

Translating Biomedical Innovations into Health-System Adoption in Low-Resource Settings: Challenges, Determinants, and Sustainability

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ABSTRACT

Biomedical innovations can demonstrate strong technical performance without achieving sustained clinical or population health benefit in low-resource settings. This critical narrative review examined how innovations progress from discovery to health-system adoption, identified points where translational value may be lost, and developed an integrated interpretation of the determinants of sustained impact. PubMed/MEDLINE, Scopus, Web of Science, and Google Scholar were searched for English-language literature published from 2004 to September 2026. Evidence was synthesised across technical performance, clinical utility, contextual fit, health-system capability, regulation, procurement, implementation, sustainability, scale, and equity, with diagnostics as the principal empirical exemplar. Technical validity was necessary but insufficient for clinical value. Implementation depended on interacting influences involving workflow, workforce, infrastructure, financing, supply systems, policy, and organizational context. Regulation and procurement affected safe introduction and life-cycle viability, while adoption, sustainability, scale, and equity represented distinct outcomes. Three author-derived failure modes were developed by comparing recurring patterns across these evidence domains: innovation failure, translation/system failure, and contextual-fit failure. They are conceptual categories, not validated constructs. The review contributes an interface-focused model that links technological, clinical, organizational, and contextual requirements across the translational lifecycle. Longitudinal, multidisciplinary research is needed to determine how innovations achieve sustained and equitable health-system impact.

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INTRODUCTION

Biomedical innovation encompasses a wide array of advancements, including biomarkers, assays, molecular platforms, point-of-care technologies, medical devices, drug-delivery systems, and digital tools. These innovations are pivotal in enhancing disease prevention, diagnosis, and treatment, ultimately transforming healthcare delivery (Mahat, 2024; Recharla, 2025; Tupe, 2025; Soni *et al.*, 2026). Scientific discovery and technical performance, however, do not automatically produce clinical value or population-health benefit. Translational research is better understood as a continuum in which evidence generated at one stage informs application, evaluation, adaptation and refinement at later stages, rather than as a one-directional laboratory-to-clinic sequence (Khouri *et al.*, 2007).

Diagnostics provide a useful empirical exemplar because they expose the links and discontinuities between technical performance, clinical decision-making, service delivery, and health outcomes. The Lancet Commission on Diagnostics identified major gaps in diagnostic access related to primary-care capacity, workforce, financing, regulation, affordability, and appropriate technology; its 2025 update documented

progress but continuing constraints in access and system capacity (Fleming *et al.*, 2021; Horton *et al.*, 2025). Facility-level evidence further demonstrates the problem: across 8,512 facilities in ten LMICs, median availability of assessed diagnostics was 19.1% in basic primary-care facilities, 49.2% in advanced primary-care facilities, and 68.4% in hospitals (Yadav *et al.*, 2021).

Low-resource setting is used here as a functional rather than an income-based term. LMIC is a country-level economic classification, whereas low-resource conditions refer to constraints that may affect particular health systems, facilities, programmes, or communities, including limited infrastructure, workforce, financing, supply chains, regulation, maintenance capacity, geography, or access. The concepts overlap but are not synonymous: resource constraints vary within LMICs, and low-resource conditions can also occur in specific settings within higher-income systems (World Health Organization [WHO], 2010; Euliano *et al.*, 2022).

Implementation evidence similarly shows that translation is shaped by multiple interacting determinants. Leonard *et al.* (2020) synthesised 79 LMIC studies and identified influences

across context, innovation, relations and networks, institutions, knowledge, actors, and resources. Recent evidence in maternal and newborn point-of-care screening and diagnosis likewise identified workflow compatibility, portability, ease of use, perceived benefit, policy support, task-shifting, training, workforce, supply chains, and programme integration as relevant to implementation (Shaetonhodi *et al.*, 2026).

Several established frameworks illuminate parts of this pathway, but none was developed as a complete model of biomedical translation in resource-constrained environments. The translational continuum clarifies movement across stages but gives less operational detail on organisational determinants; WHO health-system frameworks identify system functions but do not specify a product-level translation mechanism; CFIR structures implementation determinants but requires contextualization across health systems; and implementation-outcome frameworks distinguish uptake and sustainability from clinical outcomes without themselves explaining the entire translational sequence (WHO, 2007, 2010; Proctor *et al.*, 2011; Damschroder *et al.*, 2009, 2022). Existing reviews have consequently tended to examine individual domains, such as diagnostic access, implementation determinants, transferability, procurement, regulation, or sustainability. The unresolved question is how these domains interact across the translational interfaces at which value may be attenuated. This review addresses that gap by integrating technological, clinical, system, contextual, economic, implementation, and equity evidence around those interfaces.

