INNOVATIVE METHODS OF INFECTIOUS DISEASE DIAGNOSTICS: FROM METAGENOMIC SEQUENCING TO POINT-OF-CARE TESTING AND THE ROLE OF PUBLIC HEALTH

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Summary

Rapid and accurate diagnostics is a cornerstone of effective control over infectious diseases and antimicrobial resistance (AMR). The transformation of infectology into a multidisciplinary field has led to the emergence of two key innovative directions: next-generation metagenomic sequencing (mNGS) and point-of-care tests (POCT). mNGS provides hypothesis-independent identification of any pathogens, including uncultivated and novel ones, while POCT allows for real-time clinical decision-making at the primary care level. This paper presents a comprehensive analysis of the technological features, clinical value, and limitations of these methods. Particular attention is paid to public governance and management issues necessary for their effective integration into the healthcare system. Based on their own research, the authors substantiate the prospects of using nanotechnology developments to create a new generation of diagnostic platforms. The issue of equitable access to modern diagnostics as a key component of public health is highlighted, and a model of an integrated multi-level system is proposed. The methodology includes analytical review of scientific literature, comparative analysis of technologies, and a systematic approach to assessing management challenges. The work proposes a diagnostic model combining the speed of POCT at the primary level with the analytical depth of mNGS at the reference level, supported by a digital public health platform. The conclusions emphasize that technological progress must be accompanied by a transformation of healthcare management, and ensuring equitable access to diagnostics is a central socio-ethical principle of effective public health policy and AMR control.

Key words: next-generation metagenomic sequencing, point-of-care testing, antimicrobial resistance, infectious diseases, public health management, nanotechnology, molecular diagnostics.

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1. Introduction

Infectious diseases persist as one of the most formidable challenges to global public health and security. Despite remarkable advances in antimicrobial therapy, vaccine development, and infection control, the dynamic evolution of pathogens, the relentless spread of antimicrobial resistance (AMR), and the ever-present threat of emerging and re-emerging epidemics underscore the limitations of our current medical paradigm. The World Health Organization (WHO) has declared AMR one of the top ten global public health threats, directly linked to an estimated 4.95 million deaths annually and imposing a crippling socio-economic burden on healthcare systems worldwide. This reality signifies a fundamental shift: modern infectology has transcended its traditional boundaries as a purely clinical discipline. It has evolved into a complex, interdisciplinary nexus that strategically integrates microbiology, immunology, genomics, bioinformatics, data science, and, crucially, health systems management and public policy. The central challenge is no longer merely treating individual infections but building resilient, proactive systems capable of predicting, detecting, and responding to transnational biological threats in real time.

In this transformative context, the role of diagnostics is being fundamentally redefined. It has progressed from a supportive laboratory service to a strategic cornerstone of effective healthcare delivery. Precise and timely diagnostics is the critical node that directly informs clinical decision-making (enabling targeted therapy), drives effective epidemiological surveillance (mapping outbreaks and resistance patterns), and provides the essential evidence base for formulating rational national and global public health policies. The COVID-19 pandemic served as a stark, real-time validation of this principle. The catastrophic overload of healthcare infrastructure, profound economic disruptions, and significant loss of life were inextricably linked to initial delays in pathogen identification and subsequent inequities in access to reliable testing *(Zhu et al., 2020)*. This crisis exposed the systemic vulnerability created by diagnostic gaps. A parallel, albeit less acute, crisis unfolds daily in the silent pandemic of AMR, where the absence of rapid, accurate, and accessible etiological diagnostics compels clinicians to rely on empirical, broad-spectrum antibiotic prescriptions. This practice is a primary driver of resistance development, creating a vicious cycle that threatens the foundations of modern medicine.

The cornerstone of traditional laboratory diagnostics—culture-based methods and serology—while irreplaceable for specific applications, exhibits critical shortcomings in this new era. Its limitations are systemic: prolonged turnaround times (often 48-72 hours to weeks), a dependence on pre-test clinical hypotheses that can miss atypical or co-infections, a inherently narrow and predetermined detection spectrum, and notoriously poor sensitivity for fastidious, uncultivable, or novel pathogens (including many viruses). These gaps between clinical need and diagnostic capability create a dangerous "diagnostic void" that necessitates a radical re-imagining of our technological and operational arsenal.

