.

3.2. Applications by Disease Area

The technologies described above have been applied across the major infectious disease categories relevant to LMICs. Malaria has attracted the largest volume of smartphone diagnostic research, driven by the established role of microscopy and RDTs in malaria case management and by the availability of large labeled image datasets for CNN training (Yang et al., 2020). Tuberculosis microscopy — particularly automated reading of Ziehl-Neelsen-stained sputum smears — represents a second active area, though field validation has progressed more slowly than for malaria. HIV diagnostics have moved beyond CD4 counting (Kanakasabapathy et al., 2017; Laksanasopin et al., 2015) toward viral load estimation and early infant diagnosis, where connectivity-enabled result transmission is critical. COVID-19 accelerated development

across all categories, particularly smartphone-based LAMP and CRISPR assays (Fozouni et al., 2021; de Puig et al., 2021; Heithoff et al., 2022) and antigen test readers. NTDs have received less attention, though Ward et al. (2022) demonstrated AI-powered digital pathology for detecting soil-transmitted helminth and *Schistosoma mansoni* eggs in stool smears, offering a proof of concept for automated NTD diagnostics in endemic settings.

3.3. Technology Assessment Against REASSURED Criteria

When evaluated against the REASSURED framework (Land et al., 2019), the technologies reviewed here show uneven maturity. Real-time connectivity is a strong point: smartphones are inherently networked devices, and most platforms described above incorporate data transmission capabilities. Sensitivity and specificity are increasingly competitive with reference standards in controlled evaluations. User-friendliness varies — imaging-based approaches with automated interpretation score well, whereas molecular platforms requiring sample preparation remain operator-dependent. Affordability is mixed: smartphone-based LFA readers and microscopy attachments can be produced at low unit cost, but molecular assays carry significant consumable expenses. The criteria most consistently underperformed are Equipment-free and Deliverable. Nearly all platforms require some external hardware — lens attachments, biosensor cartridges, heating elements, or microfluidic chips — and few have established the supply chains, quality management systems, and regulatory approvals needed for routine delivery to last-mile health facilities (Kosack et al., 2017). This gap between analytical readiness and delivery readiness is a recurring theme throughout this review.

4. Task Shifting and the Role of Community Health Workers

4.1. The Concept of Task Shifting in Diagnostics

No diagnostic technology, however sophisticated, delivers health outcomes on its own. Someone must operate it, interpret the result, communicate it to the patient, and initiate the appropriate clinical response. In many LMICs, the health workforce available to perform these functions at the community level consists not of physicians or laboratory technicians but of community health workers (CHWs) — a cadre that varies widely in training, scope of practice, and institutional support across countries and programs.

Task shifting — the delegation of clinical tasks from higher-qualified to lower-qualified health workers — has been a deliberate strategy in LMICs for decades. The WHO formalised the concept in 2008, issuing global recommendations that endorsed the redistribution of specific tasks, including certain diagnostic functions, to non-specialist health workers as a pragmatic response to workforce shortages (WHO, 2008). The strategy gained traction first in HIV/AIDS service delivery, where the scale of the epidemic far exceeded the capacity of the existing clinical workforce, and was subsequently extended to maternal and child health, tuberculosis, and malaria programs (Mundeva et al., 2018). Cometto et al. (2018) synthesized the evidence base for CHW program optimization in an abridged WHO guideline, identifying supportive supervision, adequate remuneration, and integration into health systems as prerequisites for effective task shifting. Perry et al. (2021) characterized the current moment as the “dawn of a new era” for CHWs, noting both the expanding recognition of their contributions and the persistent structural challenges they face.

The emergence of smartphone-based diagnostics reframes the task-shifting question. If a device can automate the most cognitively demanding component of a diagnostic task — the interpretation of a microscopy image, the reading of a lateral flow strip, the classification of a clinical presentation — then the residual human task becomes primarily procedural: collecting a specimen, operating the device, and acting on the result. This redistribution of cognitive labor between algorithm and operator is what makes smartphone diagnostics a potentially powerful enabler of task shifting. But it also raises new questions about training, accountability, and quality assurance.

4.2. Models of Task Shifting in Smartphone-Based Diagnostics

The literature suggests three broad models through which CHWs engage with smartphone-based diagnostic technologies. These models differ in the degree of autonomy granted to the CHW and in the locus of clinical decision-making.

4.2.1. Model 1: CHW as device operator

In this model, the CHW collects the specimen — a blood smear, a stool sample, a nasal swab — and operates the smartphone-based device, but the interpretation of the result is fully automated. An AI algorithm classifies the image, reads the test strip, or analyzes the amplification curve. The CHW receives a binary or categorical output: positive or negative, species identified, treatment recommended. The CHW's role is procedural, and the cognitive burden of interpretation is delegated to the algorithm. Yang et al. (2020) demonstrated this model in the context of malaria microscopy, where deep learning classifiers matched expert microscopists in parasite detection from thick blood smears captured via smartphone. The advantage is scalability: if the algorithm is sufficiently accurate, a CHW with limited laboratory training can deliver diagnostic performance comparable to that of a skilled technician. The risk is overreliance on algorithmic output without the capacity to recognize edge cases, artefacts, or device malfunction.

4.2.2. Model 2: CHW as data collector and transmitter

Here, the CHW uses the smartphone to capture diagnostic data — images, sensor readings, clinical observations — and transmits them to a remote expert for interpretation. The smartphone functions as a data capture and communication hub rather than an autonomous diagnostic instrument. This model is exemplified by telepathology and telemicroscopy applications, where digitised slide images are reviewed by a pathologist or microscopist at a distant laboratory. The advantage is that clinical judgment remains with a qualified professional. The disadvantage is latency: the time between data capture and result delivery depends on connectivity, remote expert availability, and workflow integration. In settings with intermittent network access, this delay can undermine the point-of-care value proposition.