The review had three objectives: to examine the principal challenges affecting biomedical translation from discovery to sustained health-system adoption in low-resource settings; to identify interfaces at which translational value may be lost; and to develop a parsimonious conceptual interpretation of recurring failure patterns. The original contribution is not a replacement for established translational or implementation frameworks, but an interface-focused synthesis that connects their complementary insights and provides testable hypotheses for future empirical research.

MATERIALS AND METHODS

Conceptual and Analytical Orientation

Translation is conceptualized here as a feedback-dependent process through which biomedical innovation acquires and retains clinical and health-system value. The pathway extends from discovery and development through analytical validation, clinical evaluation and utility, regulation, procurement, implementation, adoption, sustainability, scale, equity, and health impact. Khoury *et al.* (2007) provides the conceptual starting point for a translational continuum, but its original focus on genomic medicine does not by itself specify how technology, organizations, financing, regulation, and contextual fit interact in routine health systems.

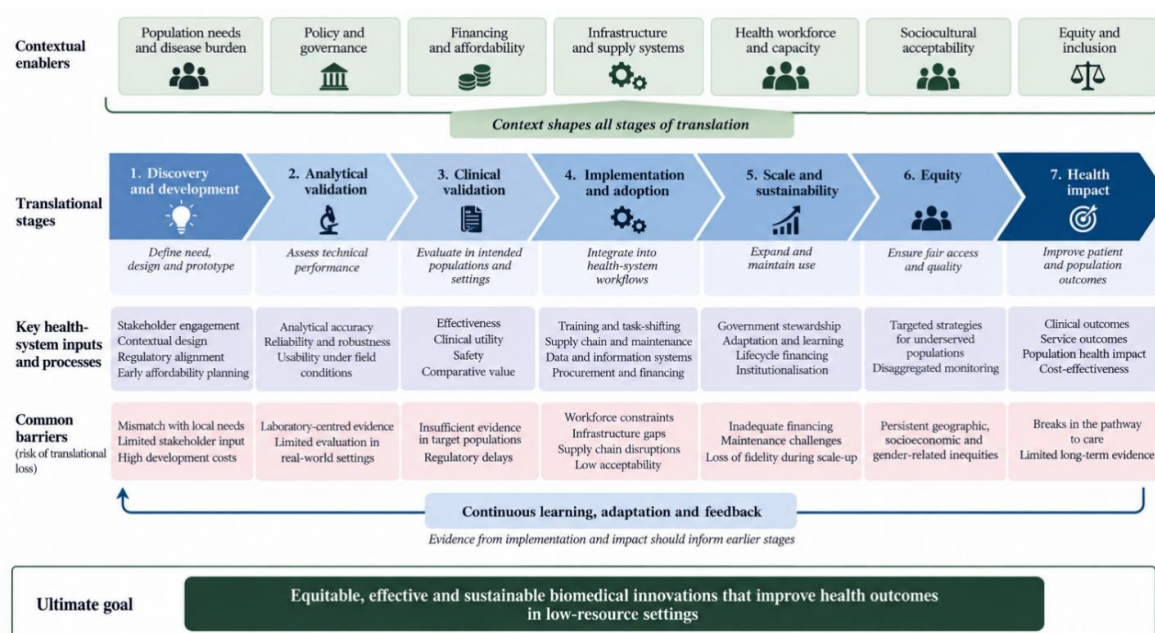
A health-system perspective is necessary because innovations enter established structures of service delivery, workforce, information, medical products and technologies, financing, and governance. WHO's framework emphasises these components as interconnected functions rather than isolated inputs (WHO, 2007, 2010). Implementation science adds a determinant-oriented lens. The original CFIR identifies domains and constructs that influence implementation, while the updated CFIR incorporates conceptual refinements and greater attention to recipients and equity (Damschroder *et al.*, 2009, 2022). Evidence examining implementation frameworks in LMICs also indicates that contextualization is necessary because health-system architecture and organizational conditions differ across settings (Means *et al.*, 2020).

Implementation outcomes provide an additional distinction between whether an innovation is accepted, adopted, feasible, delivered with fidelity, sustained, and penetrates routine services, and whether it subsequently improves clinical outcomes (Proctor *et al.*, 2011). No single framework is therefore treated as a complete theory of translation. The translational continuum identifies where value must be demonstrated; the health-system lens identifies system conditions; implementation frameworks help explain determinants; and implementation outcomes distinguish uptake and sustained use from downstream health outcomes. The complementary functions and boundaries of these perspectives are summarized in Table 1.