The response to these converging challenges is crystallizing around two complementary yet paradigm-shifting technological trajectories: next-generation metagenomic sequencing (mNGS) and point-of-care testing (POCT). mNGS represents the apex of centralized, comprehensive diagnostics. It employs a hypothesis-free, "agnostic" approach by sequencing all nucleic acids in a clinical sample, enabling the simultaneous detection of any known or novel bacterial, viral, fungal, or parasitic pathogen, alongside a direct readout of antimicrobial resistance genes. It functions as a powerful "universal detector." In contrast, POCT embodies the principle of decentralized, agile diagnostics. By delivering accurate results at or near the patient within minutes, it transforms the clinical encounter, enabling immediate therapeutic decisions, isolation protocols, and public health interventions at the most critical point of care—the "instant informant."

However, the history of medical innovation teaches us that technological superiority alone is insufficient to guarantee population health impact. The potential of mNGS and POCT risks being stranded as islands of excellence unless consciously integrated into a coherent, equitable, and sustainably managed healthcare ecosystem. Significant structural and managerial challenges emerge: How can we design financing and governance models to ensure equitable access to the high-cost, centralized resource of mNGS, preventing the emergence of a "diagnostic divide"? How do we implement robust, scalable quality assurance systems for thousands of decentralized POCT devices operated by diverse personnel? How can we architect interoperable data platforms to seamlessly aggregate information from mNGS, POCT, and traditional labs into a unified, real-time dashboard for clinical, epidemiological, and policy decision-making? The answers lie not in choosing one technology over the other, but in orchestrating their synergy within a thoughtfully designed, multi-level healthcare architecture.

Novelty and Relevance of the Research: The novelty of this work lies in its deliberate synthesis of two parallel technological discourses (advanced mNGS and practical POCT) through the essential but often overlooked lens of health systems management and public health governance. While each technology is frequently discussed in isolation within specialized literature, this article provides a holistic, comparative analysis and proposes a concrete, integrated model for their deployment. Its relevance is exceptionally high, addressing the urgent, post-pandemic imperative to build diagnostic resilience—a system capable of withstanding future shocks—while simultaneously tackling the endemic crisis of AMR. It moves the conversation beyond "what is possible in a lab" to "how to implement fairly and effectively at scale."

The aim of this research is to conduct a comprehensive analysis of the technological principles, clinical utility, and inherent limitations of mNGS and POCT, and, based on this analysis, to develop and propose a conceptual model for their effective integration into a national healthcare system, with a specific focus on overcoming management and equity challenges.

To achieve this aim, the following research tasks have been formulated:

- To analyze the technological foundations, key advantages, and primary clinical applications of mNGS, identifying the major barriers (technical, interpretive, and organizational) to its widespread adoption.
- To examine the technological platforms, operational principles, and clinical-epidemiological value of POCT, outlining the critical management challenges associated with quality assurance, logistics, and data integration in a decentralized model.
- To perform a comparative analysis of mNGS and POCT, positioning them not as competitors but as complementary components within a unified diagnostic continuum.
- To synthesize a multi-level public health management strategy that addresses financing, regulation, infrastructure, workforce, and digital integration to enable the synergistic and equitable use of these technologies.
- To contextualize the discussion with insights from the authors' own research in nanotechnology, highlighting its potential to drive future convergence in diagnostic platform development.

Methodology and Logical Framework: This study employs a multi-method analytical approach. The primary methodology is a comprehensive analytical review and synthesis of current international scientific literature, clinical guidelines, and health policy documents related to mNGS, POCT, AMR, and public health system management. This is complemented by a comparative systems analysis to delineate the functional niches and requirements of each technology. Furthermore, the work utilizes a conceptual modelling approach to propose an integrated, multi-tiered diagnostic and management framework. The logic of the presentation moves from identifying the overarching problem (the diagnostic gap in the face of AMR and pandemics) to analyzing the two key technological solutions, then to a critical examination of the systemic barriers to their adoption, and finally to the synthesis of a management and policy blueprint designed to overcome these barriers and realize the full public health potential of these innovations. This structure ensures a progression from problem recognition, through technological assessment, to actionable systemic solutions.