4.2.3. Model 3: CHW supported by algorithmic decision support

The third model embeds the diagnostic act within a broader clinical decision support system (CDSS). The smartphone guides the CHW through a structured protocol — assessing symptoms, recording vital signs, integrating rapid test results — and generates a management recommendation. The CHW retains a degree of clinical agency but is guided step-by-step by the algorithm. Sarrassat et al. (2021) evaluated an Integrated eDiagnosis Approach (IeDA) against standard Integrated Management of Childhood Illness (IMCI) protocols in Burkina Faso, finding that the electronic decision support tool improved adherence to clinical guidelines among primary health workers. Horwood et al. (2024) conducted a randomised controlled trial of electronic IMCI (eIMCI) in South African primary health care facilities, assessing whether a smartphone-based CDSS improved the management of sick children compared to paper-based protocols. This model is particularly relevant for contexts where diagnostic and treatment decisions are intertwined — as in febrile illness management, where the choice between antimalarial, antibiotic, and referral depends on a combination of test results and clinical findings.

Each model carries distinct implications for training requirements, error profiles, and governance structures. Model 1 demands the least clinical training but the highest trust in algorithmic reliability. Model 2 preserves expert oversight but sacrifices immediacy. Model 3 balances autonomy and guidance but depends on the quality of the underlying clinical algorithm. In practice, hybrid configurations are common, and the boundaries between models are not always sharp (Figure 1).

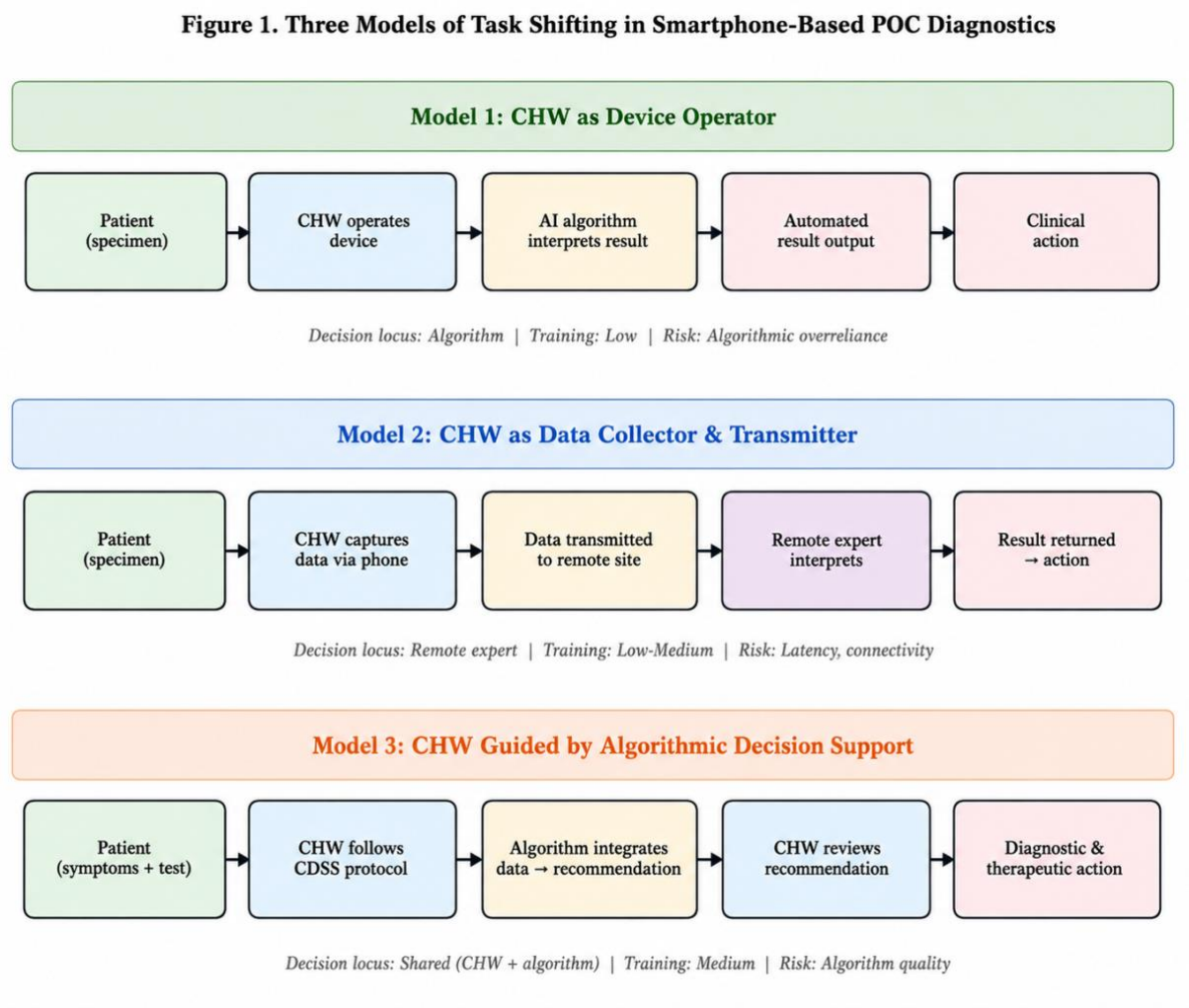

Fig. 1. *Three models of task shifting in smartphone-based POC diagnostics. Model 1 delegates interpretation entirely to the algorithm; Model 2 preserves remote expert oversight; Model 3 shares decision-making between CHW and clinical decision support system.*

4.3. Training and Competency Building

Regardless of the model adopted, task shifting to CHWs requires investment in training. The nature of that training, however, differs from traditional laboratory education. The technical skills involved — specimen collection, device operation, data entry, result communication — are procedural and can be taught in relatively short training cycles. The deeper challenge lies in digital literacy. Mahmood et al. (2020), in a systematic review of CHW-based mHealth approaches for childhood infection management, noted that the effectiveness of mobile health tools depended not only on the tool itself but on the CHW's comfort with the device and the quality of the training provided. Wang et al. (2025), in a systematic review and meta-analysis of health workers' adoption of digital health technology in LMICs, found that training quality, perceived usefulness, and organizational support were among the strongest predictors of sustained adoption.