Table 1: Analytical Architecture of Biomedical Translation in Low-resource Settings

Analytical lens	Principal question	Contribution to this review	Boundary or interpretive caution
Translational continuum	How does biomedical knowledge move toward health benefit?	Defines stages across which value must be demonstrated.	Khoury <i>et al.</i> focused on genomic translation; the continuum is used here as a conceptual scaffold, not a complete operational model.
WHO health-system lens	What system conditions enable delivery?	Identifies service delivery, workforce, information, products and technologies, financing, and governance requirements.	Building blocks are interdependent and should not be interpreted as isolated barriers.
Implementation determinants / CFIR	What influences implementation in context?	Organizes innovation, organizational, contextual, and process determinants.	Requires contextualization when applied across diverse LMIC health systems.
Implementation outcomes	Has the innovation been accepted, adopted, delivered, sustained, and integrated?	Separates implementation outcomes from clinical and population outcomes.	Implementation success does not establish health impact.
Empirical implementation evidence	What occurs in actual services?	Tests whether theoretical determinants are observed in specific technologies and settings.	Findings vary by design, technology, population, and health-system context.

Note. The table is a synthesis of complementary analytical perspectives rather than a validated composite framework. The frameworks answer different questions and are therefore used together rather than merged into a new validated theory



Note: This figure presents a synthesized conceptual framework derived from the literature reviewed in Sections 1 and 2. It illustrates the iterative and context-dependent nature of biomedical translation, highlighting key health-system inputs, common barriers and the need for continuous learning across all stages.

Abbreviations:
LMICs = low- and middle-income countries
R&D = research and development

Figure 1: Conceptual Framework for the Translation of Biomedical Innovations in Low-resource Settings

Note. Synthesised conceptual framework derived from the reviewed literature. The pathway is iterative and context-dependent rather than a fixed linear sequence. The framework is conceptual and is not presented as a validated causal model

Methods

This critical narrative review synthesized evidence from biomedical science, diagnostics, clinical evaluation, implementation science, health systems, regulation, procurement, financing, sustainability, and equity. PubMed/MEDLINE, Scopus, Web of Science, and Google Scholar were searched for English-language literature published from 2004 to September 2026. Searches were iterative, with a final update completed in September 2026. The original review was not prospectively registered and database export logs were not retained; exact calendar search dates and database-level retrieval counts could not therefore be reconstructed reliably and are not reported. This avoids presenting retrospectively reconstructed figures as contemporaneous records.

The core Boolean formulation used to guide the searches was: ("biomedical innovation*" OR "medical innovation*" OR "diagnost*" OR "biomarker*" OR "assay*" OR "medical device*" OR "point-of-care" OR "molecular diagnos*") AND ("translat* research" OR "clinical translation" OR "implementation" OR "adoption" OR "sustainab*" OR "scale-up" OR "health system*") AND ("low-resource setting*" OR "LMIC*" OR "resource-constrained*" OR "low-income countr*" OR "middle-income countr*"). Additional searches paired these blocks with regulation, procurement, financing, workforce, infrastructure, clinical utility, and equity terms. Field operators and controlled vocabulary were adapted to each database where available. Citation tracking from key reviews, empirical studies, and authoritative guidance supplemented database searches.

Evidence was included when it addressed at least one translational stage or determinant relevant to biomedical innovation in a low-resource context and provided sufficient information for clinical, service, organizational, implementation, or health-system interpretation. Eligible evidence included peer-reviewed original studies, reviews,

methodological papers, and relevant WHO guidance. Studies focused solely on technical validation without clinical, implementation, or system-level relevance, sources unrelated to health innovation, and publications with insufficient information for interpretation were excluded. Higher-resource evidence was retained selectively where it provided transferable conceptual or methodological insight; transferability was not assumed.

Evidence appraisal was collaborative rather than a formal independent duplicate risk-of-bias exercise. The authors considered study design, methodological credibility, directness to the review question, outcome scope, consistency with other evidence, contextual relevance, and inference strength. No composite quality score or inter-rater statistic was applied across heterogeneous evidence types. SANRA was used as a quality-assurance checklist for the review itself, particularly the justification of the review, search description, scientific reasoning, referencing, and presentation; it was not used as a study-level risk-of-bias instrument (Baethge *et al.*, 2019). Guidance on narrative review writing also informed the methodological presentation (Green *et al.*, 2006).

For synthesis, evidence was coded first by translational stage and then grouped into recurring determinants and outcome transitions. Themes were compared across diagnostics and broader biomedical technologies. The principal domains were technical and clinical performance; health-system readiness; contextual fit and implementation capacity; regulation and economics; and adoption, sustainability, scale, equity, and health impact. The framework mapped recurring determinants to points where value could be attenuated. The three failure modes were developed separately by comparing recurring patterns across these evidence domains and grouping them according to the apparent location of translational loss. They are author-derived analytical categories, not validated constructs.

Critical Narrative Synthesis

Technical Performance and Clinical Utility

Technical performance establishes whether an innovation can perform its intended function, but it does not establish whether that function is clinically useful under real-world conditions. Translation therefore requires progression from analytical performance to clinical validity and, where relevant, clinical utility. For technologies intended for low-resource settings, additional requirements include affordability, accessibility, infrastructure compatibility, operator skills, and performance under intended-use conditions (Euliano *et al.*, 2022).