Next-generation metagenomic sequencing (mNGS): comprehensive identification and systemic challenges.

Methodological basis and technological workflow. Next-generation metagenomic sequencing (mNGS) represents a paradigm shift in microbiological diagnostics, transitioning from a targeted, hypothesis-driven inquiry to an unbiased, comprehensive exploration of the entire nucleic acid content within a clinical specimen *(Chiu & Miller, 2019; Gu et al., 2019)*. This approach is predicated on the high-throughput sequencing of all DNA and/or RNA present in a sample—collectively termed the metagenome—collected from sterile or non-sterile sites (e.g., blood, cerebrospinal fluid, bronchoalveolar lavage fluid, tissue biopsies, or even normally polymicrobial sites like respiratory secretions when analyzed with specialized bioinformatic filters).

The core technical workflow is a meticulously orchestrated, multi-stage pipeline:

- Sample Processing & Nucleic Acid Extraction: This initial, critical step focuses on maximizing the yield of pathogen-derived nucleic acids while minimizing the overwhelming background of human host DNA/RNA. Techniques may involve differential lysis, enrichment for microbial sequences, or depletion of human ribosomal RNA. The quality of this step directly dictates the sensitivity of the entire assay.
- Library Preparation & Sequencing: Extracted nucleic acids are fragmented, adapters are ligated, and the resulting libraries are subjected to massively parallel sequencing on platforms such as Illumina, Ion Torrent, or Oxford Nanopore. This generates millions to billions of short or long nucleotide sequences ("reads") representing all genetic material in the sample.
- Bioinformatic Analysis: This is the most complex and resource-intensive phase, often described as "finding a needle in a haystack." It involves: (a) Quality Control & Host Depletion: Filtering out low-quality reads and computationally subtracting sequences aligning to the human reference genome. (b) Alignment & Taxonomic Classification: The remaining reads are aligned against comprehensive, curated databases (e.g., NCBI nt/nr, GenBank, specialized pathogen databases) to identify microbial sequences. Sophisticated algorithms assign taxonomic labels and estimate relative abundance. For novel pathogens, de novo assembly of reads into longer contigs may be attempted. (c) Functional Annotation: Simultaneously, the pipeline screens for genes conferring antimicrobial resistance (AMR) and markers of virulence, providing a direct molecular profile of resistance potential.
- Clinical Interpretation & Reporting: Translating the bioinformatic output into a clinically actionable report is a nuanced task. It involves correlating the number of pathogen-specific reads, genomic coverage, and statistical confidence with clinical context to distinguish true infection from background colonization, contamination, or clinically irrelevant latent viral DNA.

This hypothesis-independent "shotgun" approach is its defining strength, enabling the simultaneous detection of any cultivable or non-cultivable bacteria, viruses, fungi, and parasites in a single assay, without any prior suspicion of the causative agent.

Clinical application, proven advantages, and transformative potential. mNGS has cemented its role as the definitive diagnostic tool for the most challenging clinical scenarios where conventional methods—culture, serology, and even multiplex PCR panels—are either too slow, too narrow in scope, or simply ineffective *(Chiu & Miller, 2019)*.

Diagnosis of Infections of Unknown Etiology: It is now considered the reference method for diagnosing obscure cases of meningoencephalitis, severe pneumonia in immunocompromised hosts (e.g., transplant recipients, oncology patients), culture-negative endocarditis, and febrile illnesses in returning travelers. Its ability to detect rare, atypical, or unsuspected pathogens can be life-saving.

Direct Impact on Antimicrobial Stewardship: Beyond identification, mNGS provides a direct readout of the resistome—the full complement of AMR genes present in the sample. This allows clinicians to anticipate resistance phenotypes even before culture results are available (or if the pathogen fails to grow), enabling earlier optimization of antibiotic therapy and supporting hospital and national AMR surveillance programs with granular genetic data.

