

Perspective article

Bridging the implementation gap in One Health diagnostics: from point-of-care technologies to integrated diagnostic ecosystemsMatteo Mellace¹, Mohamed Samir² and Hossam Abdelhamed^{3*}¹Department of Health Science, University Magna Graecia of Catanzaro, Italy²School of Science, Faculty of Engineering and Science, University of Greenwich (Medway campus, Kent), London and South East (LASE) University Group, London, United Kingdom.³Department of Comparative Biomedical Sciences, the College of Veterinary Medicine, Mississippi State University, United States***Corresponding author:** Hossam Abdelhamed, abdelhamed@cvm.msstate.edu**Article history:** Received 2 July 2026; Accepted 22 August 2026; Available online 5 September 2026**Article information:** Mellace M et al., 2026. *One Health Microbiol. Infect.* Vol. 2, No. 1: 195-210. <https://doi.org/10.66585/ohmi.2026.2.0029>**Abstract**

Recent advances in molecular diagnostics and portable sequencing technologies have significantly expanded the technical capabilities of decentralized diagnostic platforms. Point-of-care (POC) diagnostics have emerged as essential tools for improving the surveillance and control of zoonotic diseases within the One Health framework. Despite this, translating these innovations into systematic, routine field implementation remains limited. This perspective argues that the primary barriers are no longer technological performance but rather the complex challenges of large-scale implementation. These challenges include fragmented governance, regulatory heterogeneity, economic constraints, logistical hurdles, workforce capacity, and insufficient integration among human, animal, and environmental health systems. Through a critical analysis of current evidence, this manuscript identifies a gap between technological innovation and operational implementation and advocates a transition from device-centric innovation to integrated diagnostic ecosystems that support coordinated One Health surveillance. Strategic directions are discussed, including adaptable diagnostic platforms, interoperable diagnostic networks, digital integration of surveillance systems, operational decentralization, and unified regulatory pathways. Collectively, these strategies could accelerate the translation of emerging diagnostic technologies into sustainable field applications, maximizing their potential to strengthen early detection, integrated surveillance, and preparedness for current and future zoonotic threats.

Keywords: Diagnostic ecosystems, Disease surveillance, One Health, POC testing, Zoonotic diseases**Introduction**

In the context of the global impact of infectious diseases, zoonotic diseases constitute one of the greatest global public health challenges because of their high incidence, pandemic potential, and substantial socioeconomic impact. In Europe, zoonoses remain a persistent public health concern owing to the continued burden of endemic infections and the increasing emergence of novel pathogens. Their epidemiology is shaped by complex interactions among environmental change, climate variability, wildlife ecology, livestock production, and human activities. In this perspective, zoonotic diseases represent a cornerstone of the One Health framework, which recognizes the interdependence of human, animal, and environmental health [1].

The European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC) regularly monitor zoonotic diseases through coordinated surveillance programs involving European Union Member States, the United Kingdom, and collaborating countries [2]. According to their most recent report, campylobacteriosis, salmonellosis, Shiga toxin-producing *Escherichia coli* (STEC) infections, invasive listeriosis, and echinococcosis remain the most frequently reported zoonoses in humans. In addition, vector-borne zoonoses are becoming increasingly important, with their transmission dynamics strongly influenced by climate

change [3]. Recently, the ECDC has pointed out that outbreaks of West Nile virus and Chikungunya in Europe are associated with rising temperatures, altered rainfall patterns, and prolonged warm seasons, which facilitate the expansion and persistence of vector populations and transmission cycles [4].

In the United States, the Centers for Disease Control and Prevention (CDC), together with the U.S. Department of Agriculture (USDA) and the Department of the Interior (DOI), released in 2025 the first National One Health Framework to Address Zoonotic Diseases and Advance Public Health Preparedness (NOHF-Zoonoses, 2025–2029), establishing federal-level coordination across human, animal, and environmental health sectors [5]. Comparable multisectoral efforts have emerged in Asia, where China has progressively integrated One Health principles into its national health governance architecture [6] and in Latin America, where the Pan American Health Organization (PAHO) has coordinated regional One Health initiatives across nine countries since 2021 [7]. These parallel developments indicate that the implementation gap discussed in this manuscript reflects a global challenge.

These epidemiological trends underscore the growing need for diagnostic systems capable of rapidly detecting zoonotic pathogens and enabling timely surveillance, outbreak response, and disease control. According to a

World Health Organization (WHO) report, zoonoses account for more than 60% of emerging infectious diseases globally [8]. However, conventional diagnostic techniques have intrinsic limitations, including non-immediate response times, variable sensitivity, and the need for centralized infrastructure, which inevitably produce a time lag between infection, diagnosis, and health intervention, particularly in peripheral contexts and during acute outbreaks [9].