Diagnostics make this distinction particularly clear. A test may demonstrate strong analytical characteristics yet contribute little to care if results are unavailable at the point of decision, are incorrectly interpreted, arrive too late, or do not change management. WHO's 2026 generic target product profile for IVDs in LMICs specifies operational, performance, quality, regulatory, and pricing characteristics across diagnostic categories. This is product-development guidance rather than empirical evidence of effectiveness, but it illustrates a policy shift toward incorporating resource-context requirements before deployment (WHO, 2026b). The relevant translational question is therefore not simply whether an innovation works technically, but whether it provides actionable clinical value under intended-use conditions.

Health-System Readiness

Biomedical innovations enter systems with established workflows, professional roles, infrastructure, procurement arrangements, information systems, and governance. WHO identifies service delivery, health workforce, information systems, medical products and technologies, financing, and leadership and governance as core health-system components (WHO, 2007, 2010).

LMIC implementation evidence shows that determinants span several interacting domains rather than reducing to a single resource deficit. Leonard *et al.* (2020) identified context, innovation, institutions, actors, relationships, knowledge, and resources across 79 studies. Diagnostic availability data provide a related system-level signal: access differs by facility tier and diagnostic modality (Yadav *et al.*, 2021).

A concrete implementation example is the introduction of Xpert MTB/XDR in three African low- and middle-income settings. Healthcare workers considered implementation feasible and acceptable, but unstable power, internet connectivity, temperature control, training requirements, and discordant results with Xpert MTB/RIF Ultra were reported as practical implementation considerations (Keller *et al.*, 2025). The study illustrates that even when a molecular diagnostic offers a technically plausible route to faster drug-resistance information, the surrounding service environment can shape whether it functions as intended.

Recent evidence on maternal and newborn point-of-care screening and diagnosis likewise identified interacting individual, facility, and health-system influences, including rapid turnaround, portability, ease of use, perceived clinical benefit, workflow compatibility, policy support, training, workforce, supply chains, and programme integration (Shaetonhodi *et al.*, 2026). Because that review focused specifically on maternal and newborn diagnostics, its findings should not be generalised uncritically to all point-of-care technologies. The translational unit is often therefore the technology-plus-service pathway, not the technology alone.

Contextual Fit and Workflow

Implementation is performed by people within organisations, so innovation characteristics alone cannot explain uptake. Diffusion research demonstrates that adoption and assimilation depend on interactions among the innovation, users, organisational context, communication, and implementation processes (Greenhalgh *et al.*, 2004).

In low-resource settings, contextual fit includes compatibility with available skills, infrastructure, environmental conditions, supply chains, maintenance arrangements, clinical workflows, and patient pathways. Evidence on transferability shows that effects may vary between settings because outcomes depend on interactions among the intervention, population, and environment (Schloemer & Schröder-Bäck, 2018).

Adaptation should therefore be deliberate. Uncontrolled modification may compromise essential functions, whereas preserving core functions while adapting context-sensitive features may improve fit. The updated Medical Research Council framework similarly treats intervention development, implementation, and evaluation as interacting processes rather than isolated stages (Skivington *et al.*, 2021).

Regulation and Procurement

Regulation and procurement influence which innovations enter health systems and whether they can be introduced and used safely. A scoping review of medical-device regulation in African countries identified limitations involving pre-market testing, reliance on international certification, post-market surveillance, funding, personnel, and technical expertise, while noting limitations in the evidence describing regulatory implementation (Nasir *et al.*, 2023).

Procurement creates a parallel translational interface. A systematic review of literature on medical-device and equipment procurement in LMICs identified cost, health needs, and technical suitability among prominent considerations, while incomplete costing, inadequate maintenance planning, and insufficient attention to training could contribute to suboptimal use (Diaconu *et al.*, 2017).

The economic question is therefore broader than acquisition: can the health system afford to operate, maintain, supply, regulate, and eventually replace the technology? Life-cycle cost, consumables, maintenance, training, quality assurance, and infrastructure should be considered during development and procurement rather than after deployment. WHO's product-profile approach similarly treats operational and end-user requirements as relevant to health-product development (WHO, 2026b).

Adoption, Sustainability, Scale, and Equity

Implementation success cannot be inferred from adoption alone. Proctor *et al.* (2011) distinguish implementation outcomes such as adoption, feasibility, fidelity, penetration, and sustainability from clinical outcomes. Evidence from Africa illustrates the challenge of sustained implementation. Nwaozuru *et al.* (2025) synthesized 34 publications representing 22 interventions across 12 African countries. Facilitators included stakeholder engagement, intervention fit, adaptation, capacity building, funding, and infrastructural support, whereas salient barriers included structural financial constraints. The review noted that many sustainability facilitators were micro-level, whereas important barriers were structural.