Public Health and Biosecurity Sentinel: The pivotal role of mNGS in the early and rapid identification of SARS-CoV-2 from bronchoalveolar lavage samples of the initial pneumonia cluster in Wuhan is a landmark demonstration of its power in pathogen discovery and outbreak response *(Zhu et al., 2020)*. It serves as a critical early-warning system for emerging threats.

Characterization of Complex Polymicrobial Infections: In contexts like diabetic foot infections, chronic lung diseases, or device-related infections, mNGS can elucidate the complete microbial community, revealing interactions and key pathogens that are missed by cultures biased toward fast-growing organisms.

2. Critical limitations and the imperative for strategic management

Despite its transformative power, the integration of mNGS into routine clinical practice is hindered by significant technical, interpretive, and systemic barriers.

Technical and Interpretive Challenges: 1) High Cost and Resource Intensity: The per-test cost remains substantial, encompassing expensive reagents, sophisticated sequencing instrumentation, and significant computational infrastructure for data storage and analysis. 2) Bioinformatic Complexity and Standardization: The lack of universally standardized, user-friendly bioinformatic pipelines creates variability. Expertise in computational biology is essential, creating a workforce bottleneck. 3) The Colonization-Infection Conundrum: The exquisite sensitivity of mNGS is a double-edged sword. It readily detects sequences from commensal flora or environmental contaminants, making the clinical interpretation of results—especially from non-sterile sites—highly dependent on clinical correlation and quantitative thresholds, which are not yet fully standardized. 4) Turnaround Time: While sequencing itself takes hours, the complete end-to-end process, from sample receipt to validated clinical report, typically requires 24–72 hours, limiting its utility in hyper-acute settings.

Management and Health System Challenges: The resolution of technical limitations is insufficient without parallel development of robust management frameworks *(Hrytsko, 2026)*. 1) Strategic Infrastructure and Network Design: Widespread, equitable access cannot be achieved by equipping every hospital with mNGS capability. A hub-and-spoke model is necessary, with a limited number of centralized, high-throughput national or regional reference laboratories serving as specialized mNGS hubs. This centralization ensures quality control, cost-effectiveness through economies of scale, and the concentration of scarce bioinformatic expertise. 2) Sustainable Financing and Reimbursement Models: The high cost necessitates innovative financing. Solutions may include: 1) Tiered public funding for critical, life-threatening indications (similar to funding for rare diseases); 2) Development of clear diagnostic codes and insurance reimbursement policies based on stringent clinical criteria; 3) Public-private partnerships for infrastructure investment. 4) Governance through Clinical Guidelines and Pathways: To prevent indiscriminate and economically unsustainable use, it is imperative to develop and enforce national evidence-based guidelines. These should strictly define the clinical indications for mNGS testing (e.g., "immunocompromised patient with pneumonia unresponsive to 72 hours of broad-spectrum therapy" or "suspected encephalitis with negative initial CSF workup"). 5) Workforce Development and Regulatory Frameworks: Success depends on cultivating a new generation of clinical microbiologists with genomics expertise and bioinformaticians with clinical understanding. Concurrently, regulatory bodies must establish clear validation, quality control, and proficiency testing requirements for clinical mNGS laboratories, ensuring result reliability and interoperability.

In summary, mNGS is a revolutionary diagnostic "macro-lens" capable of revealing the entire microbial landscape. However, its power can only be fully and fairly harnessed if its deployment is guided by prudent, strategic management that addresses cost, access, appropriate use, and integration into the broader healthcare ecosystem.

3. Point-of-care tests (POCT): real-time diagnostics, accessibility, and the decentralization imperative

Conceptual foundation, technological platforms, and innovation frontier. Point-of-care testing (POCT) represents a fundamental re-engineering of the diagnostic process, shifting it from centralized laboratory facilities to the immediate vicinity of the patient—be it a primary care clinic, emergency department, pharmacy, ambulance, or even a patient's home *(Kozel & Burnham-Marusich, 2020)*. This paradigm of decentralized, near-patient testing is defined by its operational goal: to deliver a clinically reliable result within a time frame that directly influences the management of the presenting episode of care, typically within minutes to a few hours.