A persistent concern is knowledge decay. Skills acquired in a one-time workshop erode if not reinforced through practice, supervision, and refresher training. The evidence base on optimal training modalities — classroom instruction versus e-learning versus peer mentoring — remains thin, and few studies have tracked competency retention beyond the initial post-training period. This is a gap that warrants dedicated investigation, particularly as the technologies themselves evolve rapidly and require periodic retraining.

4.4. Evidence of Effectiveness

The evidence that CHW-led diagnostic programs can improve health outcomes in LMICs is encouraging but incomplete. Björkman Nyqvist et al. (2019) conducted a randomised experiment in Uganda evaluating community health promoters equipped with diagnostic tools and basic treatments. The study found significant reductions in child mortality in intervention communities, demonstrating that task shifting of diagnostic and treatment functions to community-level workers can produce measurable population health gains. Ballard et al. (2020) argued that the COVID-19 pandemic underscored the essential role of CHWs in surveillance, case detection, and community engagement, and called for their systematic integration into pandemic preparedness frameworks.

However, much of the available evidence comes from controlled trial settings with dedicated project funding, external supervision, and purpose-built supply chains. Whether these results translate to routine health system conditions — where supervision is sporadic, supply chains are fragile, and CHW motivation fluctuates — remains an open question. The gap between efficacy in trial settings and effectiveness at scale is a recurring theme in global health, and smartphone-based diagnostics are not exempt from it.

4.5. Ethical and Organisational Challenges

Task shifting in diagnostics raises ethical questions that are often underexamined. Mundeva et al. (2018) explored the ethics of CHW involvement in HIV service delivery in LMICs, identifying tensions around informed consent, confidentiality, scope of practice, and the distribution of moral responsibility for diagnostic errors. When a CHW operates a smartphone-based diagnostic device and the result is incorrect — whether due to device malfunction, operator error, or algorithmic failure — the question of who bears liability is rarely resolved in existing regulatory frameworks.

Remuneration is another persistent issue. Many CHW programs in LMICs rely on volunteers or minimally compensated workers. Adding diagnostic responsibilities to an already demanding role, without commensurate pay or career progression, risks what some authors have described as “task dumping” — the transfer of duties without the transfer of resources or institutional support (Cometto et al., 2018). Perry et al. (2021) emphasized that the professionalisation and fair compensation of CHWs is not merely a workforce management issue but a matter of equity and justice.

Clinical supervision and quality assurance present further challenges. Smartphone-based platforms can, in principle, support remote supervision — a supervisor can review transmitted images, audit decision logs, and provide feedback electronically. But this requires functioning connectivity, dedicated supervisory time, and governance structures that many health systems in LMICs do not yet possess. Without adequate supervision, the risk is not only diagnostic error but also erosion of trust — both the trust of patients in the diagnostic process and the trust of the health system in the CHW cadre.

5. Last-Mile Challenges: Barriers to Implementation and Scale-Up

The preceding sections have shown that the technological building blocks for smartphone-based POC diagnostics exist and that task-shifting models can extend their reach to community-level health workers. Why, then, do so few of these technologies operate at scale? The answer lies in a cluster of interdependent barriers — infrastructural, regulatory, socio-cultural, economic, and technological — that collectively define the “last mile” between a working prototype and a functioning health intervention. This section examines each in turn (Figure 2).

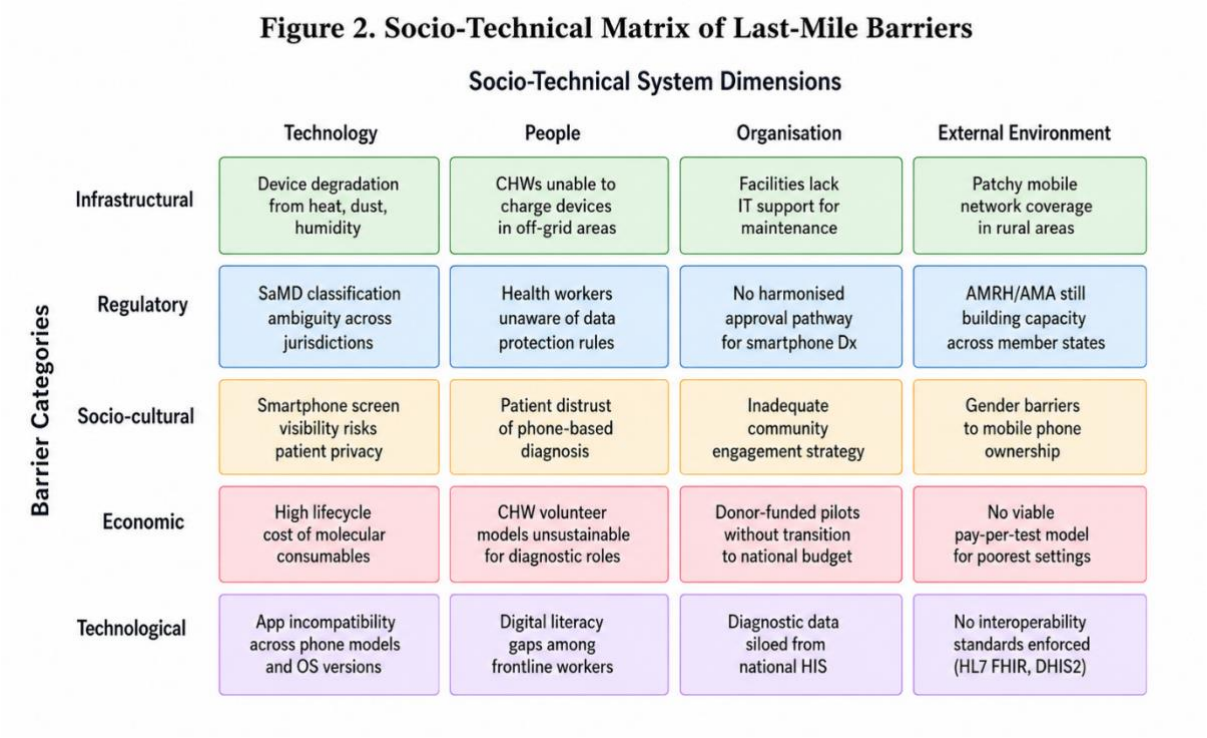

Fig. 2. *Socio-technical matrix of last-mile barriers. Rows represent five barrier categories; columns represent four dimensions of the socio-technical system (adapted from Sittig & Singh, 2010). Each cell illustrates a specific barrier identified in this review.*