In this context, these limitations have accelerated the development of rapid, decentralized point-of-care (POC) diagnostic platforms that can be deployed directly in field and community settings. The global infectious disease POC diagnostics market was estimated to exceed US\$53 billion in 2024, reflecting growing demand for rapid, accessible diagnostic technologies. European regulatory frameworks are increasingly oriented toward evaluating decentralized technologies, as evidenced by Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR). This legislation introduces more stringent requirements for analytical and clinical validation, post-market surveillance, and the evaluation of diagnostic device performance, directly influencing the development and implementation of new POC platforms [10].

Rapid advances in molecular biology, biomedical engineering, digital health, and artificial intelligence have transformed the landscape of infectious disease diagnostics. These innovations have greatly improved the ability to detect pathogens early, monitor disease transmission, predict epidemiological risk, and support evidence-based surveillance and control strategies [11, 12]. Innovations in molecular diagnostics, advanced analytical capabilities, and technologies based on artificial intelligence (AI) and biomedical engineering enable early detection, epidemiological risk prediction, and real-time monitoring [13]. In this context, rapid diagnosis, effective surveillance, and monitoring are essential to limit the spread of zoonotic diseases. Among these technologies, molecular diagnostic platforms have demonstrated particularly strong potential for One Health surveillance.

Next-generation sequencing (NGS) technologies enable the parallel analysis of millions of DNA or RNA fragments, allowing comprehensive characterization of pathogens, detection of antimicrobial resistance (AMR) genes, and real-time epidemiological surveillance [14]. Whole genome sequencing (WGS) has become the gold standard for outbreak investigation, source attribution, and genomic surveillance, whereas metagenomic next-generation sequencing (mNGS) enables unbiased detection of bacteria, viruses, fungi, and parasites directly from complex clinical samples without prior knowledge of the causative pathogen. Because mNGS is not target-specific, it is particularly valuable for detecting mixed infections, emerging pathogens, and unexpected etiologic

agents that may be missed by conventional targeted molecular assays, making it a powerful tool for future One Health diagnostic systems [14].

Alongside molecular technologies, biosensors integrated with nanomaterials are rapidly expanding the capabilities of infectious disease diagnostics. Incorporating nanomaterials has substantially improved the sensitivity, specificity, conductivity, and analytical performance of conventional biosensors, enabling faster and more accurate pathogen detection. Among these emerging technologies, CRISPR is one of the most promising innovations. Beyond genome editing, CRISPR systems can be adapted for highly specific and sensitive pathogen detection [15]. Thanks to the sequence specificity of guide RNAs and Cas effectors, CRISPR biosensors have been developed to detect numerous pathogens, including SARS-CoV-2, Ebola and Dengue viruses, *Mycobacterium tuberculosis*, *Staphylococcus aureus*, *Escherichia coli*, and *Salmonella enteritidis* [16].

Research in the field of AI is increasingly prominent. Thanks to its enormous data-processing capacity, the decision support it can provide, and its ability to recognize patterns. AI can enable accurate identification of microorganisms, assess epidemic trends, and predict potential antibiotic resistance. In high-throughput sequencing (HTS), AI demonstrates high efficacy in multiple resistance analysis and quality control of sequencing data [12].

Machine learning algorithms can be used to develop tools for rapid pathogen detection, thanks to their ability to efficiently and rationally manage and update sequence identification and classification [17, 18]. When applied to epidemiological, clinical, and environmental datasets, these algorithms can identify patterns of disease spread, pinpoint high-risk areas in advance, and support the development of targeted preventive strategies. Nanotechnology further complements these advances by improving biosensor performance and enabling highly sensitive detection of pathogens at very low concentrations. Integrating nanobiosensors with AI-driven analytical platforms has the potential to further improve diagnostic accuracy through real-time data analysis, automated interpretation, and reduced operator-dependent variability [13].

Collectively, advances in AI, genomic sequencing, biosensors, nanotechnology, CRISPR systems, and smart diagnostic tools are transforming the landscape of zoonotic disease diagnostics and creating unprecedented opportunities for rapid, decentralized, and precision surveillance. However, technological innovation alone is insufficient to achieve meaningful public health impact. Effective implementation requires robust digital infrastructure, interoperable data-sharing systems, secure cloud-based platforms, and coordinated integration of AI,

genomic surveillance, and public health networks. Without these supporting systems, even the most advanced diagnostic technologies cannot be fully translated into routine field practice.