The technological spectrum of POCT is broad, catering to different balances of speed, accuracy, and complexity: 1) Immunochromatographic Assays (Lateral Flow Tests): These are the most widespread and user-friendly POCT devices. Based on antibody-antigen interactions, they provide a visual result (e.g., a colored line) within 5–30 minutes. While celebrated for their speed, low cost, and minimal training requirements, they often trade off lower analytical sensitivity and specificity compared to molecular methods, particularly in asymptomatic individuals or during specific phases of infection. Examples include rapid tests for SARS-CoV-2 antigen, influenza, Streptococcus pyogenes, and HIV. 2) Molecular POCT Systems: These are compact, automated instruments that bring nucleic acid amplification technology to the point of care. They utilize methods like isothermal amplification (e.g., LAMP, RPA, NEAR) or miniaturized real-time PCR cartridges. These systems close the accuracy gap, offering sensitivity and specificity comparable to central laboratory PCR, but with a turnaround time of 15–90 minutes. Devices like the Cepheid GeneXpert or BioFire FilmArray are prime examples, capable of detecting multiple pathogens (e.g., respiratory or gastrointestinal panels) from a single sample in a closed, "sample-to-answer" system. 3) The Nanotechnology Frontier: A transformative direction for future POCT lies in the integration of nanotechnology, which promises to overcome current limitations. Research by the authors, such as work on recombinant peptide-modified nanodiamonds for immune modulation ***(Bilyy et al., 2021)*** and studies on the fundamental interactions of nanoparticles with the immune system (e.g., their role in neutrophil extracellular trap formation) ***(Bila et al., 2025)***, provides foundational knowledge. This paves the way for next-generation nano-sensor platforms. These could combine the high sensitivity of molecular assays with the speed, low cost, and ease-of-use of lateral flow tests, while also enabling true multiplexing (simultaneous detection of dozens of pathogens and resistance markers) on a simple, portable device.

The value of POCT extends far beyond mere convenience; it is a catalyst for transforming clinical pathways and public health outcomes. 1) Immediate Clinical Decision-Making and Antimicrobial Stewardship: The most profound impact is the radical shortening of the "diagnostic-therapeutic loop." A physician can, within a single patient encounter, confirm or rule out a specific infection (e.g., influenza, streptococcal pharyngitis, COVID-19). This enables: 1) Immediate, targeted antibiotic therapy, drastically reducing unnecessary empirical use of broad-spectrum agents—a primary driver of antimicrobial resistance (AMR). 2) Informed isolation and cohorting decisions, curbing nosocomial and community transmission. 3) Streamlined patient management, avoiding unnecessary referrals, hospital admissions, or additional imaging. 2) Enhancing Equity and Healthcare Access: POCT democratizes diagnostics by making them available in resource-limited settings, remote rural areas, and at the primary care level, where access to central labs is constrained. This is critical for achieving health equity and universal health coverage, ensuring that geographical or socio-economic status does not dictate diagnostic quality. Revolutionizing Epidemiological Surveillance: When deployed at scale and connected digitally, POCT becomes a powerful, real-time syndromic surveillance network. Aggregated, de-identified data from thousands of testing points can provide instantaneous insights into the community prevalence, geographic spread, and temporal trends of infectious diseases, allowing public health authorities to detect outbreaks early, monitor intervention effectiveness, and allocate resources dynamically.

Inherent limitations and the complex management architecture for integration. The decentralization that confers POCT its strengths also introduces significant systemic challenges that cannot be solved by the device alone but require a sophisticated management framework. Inherent Technological and Operational Limitations: 1) Limited Multiplexing Scope: Most current POCT devices are designed for a narrow, pre-defined panel of pathogens (often 1-6 targets). This contrasts with the complex, often polymicrobial differential diagnosis faced in clinical practice. 2) Variable Performance Characteristics: Particularly for antigen tests, sensitivity and specificity can vary widely between manufacturers, lot-to-lot, and based on operator technique and timing of testing relative to disease onset. This variability risks false reassurance or unnecessary anxiety. 3) Absence of Standardization and Quality Assurance: The proliferation of different platforms and tests, operated by non-laboratory personnel in diverse settings, creates a formidable challenge for ensuring consistent, high-quality results across the system.