Scale creates another translational test. Increasing the number of facilities using an innovation does not guarantee preservation of quality, contextual fit, or equity. WHO's 2026

scaling guidance is policy guidance rather than empirical implementation evidence; it positions governments as stewards of scaling and uses exploring, adapting, and learning as interconnected processes for moving from promising pilots toward system-wide adoption (WHO, 2026a).

Equity must be assessed separately from aggregate coverage. An intervention can achieve substantial adoption while systematically excluding geographically remote, poorer, or otherwise underserved populations. Scale should therefore be judged not only by the number of facilities or users reached but also by whether essential functions, quality, affordability, and access are maintained across population groups.

Translational Value is Lost at Interfaces

Across the evidence, translational loss frequently occurs between stages rather than within a single stage. Five interfaces are particularly consequential: innovation to clinical use, where technical performance may not establish utility; technology to health system, where functional technology may lack workforce, infrastructure, or supply support; technology to workflow, where poor integration may constrain adoption; procurement to sustainability, where

acquisition does not establish life-cycle viability; and scale to equity and health impact, where broader coverage may not preserve quality or distribute benefits fairly.

For diagnostics, the downstream pathway can be represented as test performance, result generation, interpretation, clinical decision, treatment or referral, continuity of care, patient outcome, and population health impact. This pathway is a review-derived analytical representation rather than a validated causal model. Its purpose is to identify points at which potential benefit can be attenuated. An accurate test that does not generate an actionable decision has limited clinical value; an appropriate decision without available treatment cannot reliably improve outcomes; and improved facility-level care may not produce population benefit if access remains inequitable.

The resulting proposition is that biomedical translation in low-resource settings is a coupled process of technological validation and health-system adaptation in which value must be demonstrated repeatedly as an innovation moves across translational interfaces. This diagnostic-specific transition chain is shown in Figure 2; the broader evidence synthesis is summarized in Table 2.

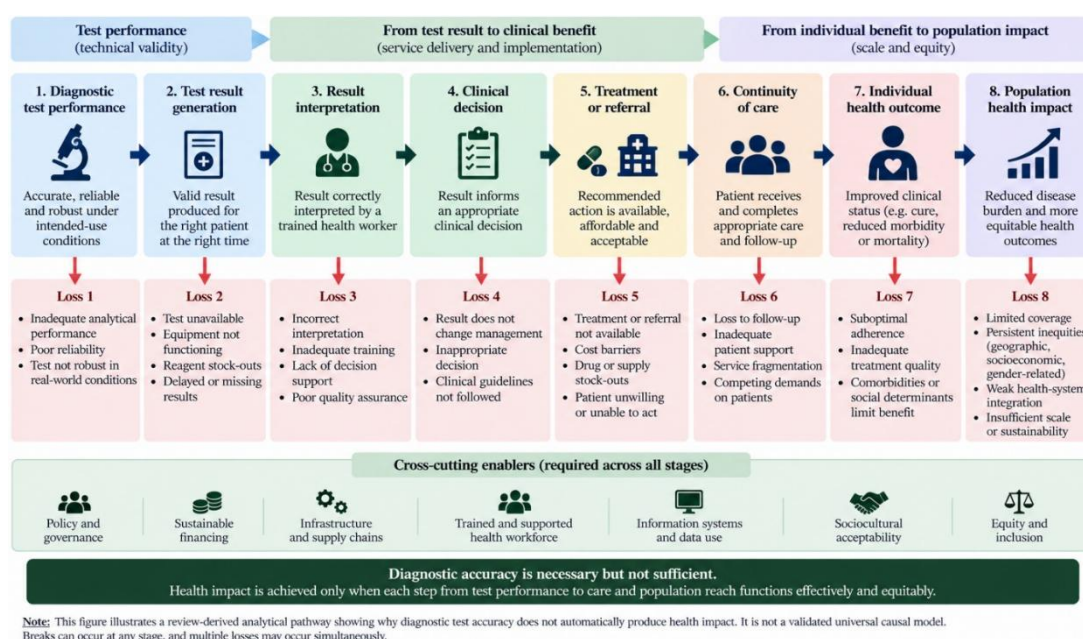


Figure 2: Why Diagnostic Accuracy does not Automatically Produce Health Impact

Note: Review-derived analytical pathway showing potential points at which diagnostic benefit can be attenuated between test performance and health outcomes. It does not constitute a validated causal model.