5.1. Infrastructural Barriers

The most basic requirement for any smartphone-based diagnostic is a charged smartphone. This is not a trivial condition. Moner-Girona et al. (2021) identified over 55,000 rural healthcare facilities in Sub-Saharan Africa without access to electricity. While decentralized solar photovoltaic systems offer a technically viable and increasingly affordable solution, their deployment remains uneven. In practice, CHWs in off-grid settings often depend on personal arrangements — charging phones at market towns, using car batteries, or rationing device use to conserve power. A diagnostic platform that requires a fully charged smartphone and a stable internet connection assumes an infrastructure that does not yet exist in many of the communities where diagnostic need is greatest.

Connectivity presents a related challenge. Holst et al. (2020) described Sub-Saharan Africa as a "new breeding ground for global digital health" but acknowledged the stark disparities in network coverage between urban and rural areas. Mobile broadband access has expanded, yet coverage remains patchy in the remote regions where infectious disease burden is concentrated. Diagnostic platforms that depend on cloud-based processing or real-time data transmission to a remote server become unreliable or non-functional under these conditions. Offline-capable architectures — where the smartphone performs all computation locally and synchronises data when connectivity becomes available — are a partial solution, but they impose constraints on the complexity of the algorithms that can be deployed on-device.

Environmental conditions compound these difficulties. Smartphones and their associated consumables are designed for temperate, indoor use. Extreme heat, humidity, and dust — routine conditions in tropical field settings — accelerate device degradation and can compromise reagent stability. Lateral flow assay strips, enzyme-based reagents, and microfluidic cartridges may have narrow storage temperature ranges that are difficult to maintain without cold-chain infrastructure.

Finally, the supply chain for consumables represents a critical bottleneck. Kuupiel et al. (2019) conducted a systematic scoping review of supply chain barriers to POC testing in resource-limited settings and found recurring problems with procurement, inventory management, stockouts, and distribution logistics. A smartphone-based diagnostic device is useless without a steady supply of test strips, reagent cartridges, or

specimen collection materials. Supply chain failures, often invisible to technology developers working in well-resourced laboratories, are among the most common proximate causes of diagnostic program collapse in the field.

5.2. Regulatory and Policy Barriers

Regulatory frameworks for medical devices were not designed with smartphone-based diagnostics in mind. A traditional medical device is a discrete, purpose-built object. A smartphone-based diagnostic, by contrast, is a composite of consumer electronics hardware, third-party operating system software, a purpose-built diagnostic application, and — often — a disposable consumable component. Which of these elements constitutes the "medical device"? Is it the software alone? The software-hardware combination? The consumable cartridge? The answer varies across jurisdictions, and in many LMICs the question has not been formally addressed.

Carolan et al. (2022) analyzed the regulatory landscape for software as a medical device (SaMD), noting that even high-income countries with mature regulatory systems are still developing coherent frameworks for AI-driven and smartphone-based diagnostics. The challenge is amplified in LMICs, where national regulatory agencies may lack the technical capacity, staffing, or legal mandate to evaluate software-based diagnostic tools. Ndomondo-Sigonda et al. (2023) reviewed the African Medicines Regulatory Harmonization (AMRH) initiative, which seeks to streamline regulatory processes across the continent. While progress has been made, harmonization remains incomplete. Ncube et al. (2021) assessed regulatory readiness for the establishment of the African Medicines Agency and found significant variation in capacity across member states.

The result is a fragmented regulatory environment. A smartphone diagnostic validated and approved in one country may face entirely different requirements in a neighbouring jurisdiction. For developers — particularly small academic teams or non-profit organizations — navigating this patchwork is costly and time-consuming. For health ministries, the absence of clear regulatory pathways creates uncertainty about which products can be legally deployed, who bears liability for their use, and how post-market surveillance should be conducted.

Health data privacy adds a further layer of complexity. Diagnostic data transmitted via smartphone — test results, patient identifiers, GPS coordinates — are sensitive personal health information. Staunton et al. (2021) examined stakeholder perspectives on health data protection in South Africa and identified persistent tensions between the imperative to share data for public health purposes and the obligation to protect individual privacy. Many LMICs have enacted data protection legislation in recent years, but enforcement mechanisms remain weak and awareness among frontline health workers is limited.

5.3. Socio-Cultural Barriers

The acceptance of a diagnostic technology by patients and communities is not automatic. It is shaped by trust, prior experience, cultural norms, and the social dynamics of the clinical encounter. A patient accustomed to receiving a diagnosis from a white-coated laboratory technician in a clinic may view a CHW pointing a smartphone at a blood smear with skepticism. The material culture of diagnosis matters: the physical setting, the perceived authority of the operator, and the tangibility of the test all influence whether a result is trusted and acted upon.

Engel and Wolffs (2020) explored the alignment between diagnostics and point-of-care realities for TB and HIV, highlighting that the social context in which a test is performed profoundly affects its impact on clinical decision-making and patient behavior. A test result delivered in a community setting, by a peer health worker, using an unfamiliar device, carries different social meaning than the same result delivered in a hospital laboratory.