Despite technological innovation, recent scientific literature highlights a paradox: the pace of developing and validating new technologies does not match the pace at which they translate into widespread, accessible operational tools in the field. This manuscript examines the scientific, regulatory, economic, and operational barriers that limit the widespread implementation of POC diagnostics for zoonotic diseases and discusses strategies to translate technological innovation into integrated diagnostic ecosystems that strengthen One Health surveillance and preparedness. A “diagnostic ecosystem” is an integrated framework that connects diagnostic technologies with trained personnel, data systems, laboratory and connectivity infrastructure, supply chains, and governance to support effective One Health surveillance. By linking innovative diagnostic platforms with real-time data, genomic surveillance, interconnected laboratory networks, coordinated supply systems, and harmonized standards, this framework enables diagnostic information to move efficiently from detection to decision-making. Within this ecosystem, POC platforms can strengthen early detection, surveillance, preparedness, and coordinated responses to zoonotic threats. POC diagnostics are therefore considered a cross-sectoral area encompassing both human and veterinary applications within the One Health framework. Rather than treating diagnostic technologies as separate tools for individual sectors, this manuscript examines their role as integrated components of surveillance systems aimed at improving the early detection, monitoring, and control of zoonotic threats.

The evidence discussed in this perspective was identified through a critical synthesis of scientific literature, institutional reports, and documented field applications related to POC diagnostics and zoonotic disease surveillance. The examples were deliberately selected to illustrate recurring implementation patterns and challenges across technological, regulatory, and geographic contexts, rather than to provide an exhaustive systematic assessment of all available evidence. The focus has been intentionally placed on implementation barriers and unresolved bottlenecks, rather than on technological advances and successful validation studies. Therefore, the discussion should not be interpreted as an assessment of the failures of POC technologies per se, but rather as an analysis of the systemic factors that limit their implementation in routine practice.

Point-of-care diagnostics for zoonotic diseases: current landscape

Among the main applications of the technological innovations mentioned, POC diagnostics represents a concrete response to the need for rapid diagnosis, especially in zoonoses, and occupies a central position in the sector's development prospects. “Point-of-care testing” (POCT) refers to diagnostic platforms performed directly at or near the site of patient care, thereby reducing dependence on centralized laboratories and shortening the time between sample collection and clinical decision-making [19]. The implementation of POCT represents a fundamental shift in diagnostic practice. Rather than transporting samples to centralized laboratories, diagnostic capability is brought directly to the point of need, enabling earlier case detection and more rapid public health interventions. Successfully implementing this paradigm requires coordination among clinicians, veterinarians, laboratory scientists, engineers, public health authorities, and regulatory agencies.

This logic explains why recent scientific literature considers the development and implementation of POCTs among the most promising diagnostic applications for zoonoses. Shortening the time between sampling and diagnosis reduces the period during which infections remain undetected, facilitating timely treatment, outbreak containment, and more effective epidemiological surveillance [20]. The ever-growing market and projections indicating it could double in value by 2033 reflect the potential of these tests in business and application fields [10]. The constant advancement of innovative technologies and intensive research in the fields of molecular diagnostics, biosensors, microfluidics, and AI represent an important economic and technical driver of POC diagnostics [16]. Within this category, there are currently different types of tests that differ mainly in their adoption and the technology used.

Although polymerase chain reaction (PCR) has traditionally been laboratory-based, portable PCR platforms have successfully expanded its use in decentralized settings. One representative example is the Truenat system, a battery-powered, chip-based PCR platform originally developed for malaria diagnosis in resource-limited settings. Truenat assays are performed using the Truelab Uno® portable analyzer, which serves as the platform for chip-based molecular testing. Designed to overcome the limited sensitivity of microscopy and rapid antigen tests, particularly in patients with low parasitemia, Truenat demonstrated superior diagnostic performance and correctly identified mixed *Plasmodium falciparum* and *Plasmodium vivax* infections that were frequently missed by conventional diagnostic methods [21]. Based on these results, the same authors proposed considering its use not only for individual diagnosis but also as a tool for active surveillance and support for epidemiological interventions in the field.

However, diagnostic performance remains pathogen-dependent. For tuberculosis, the sensitivity of Truenat MTB was 80.5% in one Ugandan study, compared with GeneXpert Ultra, but declined to 34.4% in a Tanzanian evaluation, underscoring the importance of disease-specific validation before widespread implementation [22]. Despite advances in molecular diagnostics, immunoassays, particularly lateral flow assays (LFAs), remain the most widely used POC technology because of their simplicity, rapid turnaround time, and low cost. In contrast, PCR-based platforms require more sophisticated instrumentation, supply chains, and quality assurance systems, which continue to limit their deployment in many resource-limited settings.