Table 2: Evidence-dense Synthesis of Barriers and Facilitators across the Translational Lifecycle

Translational stage	Key determinant	Barrier / facilitator	Evidence type	Main implication	Primary outcome
Discovery / development	Intended-use conditions	Infrastructure-intensive designs may reduce feasibility.	Review / guidance (Euliano, 2022; WHO, 2026b)	Design should anticipate resource and operator constraints.	Feasibility
Analytical validation	Reliability and usability	Performance may change under routine conditions.	Review (Euliano, 2022)	Validate under intended-use conditions.	Technical validity
Clinical evaluation / utility	Actionability	Results may not alter management.	Diagnostic commission / update (Fleming,	Evaluate decision and patient pathways.	Clinical utility

Translational stage	Key determinant	Barrier / facilitator	Evidence type	Main implication	Primary outcome
Service delivery	Workflow compatibility	Poor integration can disrupt care processes.	2021; Horton, 2025) Implementation review / primary study (Greenhalgh, 2004; Keller, 2025)	Design and test the technology within actual workflows.	Adoption
Implementation	Context and resources	Workforce, financing, infrastructure, supply constraints.	Systematic review (Leonard, 2020)	Assess determinants prospectively.	Implementation
Workforce	Skills and training	Competency gaps undermine safe and consistent use.	Diagnostic commission / POC review (Fleming, 2021; Shaetonhodi, 2026)	Plan training and supervision across the life cycle.	Fidelity
Regulation	Governance and oversight	Limited capacity may weaken oversight and surveillance.	Scoping review (Nasir, 2023)	Strengthen regulatory pathways and post-market surveillance.	Safety / access
Procurement	Total cost of ownership	Purchase price may obscure recurrent costs.	Systematic review (Diaconu, 2017)	Apply life-cycle costing and maintenance planning.	Sustainability
Sustainability	Financing and institutionalisation	Short-term project dependence can undermine continuity.	Systematic review (Nwaozuru, 2025)	Plan recurrent financing and institutional ownership.	Sustainability
Scale-up	Adaptation and learning	Expansion may expose new system constraints.	WHO policy guidance (WHO, 2026a)	Scale through iterative adaptation and monitoring.	Penetration
Equity	Distribution of access and benefit	Aggregate coverage may conceal exclusion.	Diagnostic commission / update (Fleming, 2021; Horton, 2025)	Measure distribution as well as average coverage.	Equity
Health impact	Continuity across the pathway	Failure downstream can attenuate population benefit.	Author synthesis informed by evidence base	Evaluate the complete pathway to health outcomes.	Health impact

Note. Evidence type distinguishes empirical or secondary literature from WHO policy/product-development guidance and author-derived synthesis. Shaetonhodi et al. (2026) specifically addresses maternal and newborn point-of-care screening and diagnosis. WHO (2026a, 2026b) are guidance documents, not empirical implementation studies.

Integrative Interpretation

The evidence indicates that translational failure is rarely explained by one deficit. Outcomes emerge from interactions among innovation value, system capability, and contextual fit. This interpretation extends established implementation science without replacing it: CFIR is designed to organise determinants, Proctor *et al.* distinguish implementation outcomes from clinical outcomes, and transferability frameworks emphasise interactions between intervention and context (Proctor *et al.*, 2011; Schloemer & Schröder-Bäck, 2018; Damschroder *et al.*, 2022).

Three author-derived analytical failure modes provide a parsimonious interpretation. Innovation failure occurs when the technology itself provides insufficient technical, clinical, or practical value. Evidence from low-resource technology translation supports early attention to accessibility, affordability, operator requirements, and intended-use

conditions (Euliano *et al.*, 2022). Translation/system failure occurs when the innovation is sufficiently credible but the health system cannot reliably deliver it; the GeneXpert MTB/XDR experience provides a concrete example of how power, connectivity, temperature control, training, and related workflow conditions can affect implementation (Keller *et al.*, 2025). Contextual-fit failure occurs when the innovation and system may each appear adequate but interact poorly with local clinical, organizational, or sociocultural conditions; transferability evidence supports the importance of comparing intervention, population, and environmental conditions before and after transfer (Schloemer & Schröder-Bäck, 2018).

These modes are not mutually exclusive. A technically weak innovation may also impose excessive system demands; a capable system may fail to adopt a poorly fitting technology; and contextual mismatch may make an effective innovation

appear ineffective in routine practice. They should therefore be used as diagnostic hypotheses about where value is being lost, not as labels for assigning blame or as a replacement for established implementation constructs.

The interpretation can be summarized as: innovation value $\times$ system capability $\times$ contextual fit $\rightarrow$ implementation performance $\rightarrow$ sustained clinical value. This is neither a validated mathematical relationship nor a causal equation. It is a conceptual device for emphasizing interdependence and for directing empirical research toward interactions that may otherwise be overlooked.