Stigma is a particular concern for diseases such as HIV. A smartphone screen displaying a test result is potentially visible to bystanders. A CHW conducting a test in a household may inadvertently disclose a diagnosis to family members. These privacy risks are not hypothetical — they shape whether individuals consent to testing in the first place. Technology design choices that seem minor from an engineering perspective — screen visibility, result encoding, data storage location — can have significant consequences for patient dignity and willingness to engage.

Gender barriers further complicate the picture. LeFevre et al. (2020) analyzed data from fifteen countries and found that women's mobile phone ownership was associated with improved health outcomes, but that ownership itself was unevenly distributed. In many LMIC contexts, women have less access to mobile technology than men, whether due to cost, cultural norms, or household power dynamics. A diagnostic strategy that depends on the patient's or the health worker's access to a smartphone may inadvertently widen gender-based health inequities if these access disparities are not explicitly addressed.

5.4. Economic Barriers and Sustainable Financing Models

Cost-effectiveness analyses of smartphone-based diagnostics typically focus on the unit cost of the device or the per-test cost of consumables. These figures can be favourable. A smartphone lens attachment may cost a few dollars. A lateral flow test strip is inexpensive. But unit cost is a misleading metric if it excludes the lifecycle costs of deployment: training, supervision, quality assurance, device maintenance and replacement, software updates, connectivity fees, supply chain logistics, and program management overhead. When these are included, the economics become considerably less straightforward.

Financing models for POC diagnostics in LMICs fall into several categories: donor-funded projects, government-integrated programs, pay-per-test schemes, and public-private partnerships. Each has limitations. Donor funding enables rapid piloting but rarely sustains programs beyond the funding cycle. Government integration requires political commitment and fiscal space that competing health priorities may not permit. Pay-per-test models shift costs to patients or facilities, raising equity concerns. The scalability paradox identified by Huang et al. (2017) — the observation that technologies proven cost-effective at pilot scale fail to attract sustainable financing at national scale — applies directly here. Bhatia et al. (2020) proposed regulatory sandboxes as a mechanism to bridge this gap, allowing innovative diagnostic tools to be deployed under controlled conditions while evidence on cost-effectiveness and safety accumulates. Whether such approaches gain traction in LMIC regulatory environments remains to be seen.

5.5. Technological Barriers and Interoperability

A final category of barriers is internal to the technology ecosystem itself. The global smartphone market is characterized by extreme fragmentation. Hundreds of device models, running multiple versions of two dominant operating systems, with varying camera specifications, processor speeds, and sensor configurations, are in active use across LMICs. A diagnostic application validated on one device-operating system combination may perform differently — or fail entirely — on another. This heterogeneity complicates development, testing, and quality assurance.

Interoperability with national health information systems is equally problematic. Diagnostic data generated at the point of care has limited value if it cannot be integrated into the patient's health record, aggregated for disease surveillance, or reported to national health authorities. Standards such as HL7 FHIR and platforms such as DHIS2 and OpenMRS offer technical solutions, but their adoption is inconsistent. Muinga et al. (2018) documented the challenges of implementing an open-source electronic health record system in Kenyan health care facilities, identifying infrastructure limitations, user resistance, and interoperability gaps as persistent obstacles. The diagnostic data generated by a smartphone-based POC device too often remains siloed in the application that produced it, disconnected from the broader information architecture of the health system.

Software maintenance represents an underappreciated challenge. Diagnostic applications require updates — to fix bugs, adapt to new operating system versions, retrain machine learning models, and respond to evolving pathogen characteristics. In high-resource settings, continuous software maintenance is routine. In LMICs, where IT support capacity at the facility level is minimal, an application that ceases to function after an operating system update may simply be abandoned. This fragility stands in contrast to the durability expected of conventional diagnostic tools, which typically operate without software dependencies.

6. Socio-Technical Integration Framework

6.1. Synthesizing the Socio-Technical Perspective

The preceding sections have deliberately separated the technological, workforce, and contextual dimensions of smartphone-based POC diagnostics for analytical clarity. In practice, these dimensions do not operate in isolation. A diagnostic device fails not because of a single deficiency but because of the interaction between multiple factors — an algorithm that performs well on one phone model but not another, deployed by a CHW who received training six months ago and has had no refresher, in a facility with intermittent electricity and no internet access, within a regulatory environment that has not yet classified the tool as a medical device. The failure is systemic, not singular.

The socio-technical systems model proposed by Sittig and Singh (2010) provides a vocabulary for describing these interactions. Its eight dimensions — hardware and software, clinical content, human-computer interface, people, workflow and communication, organizational policies, external rules and regulations, and system measurement and monitoring — map directly onto the challenges documented in this review. The REASSURED criteria (Land et al., 2019) address the technology-facing dimensions effectively, particularly sensitivity, specificity, affordability, and connectivity. But they say little about the human and organizational dimensions: Who will operate the device? Under whose supervision? With what training? Within what regulatory framework? Funded by whom? A comprehensive assessment of deployment readiness requires both lenses operating in tandem.

The COVID-19 pandemic offered an involuntary natural experiment in this regard. The urgency of the crisis compressed timelines that normally stretch over years. Regulatory agencies issued emergency use authorisations for diagnostic tools that would ordinarily require multi-year approval pathways. Donor funding surged. Smartphone-based LAMP assays and antigen test readers moved from laboratory prototypes to field deployment within months (Heithoff et al., 2022; Fozouni et al., 2021). CHWs were mobilized at unprecedented scale for community-based testing and surveillance (Ballard et al., 2020). In this sense, the pandemic demonstrated that rapid deployment is technically and organisationally possible when political will, funding, and regulatory flexibility align.

But the pandemic also exposed structural weaknesses. Supply chains for reagents and consumables buckled under global demand. Digital divides between connected and unconnected communities widened rather than narrowed. CHWs were deployed into new diagnostic roles with minimal preparation and often inadequate protection. The gains in diagnostic access proved uneven, and in many cases they receded as emergency funding waned. The lesson is that crisis-driven acceleration is not a substitute for the slower, harder work of building durable systems. Scale-up achieved under emergency conditions does not automatically translate into sustainable integration.