Essential Management and Systemic Integration Tasks: For POCT to fulfill its promise as a reliable public health tool, a comprehensive management infrastructure must be built. Establishing a National Quality Management System: This is the non-negotiable foundation. It requires: a) Mandatory registration of all POCT devices and testing sites. b) A robust External Quality Assessment (EQA) scheme that regularly ships blinded control samples to all testing points. c) Standardized training and certification programs for operators. d) Implementation of built-in electronic readers or barcode scanners to minimize human error in result interpretation and recording. Digital Integration and Data Governance: The data generated by POCT is a public health asset. A mandatory, seamless digital linkage is required to automatically feed test results—with key metadata (test type, patient ID [anonymized for surveillance], location, timestamp)—into Electronic Health Records (EHRs) and a national public health surveillance platform. This creates a learning health system where data directly informs both individual care and population health strategy. Supply Chain and Logistics Mastery: Successful national scaling depends on a reliable, temperature-controlled supply chain for test kits and reagents, efficient distribution networks to prevent stock-outs in remote areas, and systems for managing inventory and preventing the use of expired tests. Sustainable Economic and Reimbursement Models: The business case for POCT must be clear. Financing models could include: a) Bundled payments that incorporate the cost of essential POCT into the tariff for a primary care consultation. b) Specific reimbursement codes for POCT procedures. c) Direct public procurement and provision for high-priority public health programs (e.g., AMR stewardship, outbreak control). The cost must be justified by the savings achieved through reduced antibiotic misuse, fewer hospitalizations, and more efficient healthcare delivery.

In conclusion, POCT is not merely a simple test, but a strategic lever for healthcare system transformation. Its ultimate success hinges on recognizing it as a system-of-systems challenge, where the technological device is merely one component within a larger ecosystem of quality control, data connectivity, logistics, financing, and trained human resources. Only with this holistic management approach can POCT's potential to deliver equitable, timely, and impactful diagnostics be fully realized.

4. Integration of approaches and systemic management: Building a resilient diagnostic architecture

Comparative analysis, functional synergy, and the diagnostic continuum. A simplistic view might pit the comprehensive power of mNGS against the operational speed of POCT. However, a strategic analysis reveals that these technologies are not competitors but complementary and synergistic components of a modern, tiered diagnostic ecosystem. Their relationship can be likened to that between a wide-area surveillance radar (mNGS) and a targeting system for point defense (POCT). One provides broad, unbiased situational awareness to detect any potential threat, while the other enables rapid, localized engagement of known, immediate dangers.

Table 1

Comparative characteristics of mNGS and POCT within an integrated system

Criterion	Metagenomic Sequencing (mNGS)	Point-of-Care Tests (POCT)
Strategic Role	Detective of last resort; Universal pathogen discovery tool	First-line screening and triage; Tool for immediate clinical action
Analysis Time	24–72 hours (from sample to validated report)	Minutes to 1 hour (sample-to-answer at site)
Pathogen Coverage	Universal, hypothesis-free. Detects all nucleic acids (bacteria, viruses, fungi, parasites), including novel/unknown agents.	Targeted, hypothesis-driven. Detects a pre-defined, limited panel of pathogens (typically 1-20 targets).
Primary Output	Comprehensive microbial identification + full resistome/virulome profile.	Binary or semi-quantitative result for specific pathogen(s).
Clinical Decision Impact	Guides definitive, often life-saving therapy in complex, unresolved cases; informs long-term management and public health policy.	Enables immediate therapeutic, isolation, or referral decisions during the clinical encounter.
Infrastructure and Expertise	Centralized, high-complexity reference laboratories requiring significant capital investment, bioinformatics infrastructure, and specialized expertise.	Decentralized, low-to-moderate complexity devices deployable at primary care, pharmacies, emergency departments; operated with minimal training.
Key Management Challenge	Ensuring equitable access and rational use through centralized hubs and clear referral pathways; managing high cost and data complexity.	Ensuring quality assurance, data integration, and sustainable financing across thousands of decentralized nodes.
Synergistic Link	Receives complex referrals from POCT/PCR-negative or immunocompromised patients. Provides validation and discovery data to refine future POCT panels.	Rapidly filters and triages the majority of cases. Creates an epidemiological map that guides mNGS utilization and public health response.