More recent technologies, such as CRISPR-based platforms and nucleic acid amplification tests, offer

substantially higher analytical sensitivity than many conventional POC assays but have yet to achieve widespread implementation because of manufacturing, regulatory, and technology-transfer challenges [23]. In this sense, CRISPR-based diagnostics such as "SHERLOCK" and "DETECTR" combine nucleic acid amplification with collateral cleavage-mediated fluorescent or colorimetric detection, providing highly sensitive pathogen identification within simplified workflows that are well suited for decentralized testing [24]. Other devices used include so-called "lab-on-chip" microfluidic devices and multiplex tests on paper, tools that detect multiple pathogens simultaneously, expanding diagnostic capacity [10]. The principal POC diagnostic technologies currently available for zoonotic disease surveillance are summarized in Table 1.

Table 1: The main POC platforms used, along with their strengths and limitations.

Technology	Diagnostic principle	Strengths	Main limitations	Relative cost	Application example	Ref.
Lateral Flow Assays (LFA)	Immunochromatographic detection of antigens/antibodies	Low cost, ease of use	Lower sensitivity than molecular testing	< \$5/test* [25]	Rapid diagnosis of zoonoses and field surveillance	[23]
PCR on chip (Truenat)	Nucleic acid amplification on a chip	High accuracy, identification of coinfections	Higher costs, critical supply chains	\$13.20/test* [26]	Malaria, tuberculosis	[21, 22]
GeneXpert (Xpert MTB/RIF)	Automated PCR	Automated workflow, large-scale implementation	Variable sensitivity, high costs	\$12.63/test* [26]	Tuberculosis control	[27]
CRISPR-based assays (SHERLOCK, DETECTR, CRISPR/Cas13)	Collateral cleavage, isothermal amplification	High sensitivity and specificity, simplified workflows	Technology transfer is still limited	\$5–15/test* [28]	Surveillance of infectious diseases	[24, 29, 30]
Lab-on-chip and paper-based multiplex assays	Microfluidics	Low sample volume, multiplexing, portability, high degree of integration	Limited production and standardization across sample types and environmental conditions	\$9.5/test* [31]	Multi-pathogen diagnosis	[10]
Nanopore sequencing (MinION)	Genomic sequencing	Field genomic analysis, identification, and epidemiological tracking	Requires bioinformatics skills and sample preparation	\$115–173/test* [32]	Ebola, Lassa fever	[33, 34]

*These are illustrative data extracted from articles and reviews that address application contexts and conditions different from those discussed in this perspective. Since the articles on the technologies discussed in the text do not provide cost information, these values should not be used for direct comparisons among technologies and should be interpreted only as indicative estimates.

Field applications

Although technological advances have greatly expanded the capabilities of POC diagnostics, their true value is best illustrated by successful field implementation. Several recent examples show how innovative diagnostic platforms have improved outbreak response and disease surveillance in real-world conditions. One of the earliest and most influential examples was the deployment of the

portable Oxford Nanopore Technologies MinION sequencer during the 2014–2016 Ebola outbreak in Guinea. This pocket-sized device enabled the establishment of a mobile genomic laboratory that generated whole-genome sequencing data within 24 h of sample collection, eliminating delays associated with transporting samples to centralized laboratories. Its portability, ease of operation, and minimal infrastructure

requirements demonstrated the feasibility of real-time genomic surveillance in outbreak settings [33]. The same platform was subsequently adopted by the Institute for Lassa Fever Research and Control in Nigeria, demonstrating that portable sequencing could be successfully applied to the surveillance of other high-priority zoonotic pathogens, including Lassa virus [34].

Beyond emergency outbreak response, the greatest value of POC diagnostics lies in their sustainable integration into routine healthcare systems, particularly in low-resource settings where access to centralized laboratories is limited. A representative example is the GeneXpert (Xpert MTB/RIF) platform, which has been widely implemented across several African countries for diagnosing *Mycobacterium tuberculosis*. Large-scale implementation of this automated molecular platform was associated with a fourfold increase in tuberculosis case detection between 2015 and 2018, and treatment success rates reached 92.6%, illustrating the public health impact achievable when POC diagnostics are effectively integrated into national healthcare systems [27]. These achievements were achieved despite the platform's limitations, including higher costs and variability in diagnostic sensitivity across settings.