6.2. The Implementation Ecosystem: Actors and Interactions

Smartphone-based diagnostics exist within a complex ecosystem of actors whose interests, incentives, and capabilities do not always align. Technology developers — whether academic research groups, start-ups, or multinational corporations — optimize for analytical performance, novelty, and publication impact. Ministries of health prioritize coverage, cost containment, and alignment with national disease control strategies. International organizations such as WHO, FIND, and UNITAID operate at the interface, seeking to broker standards, fund evaluations, and shape market dynamics. CHWs and patients, the ultimate end-users, are rarely involved in design decisions and often encounter the technology as a fait accompli.

This misalignment produces what information systems researchers have termed the “design-reality gap” — the distance between the assumptions embedded in a technology and the conditions of its actual use. A diagnostic application designed in a well-equipped university laboratory in Europe or North America may assume stable internet connectivity, a recent-model smartphone, a literate operator, and a clinical workflow that bears little resemblance to the reality of a rural health post in Mozambique or Cambodia. Bridging this gap requires participatory design approaches that involve end-users from the earliest stages of development. The principles of co-design and responsible innovation offer methodological frameworks for this purpose, though their application in LMIC diagnostic development remains the exception rather than the norm.

6.3. From Pilot to Scale: Implementation Models

Implementation science offers structured frameworks for analyzing the transition from pilot to scale. The Consolidated Framework for Implementation Research (CFIR), recently updated by Damschroder et al. (2022), identifies five domains — intervention characteristics, outer setting, inner setting, individuals, and implementation process — that collectively determine whether an evidence-based intervention is adopted, sustained, or abandoned. The NASSS framework developed by Greenhalgh et al. (2017) addresses non-adoption, abandonment, and challenges to scale-up, spread, and sustainability of health technologies, providing a diagnostic tool for identifying where and why implementation stalls.

Applied to smartphone-based POC diagnostics, these frameworks highlight several recurring failure points. At the intervention level, technologies that require complex consumable supply chains or frequent software updates face higher implementation friction than those with simpler operational requirements. At the organizational level, facilities without dedicated IT support or supervisory structures struggle to maintain digital tools. At the outer setting level, the absence of harmonized regulatory pathways and sustainable financing mechanisms creates uncertainty that deters investment in scale-up.

Successful examples exist but remain instructive exceptions. Williams et al. (2022) reviewed the rollout of GeneXpert — a molecular TB diagnostic platform — across three high-burden African countries and found that despite substantial international investment, improvements in case notification were modest due to implementation barriers including inconsistent scale-up and health system constraints. While GeneXpert is not a smartphone-based tool, the implementation challenges it encountered — supply chain fragility, maintenance requirements, integration with referral systems, workforce training — are directly analogous to those facing smartphone diagnostics. The GeneXpert experience serves as a cautionary precedent: even a well-funded, technically proven diagnostic platform can underperform when the implementation ecosystem is not adequately prepared.

Huang et al. (2017) documented a contrasting trajectory in their analysis of digital health interventions that successfully transitioned to national scale in China and Uganda. The common factors they identified — government ownership, integration with existing health information systems, iterative adaptation to local contexts, and long-term financing commitments — constitute a roadmap that is conceptually clear but operationally demanding. Bhatia et al. (2020) proposed regulatory sandboxes as a mechanism to facilitate this transition, creating protected spaces where innovative tools can be tested under real-world conditions with relaxed regulatory requirements while evidence accumulates. Whether this model can be adapted to the diagnostic sector in LMICs is an open question with significant policy implications.

The overarching lesson from implementation science is that scale-up is not a linear extension of piloting. It requires deliberate attention to governance, financing, workforce development, supply chain design, and stakeholder alignment — dimensions that lie largely outside the expertise of the technologists who develop the devices. Interdisciplinary collaboration is not optional; it is a precondition for impact (Figure 3).

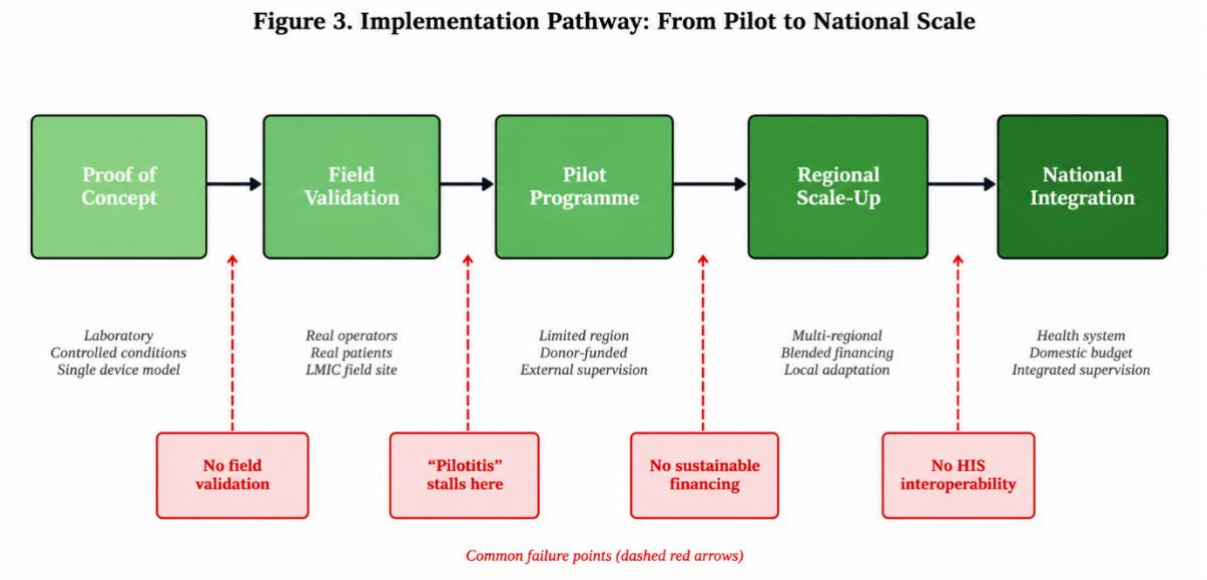

Fig. 3. *Implementation pathway from proof of concept to national scale. Green boxes represent stages; red dashed arrows indicate common failure points. Each stage is annotated with its characteristic setting, funding model, and supervision structure.*

7. Discussion

7.1. Synthesis of Key Findings

This review has traced the trajectory of smartphone-based POC diagnostics for infectious diseases in LMICs across four dimensions: technological development, workforce adaptation through task shifting, implementation barriers, and socio-technical integration. Several patterns emerge from this synthesis.