Translation should also be treated as a learning process rather than a one-time sequence of evidence gates. Implementation may reveal usability problems requiring redesign; procurement experience may alter product specifications; scale-up may expose financing or workforce constraints; and equity analysis may reveal populations for whom adaptation is necessary. WHO's 2026 scaling guidance explicitly organises scaling around exploring, adapting, and learning (WHO, 2026a).

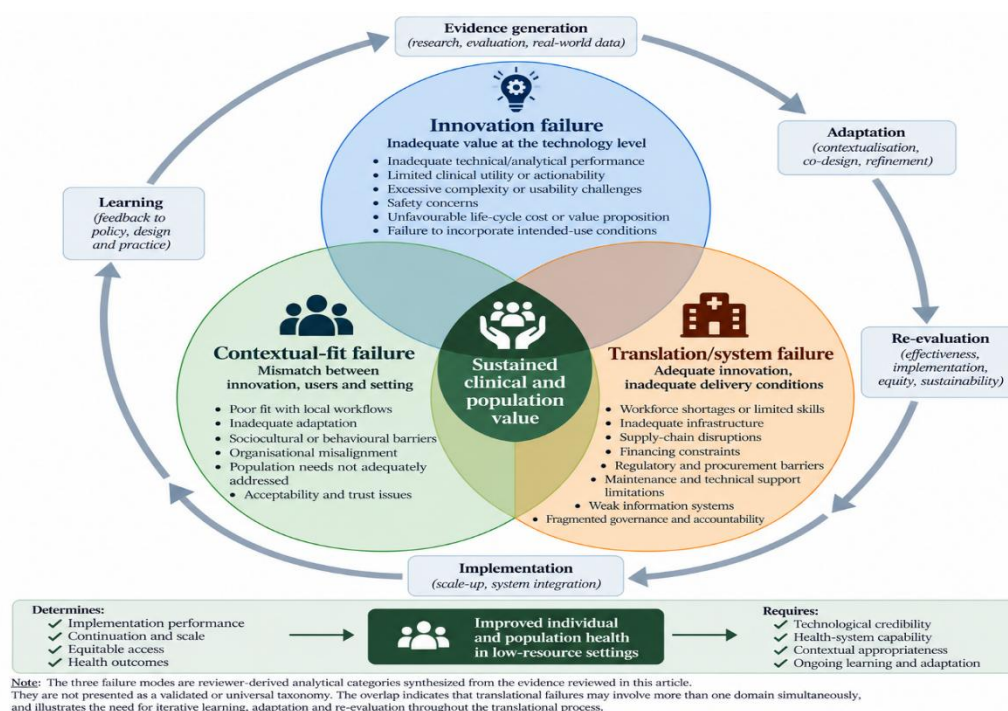


Figure 3: Three Interacting Translational Failure Modes in Low-resource Settings

Note: The three failure modes are author-derived analytical categories synthesised from recurring evidence patterns. They are not presented as a validated or universal taxonomy and may coexist or interact. Representative supporting evidence includes Euliano et al. (2022) for innovation considerations, Keller et al. (2025) and Leonard et al. (2020) for system-level implementation constraints, and Means et al. (2020) and Schloemer and Schröder-Bäck (2018) for contextual and transferability considerations.

Discussion

The literature converges on a central observation: biomedical translation in low-resource settings is constrained not simply by the existence of promising technologies but by discontinuities between technical performance, clinical use, health-system capacity, and sustained delivery. Evidence from low-resource technology translation, diagnostic access, LMIC implementation studies, and implementation of molecular diagnostics converges on this interpretation (Leonard et al., 2020; Yadav et al., 2021; Fleming et al., 2021; Euliano et al., 2022; Keller et al., 2025).

The principal contribution of this review is therefore analytical rather than taxonomic. Established frameworks remain necessary, but their functions differ: the translational continuum identifies stages; WHO health-system frameworks identify system capacities; CFIR organises determinants; implementation-outcome frameworks separate uptake from outcomes; and transferability and complex-intervention frameworks address contextual adaptation. The present synthesis connects these perspectives around the interfaces at which value can be attenuated. The three failure modes are intentionally broader and more operational: they locate

potential loss in the innovation, the delivery system, or the interaction between innovation and context. They should be viewed as testable hypotheses rather than validated constructs.

For researchers, the model argues for evaluation designs that follow an innovation beyond technical validation and explicitly measure clinical utility, implementation, sustainability, equity, and downstream outcomes. For technology developers, it supports incorporating intended-use conditions, affordability, maintainability, workflow, and user requirements before scale-up. For healthcare managers, it highlights the technology-plus-service pathway and the need to monitor training, supply, quality assurance, maintenance, and continuity. For policymakers, it places regulation, procurement, recurrent financing, and equity within the translational pathway rather than outside it. WHO's 2026 IVD target product profile provides policy-level support for moving operational requirements upstream into product development, while its scaling guidance emphasizes public-sector stewardship and iterative learning (WHO, 2026a, 2026b).