This comparative analysis underscores that POCT and mNGS operate on different axes of the diagnostic space: speed vs. breadth, and decentralization vs. centralization. The optimal system leverages the strength of each: POCT acts as a high-throughput filter and rapid responder, managing the vast majority of common infections at the point of need, while mNGS serves as a deep-investigation resource for the minority of perplexing, severe, or high-stakes cases that pass through this filter.

A multi-level national model: From point-of-care to reference genomics. To translate this synergy into practice and actively prevent the emergence of "diagnostic inequality"—where advanced tools become the privilege of major urban centers—a deliberately architected, multi-level national diagnostic strategy is essential. This model clearly defines the role and place of each technology within the healthcare delivery chain (See Figure 1).

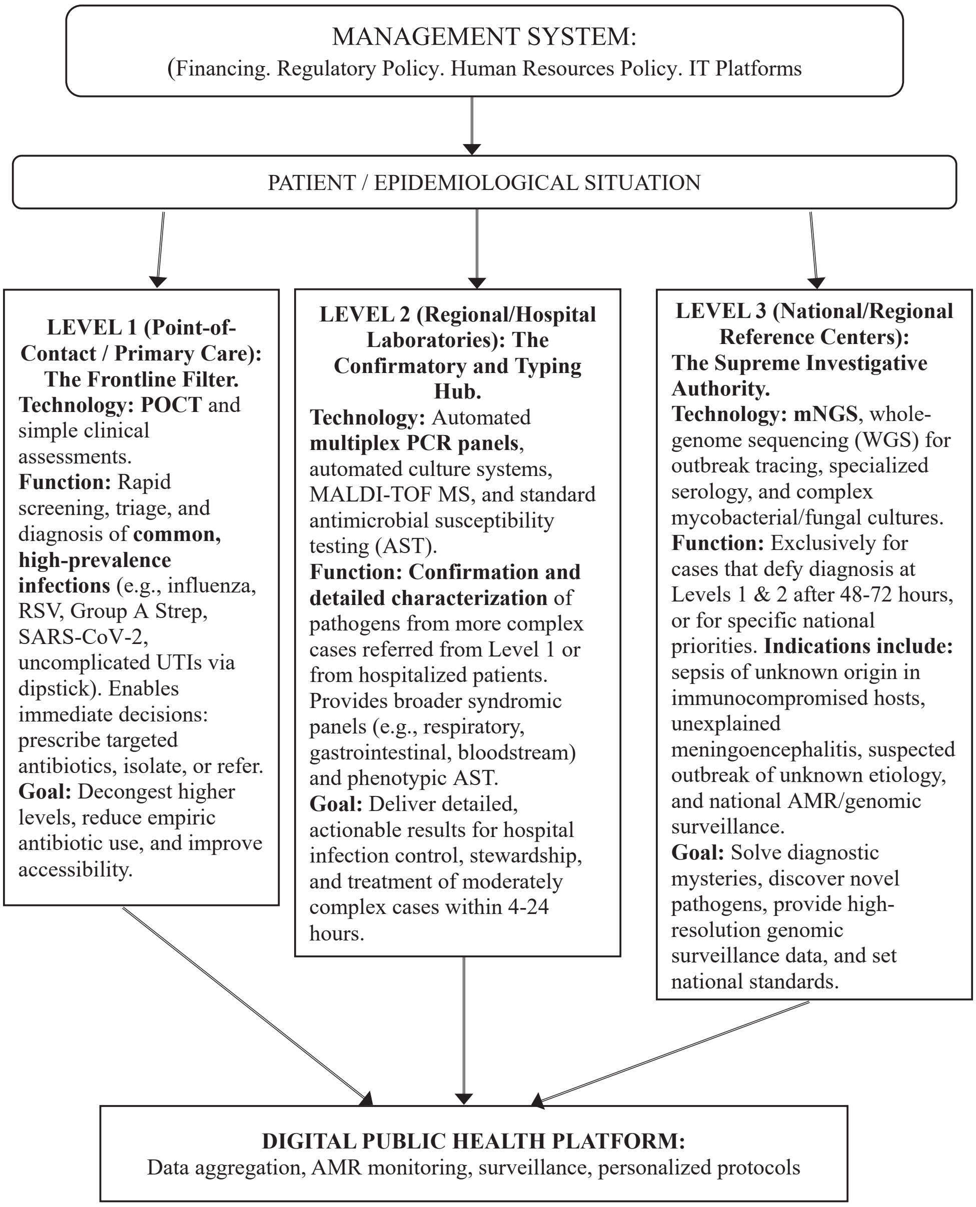
5. Foundational pillars for systemic implementation