First, the technological landscape has matured considerably. Imaging-based diagnostics with AI-powered interpretation, isothermal amplification with smartphone readout, CRISPR-based detection platforms, and integrated biosensor systems have all demonstrated analytical performance sufficient for clinical application in controlled settings (Yang et al., 2020; Fozouni et al., 2021; García-Bernalt Diego et al., 2022; Baker et al., 2025). The breadth of disease targets — malaria, TB, HIV, COVID-19, NTDs — confirms that the pocket laboratory concept is not confined to a single pathology but represents a general-purpose diagnostic strategy.

Second, the evidence on task shifting indicates that CHWs can operate smartphone-based diagnostic tools effectively when provided with appropriate training, supervision, and algorithmic support (Björkman Nyqvist et al., 2019; Sarrassat et al., 2021; Horwood et al., 2024). The three models identified in this review — CHW as device operator, as data collector, and as algorithmically guided clinician — offer different trade-offs between autonomy, accuracy, and scalability. None is universally optimal; the choice depends on the disease context, the health system architecture, and the regulatory environment.

Third, and most critically, the barriers to implementation remain formidable and systemic. They are not isolated obstacles to be addressed one at a time but interconnected constraints that reinforce each other. A regulatory gap discourages investment, which limits supply chain development, which undermines device availability, which reduces the incentive for training, which erodes CHW competency, which diminishes clinical impact, which weakens the case for policy adoption. This vicious cycle explains why so many technologies stall at the pilot stage despite favourable analytical performance. Breaking it requires coordinated, multi-level intervention — not a better sensor.

Fourth, the COVID-19 pandemic demonstrated that rapid mobilisation is possible under crisis conditions but that crisis-driven deployment does not produce durable systems. The gains achieved during the pandemic in regulatory flexibility, CHW mobilisation, and technology adoption were real but fragile. Sustaining them requires institutional structures that outlast the emergency.

7.2. Implications for Health Policy

Several policy implications follow from this analysis. LMIC governments, supported by international technical agencies, need to develop coherent regulatory pathways for software-based and smartphone-based diagnostics. The current ambiguity — where a smartphone diagnostic exists in a regulatory grey zone between consumer electronics and medical device — serves no one. The AMRH initiative (Ndomondo-Sigonda et al., 2023; Ncube et al., 2021) provides a continental platform for harmonization, but progress must accelerate. Regulatory clarity is a prerequisite for private sector investment, donor confidence, and health system adoption alike.

The integration of validated smartphone-based diagnostics into the WHO Essential Diagnostics List (EDL) would send a strong signal. The EDL shapes procurement decisions, national formularies, and donor priorities. Including smartphone-based tools — where evidence supports their use — would legitimize the technology class and catalyse the development of the supply chains and quality assurance systems needed for routine deployment. Fleming et al. (2021) made a compelling case that diagnostics, broadly, remain underprioritised in global health architecture. Smartphone-based POC tools exemplify this neglect.

Financing models must move beyond project-based donor funding toward embedded health system budgets. This requires demonstrating cost-effectiveness not merely at the per-test level but at the system level — accounting for the downstream effects of earlier diagnosis on treatment costs, transmission reduction, and health worker productivity. The health economics evidence base for smartphone diagnostics remains thin and warrants dedicated investment.

7.3. Implications for Technology Design

For technology developers, this review underscores that analytical performance is necessary but not sufficient. Devices must be designed for the conditions of actual use: intermittent power, limited connectivity, high ambient temperatures, heterogeneous smartphone models, and operators with variable digital literacy. Offline capability, low consumable complexity, and intuitive interfaces are not optional refinements but core design requirements. Field validation — in the communities where the device is intended to be used, by the health workers who will operate it — must occur early in the development cycle, not as a final step before publication (Engel & Wolffs, 2020; Kosack et al., 2017).

Open-source software and open hardware models offer a promising path toward democratizing diagnostic innovation. They lower barriers to adaptation, enable local customisation, and reduce dependence on proprietary supply chains. Muinga et al. (2018) documented both the potential and the challenges of open-source health technology deployment in Kenya. The trade-off between openness and quality assurance — ensuring that locally adapted tools meet minimum performance standards — is real but manageable with appropriate governance structures.

7.4. Limitations of This Review

This review has several limitations that should be acknowledged. As a narrative review, it did not follow a registered systematic protocol and is therefore susceptible to selection bias. The choice of studies was guided by relevance and quality rather than by exhaustive retrieval, and it is possible that relevant work was missed. The restriction to English-language publications excludes a potentially significant body of evidence published in French, Portuguese, Spanish, and other languages prevalent in LMICs. The rapid pace of technological development means that some of the tools described here may already have been superseded or abandoned by the time of publication. Finally, the heterogeneity of LMIC contexts — encompassing vast differences in health system capacity, regulatory maturity, disease epidemiology, and cultural norms — limits the generalisability of any single set of conclusions. What works in a peri-urban Kenyan health center may not translate to a rural Cambodian village or a Brazilian favela. Context specificity is both a methodological limitation and a substantive finding of this review.