The evidence base also has an important limitation. Much of the literature reports technical performance, initial feasibility, adoption, or implementation determinants, whereas fewer studies follow innovations longitudinally from deployment through sustained clinical and population outcomes. This limits inference about which early determinants predict long-term value and how barriers change during scale-up. Diagnostic availability studies show access gaps, and sustainability reviews identify determinants of continuity, but neither alone establishes a causal pathway from a specific innovation to sustained population benefit (Yadav *et al.*, 2021; Nwaozuru *et al.*, 2025).

Scale should therefore be treated as an additional translational test rather than as the endpoint of implementation. A technology may be accepted and widely deployed yet lose

quality, affordability, or equity during expansion. Conversely, a modestly adopted innovation may generate meaningful benefit in the population reached. The relevant question is whether essential functions and equitable benefit are retained as implementation moves from demonstration to routine and larger-scale use.

Overall, the review supports a shift from stage-specific proof toward continuity of evidence across the translational lifecycle. Later-stage findings should be capable of revising earlier assumptions, creating an iterative cycle of evaluation, adaptation, re-evaluation, and learning rather than a one-directional sequence from discovery to deployment. The distinctions among downstream translational outcomes are summarized in Table 3.

Table 3: From Technical Performance to Health Impact: Translational Outcome Transitions

Level	Core question	Illustrative outcome	Potential translational loss	Evidence required
Technical performance	Does the technology perform as intended?	Accuracy, precision, reliability	Poor performance	Analytical validation
Clinical validity	Does performance identify the relevant clinical state?	Diagnostic discrimination / valid classification	Weak clinical relevance	Clinical evaluation
Clinical utility	Does the result improve a clinical decision?	Appropriate treatment or referral	Non-actionable result	Utility study
Implementation	Can the innovation be delivered in routine care?	Feasibility, fidelity	Workflow or resource failure	Implementation evaluation
Adoption	Do intended users and organisations take it up?	Uptake / routine use	Limited use or rejection	Adoption evaluation
Sustainability	Can use continue over time?	Continued delivery	Financing or maintenance failure	Longitudinal evaluation
Scale	Can coverage expand while preserving function?	Facility or population reach	Quality or functionality degradation	Scale-up evaluation
Equity	Who receives the benefits?	Distribution of access and outcomes	Exclusion of underserved groups	Disaggregated equity analysis
Health impact	Does the innovation improve health outcomes?	Morbidity, mortality, quality of life	Loss across downstream pathway	Impact evaluation

Note: This table presents a review-derived sequence of increasingly downstream translational questions rather than a universal linear pathway. Stages may overlap, recur, or generate evidence requiring reassessment of earlier assumptions.

Limitations

This critical narrative review synthesised heterogeneous evidence rather than conducting a systematic review or meta-analysis; it therefore cannot claim exhaustive identification, pooled effects, or freedom from selection bias. The review was restricted to English-language sources, the original database export logs were not retained, and exact retrieval and screening counts could not be reconstructed reliably; heterogeneity in technologies, settings, and outcome definitions also limits direct transferability. Longitudinal evidence linking biomedical innovations to sustained clinical and population-health outcomes remains comparatively limited, and the three failure modes are author-derived analytical categories requiring prospective empirical validation.

CONCLUSION

Biomedical translation in low-resource settings is best understood as continuity across technical performance, clinical utility, system capability, contextual fit, implementation, sustainability, scale, and equity rather than success at a single stage. The review's contribution is an interface-focused interpretation that complements established

frameworks by distinguishing three interacting, testable patterns of translational loss: innovation failure, translation/system failure, and contextual-fit failure. These categories are conceptual propositions, not validated constructs. Future research should prioritise longitudinal, multidisciplinary evaluation from development through scale-up, linking technical and clinical measures with life-cycle cost, implementation performance, equity, and sustained health outcomes.

Declarations

Ethics Approval and Consent to Participate

Not applicable. This critical narrative review used published literature and publicly available policy and guidance documents and did not involve primary human participants or identifiable human data.

Consent for Publication

All authors consent to publication of this article.

AVAILABILITY OF DATA AND MATERIALS

No primary dataset was generated or analysed for this critical narrative review.

COMPETING INTERESTS

The authors declare that they have no competing interests.

FUNDING

The authors received no funding for this work.

AUTHORS' CONTRIBUTIONS

OAo conceived and designed the review and developed the analytical framework. OAo, AAA, BTA, IEU, and ATO conducted the literature searches and collated the retrieved evidence. OAo, ATO, BTA, IEU, AAA, and OTK contributed to evidence examination, appraisal, synthesis, and interpretation. OAo and ATO drafted and critically revised the manuscript. All authors reviewed and approved the final manuscript and agreed to be accountable for all aspects of the work.

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