Building and sustaining this model requires concerted action on several interdependent management fronts: 1) Governance and Financing: Develop a National Diagnostic Strategy with a clear roadmap, milestones, and accountable agencies. Implement blended financing: Public investment in Level 3 reference infrastructure, insurance reimbursement for medically necessary mNGS (with strict criteria), and innovative purchasing models for POCT (e.g., volume-based guarantees, bundled payments for primary care episodes). Foster Public-Private Partnerships (PPPs) for technology deployment, local reagent production, and R&D, particularly for next-generation nanotechnology-based POCT. 2) Regulatory and Quality Framework: Create an accelerated but rigorous regulatory pathway for validating and approving novel diagnostic platforms, especially domestically developed ones. Mandate a national EQA scheme encompassing all levels, from POCT operators to mNGS bioinformatic pipelines. Establish national clinical guidelines with explicit criteria for patient and sample referral between levels. 3) Digital Health and Data Unification: Build a unified national digital health platform that integrates data from all three levels. This platform must: Securely aggregate anonymized POCT results for real-time syndromic surveillance. Facilitate electronic referral of samples and clinical data to higher-level laboratories. Host a national genomic epidemiology dashboard displaying mNGS/WGS-derived data on pathogen evolution and AMR trends. Provide decision-support tools for clinicians at all levels. 4) Workforce Development: Modernize medical and laboratory education curricula to include principles of genomics, POCT data management, and antimicrobial stewardship. Establish specialized training and certification programs for POCT coordinators, clinical bioinformaticians, and genomic epidemiologists.

In essence, the integration of mNGS and POCT is not a technical exercise but a systemic redesign of the diagnostic value chain. It demands moving from a fragmented, reactive model to a coherent, proactive, and intelligence-driven National Diagnostic Network. Only through such a structured, managed approach can the full potential of these transformative technologies be harnessed to deliver equitable, effective, and resilient healthcare for all.

6. Conclusions

mNGS and POCT technologies are complementary foundations of a new paradigm in infectious disease diagnostics, focused on personalized medicine, effective public governance, and global biosecurity.



Legend/Key Elements:

AST: *Antimicrobial Susceptibility Testing*
AMR: *Antimicrobial Resistance*
The arrows indicate the flow of samples and data, as well as management directives.
The ***Digital Public Health Platform*** *serves as the unifying layer, integrating data from all levels to inform clinical and public health actions.*

Fig. 1. Integrated Multi-Level Model for Infectious Disease Diagnostics: Synergy of Technologies and Management System

Successful integration of these technologies requires a systemic transformation of healthcare management, including financial, regulatory, personnel, and organizational aspects.

Nanotechnology research opens prospects for creating next-generation diagnostic systems that combine the advantages of both approaches.

A key principle of state policy should be ensuring equitable access to diagnostics through a balance between centralization of mNGS and decentralization of POCT.

Only a comprehensive multidisciplinary approach that integrates advanced technologies, management competence, and an unwavering focus on equity can form the basis of a sustainable public health system capable of withstanding modern and future global infectious threats.

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