8. Future Directions and Research Agenda

8.1. Technological Frontiers

Several emerging technological trajectories are likely to reshape the field in the coming years. The integration of smartphone diagnostics with wearable sensors and Internet of Things (IoT) architectures could enable continuous or passive health monitoring — shifting the diagnostic paradigm from episodic testing to longitudinal surveillance. A wearable device that monitors physiological parameters and triggers a smartphone-based confirmatory test when an anomaly is detected would represent a qualitative advance over current models, which depend on the patient presenting to a health worker or testing site.

Advances in on-device machine learning — often termed edge AI — hold particular promise for connectivity-constrained settings. Federated learning approaches, in which algorithms are trained across distributed devices without centralising raw data, could address both the connectivity barrier and the data privacy concerns identified in this review (Staunton et al., 2021). If diagnostic algorithms can be updated and improved without requiring each device to upload patient data to a cloud server, the tension between analytical improvement and data protection would be substantially eased.

Next-generation biosensor technologies — aptamer-based recognition elements, nanoparticle-enhanced detection, organic electrochemical transistors — promise to extend the range of analytes detectable at the point of care while reducing consumable costs and cold-chain dependence. Baker et al. (2025) surveyed these developments and noted that while many remain at the proof-of-concept stage, the pace of translation from laboratory to portable format is accelerating. Whether these advances reach LMIC end-users will depend less on the sensors themselves than on the supply chain, regulatory, and financing conditions discussed in this review.

8.2. Social Science Research Priorities

The most pressing research gaps are not technological but social, organizational, and economic. Longitudinal implementation studies — tracking diagnostic programs over years rather than months — are needed to understand adoption trajectories, sustainability, and de-adoption patterns. Most published evaluations capture a snapshot at or shortly after deployment. The longer-term questions — Does the CHW continue to use the device after the research team departs? Does the supply chain hold? Does the algorithm maintain accuracy as disease epidemiology shifts? — remain largely unanswered.

Health equity-focused research deserves particular attention. LeFevre et al. (2020) demonstrated that mobile phone ownership is unevenly distributed along gender lines. Similar inequities likely exist along dimensions of age, socioeconomic status, geography, and disability. Understanding whether smartphone-based diagnostics narrow or widen these disparities requires disaggregated outcome data that few studies currently collect.

Ethnographic and qualitative research on the lived experiences of CHWs and patients interacting with diagnostic technology is scarce. Quantitative performance metrics — sensitivity, specificity, time-to-result — capture what the device does but not what the experience of using it means to the people involved. How does a CHW perceive the shift from clinical judgment to algorithmic recommendation? How does a patient interpret a diagnosis delivered on a phone screen? These questions demand methodologies that complement the dominant quantitative paradigm.

Finally, the health economics evidence base requires substantial strengthening. Cost-effectiveness analyses must move beyond per-test calculations to system-level modeling that incorporates downstream effects: reduced transmission from earlier diagnosis, averted hospitalisations, preserved economic productivity, and strengthened surveillance capacity. Without this evidence, the case for domestic budget allocation — as opposed to continued donor dependence — will remain difficult to make.

8.3. A Note on Interdisciplinarity

The research agenda outlined above cannot be pursued within any single discipline. Biomedical engineers can build the devices. Public health researchers can evaluate their clinical impact. Social scientists can investigate their human dimensions. Health economists can model their costs and benefits. Implementation scientists can identify the conditions for sustainable adoption. But meaningful progress requires these disciplines to work together, not in parallel. The fragmentation of the research landscape — where engineers publish in biosensor journals, clinicians in medical journals, and social scientists in health policy journals, with minimal cross-citation — is itself a barrier to the integrated understanding that this field requires.

9. Conclusions

Smartphone-based point-of-care diagnostics for infectious diseases represent one of the most widely discussed innovations in global health technology. The appeal is intuitive: a device already carried by billions of people, repurposed to detect the diseases that disproportionately affect the poorest populations on earth. The technological progress documented in this review is real. Smartphone microscopy with deep learning interpretation rivals expert performance for malaria and TB. CRISPR-based and LAMP-based molecular assays have reached clinically relevant sensitivity with minimal instrumentation. Integrated biosensor platforms can detect HIV, syphilis, and respiratory pathogens from a finger-prick sample in minutes. The pocket laboratory is no longer a metaphor. It exists.

But existence is not impact. The central finding of this review is that the gap between technological capability and population-level health benefit is not primarily a gap in engineering. It is a gap in implementation. The barriers documented here — fragile power and connectivity infrastructure, fragmented regulatory frameworks, consumable supply chain failures, socio-cultural resistance, unsustainable financing models, workforce limitations, and ecosystem interoperability deficits — are not incidental obstacles. They are structural features of the health systems in which these technologies must operate. Addressing them requires a fundamentally different orientation from the one that dominates the current literature, which remains largely preoccupied with analytical performance.

Task shifting to community health workers is the most plausible delivery mechanism for smartphone diagnostics at scale. The evidence reviewed here confirms that CHWs can operate these tools competently and that algorithmic decision support can compensate for gaps in formal training. Yet task shifting without institutional support — without fair remuneration, clinical supervision, legal clarity, and reliable supply chains — is not empowerment. It is exploitation. The professionalisation and adequate resourcing of the CHW cadre is a precondition, not a secondary consideration, for any scaled diagnostic program.

The transition from pilot to sustainable program demands coordinated action across multiple domains simultaneously. Regulatory harmonization must keep pace with technological innovation. Financing models must shift from project-based donor cycles to embedded domestic health budgets. Technology design must center the constraints of the end-user rather than the priorities of the developer. Implementation science frameworks such as CFIR and NASSS provide the conceptual tools for managing this complexity, but their application to smartphone-based diagnostics in LMICs remains limited.

None of this is easy. But the alternative — continued accumulation of proof-of-concept publications while diagnostic deserts persist — is untenable. The pocket laboratory has earned its place in the diagnostic toolkit. The task ahead is not to build a better device. It is to build the systems, institutions, and partnerships that allow the device to reach the people who need it most.

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