The surveillance of highly pathogenic avian influenza (HPAI) further illustrates the importance of POC diagnostics within a One Health framework, in which monitoring animal reservoirs is essential to prevent zoonotic transmission to humans. Researchers at the China Animal Health and Epidemiology Center (CAHEC) developed a CRISPR/Cas13a-based diagnostic platform that combines isothermal amplification with lateral-flow detection for rapid surveillance of avian influenza in poultry [30]. Although RT-qPCR remains the reference method for avian influenza diagnosis, its dependence on specialized laboratories and trained personnel limits its use in rural and resource-constrained settings. The CAHEC assay addresses these limitations by delivering results in approximately 40 min at 37°C, enabling direct visual interpretation using a lateral flow strip, and requiring no advanced laboratory instrumentation [30]. The most significant aspect was validation on clinical samples (380 in total), in which the test showed high agreement with the reference RT-qPCR. In addition, evaluation against multiple poultry pathogens, including H3, H7, H9, and H10 avian influenza subtypes, infectious bronchitis virus, Newcastle disease virus, and avian rotavirus, confirmed high analytical specificity with no evidence of cross-reactivity [30].

In 2024, HPAI affected dairy cattle in the United States, marking the first documented case of transmission of this virus to a ruminant species. In response, the USDA imposed pre-movement testing on dairy cattle and implemented nationwide testing of raw milk [35]. The

initial cases were identified through passive surveillance of affected livestock, which underestimated the true extent of the virus's spread. Retrospective monitoring of retail milk, however, confirmed the presence of viral RNA in more than one-third of the milk samples collected during the early phase of the outbreak [35]. This underscores how complete dependence on a passive surveillance strategy can delay the recognition of an outbreak even in highly industrialized surveillance systems.

Together, these examples demonstrate that recent technological advances have moved beyond laboratory proof of concept and can provide substantial benefits for field surveillance, outbreak response, and disease control. However, they also illustrate that successful implementation depends not only on analytical performance but also on integration with healthcare infrastructure, workforce training, regulatory acceptance, and sustainable deployment strategies—issues that remain major barriers to the widespread adoption of POC diagnostics for zoonotic diseases.

Key advantages

As widely documented in the literature and discussed in the previous paragraphs, decentralized diagnostic technologies used in POC play a strategic role not only in the control and surveillance of infectious diseases but also in community-based care, the management of clinical emergencies, perioperative and hospital settings, the monitoring of chronic diseases, and numerous other health contexts [36, 37]. However, the reason these technologies are highly promising, especially for the diagnosis of zoonoses, is linked to specific interrelated characteristics. Portability, understood as independence from high-tech instrumentation and centralized laboratories, is the feature that most clearly underscores the intrinsic dynamism of POCTs.

The elimination of this dependency reduces transport times and the associated risks of sample degradation and contamination [38]. The decentralization of diagnostic and instrumental capacities also favors the creation of more widespread, timely, and reactive surveillance networks, capable of integrating data obtained on the farm or on the patient, with epidemiological surveillance systems at the population level.

Analytical speed, defined as the reduction in the time from sample collection to the availability of results, is another major advantage. Conventional laboratory testing involves multiple steps, including sample collection, transportation to a centralized laboratory, and subsequent processing, all of which contribute to delays. In contrast, POCT eliminates or minimizes these intermediate steps by bringing diagnostic capacity directly to the patient or the field [39]. The case of the MinION sequencer during the Ebola outbreak in Guinea mentioned above is exemplary, as a centralized workflow that would have required

shipping the sample to a reference laboratory would never have made genomic results available within 24 hours of collection.

Another characteristic is the ability to use these tests in low-resource settings. Diagnostic tests with high technological complexity can face application barriers in economic and logistical terms in certain contexts; in this sense, developing and disseminating POCT could bridge the gap in resource availability. The large-scale adoption of the GeneXpert system already mentioned in the control of tuberculosis has shown that, in conditions of scarcity of resources, the value of a POC test is measured primarily by its ability to be effectively adopted and maintained over time on a large scale.

What remains to be critically examined is the extent to which, beyond individual applications and studies, these positive characteristics can be sustained and standardized to have a real impact on global health systems over time. There remains an open discussion about the extent to which regulatory, logistical, and infrastructural barriers contribute to widening the gap between the theoretical potential of technological innovations and their real impact.

Understanding the implementation gap

The validation of POCT platforms under controlled conditions does not directly guarantee equivalent performance in real-world contexts; the "Truenat" platform discussed above is a clear example. A reduction of more than 50% in the instrument's sensitivity, observed with the same device after use in Tanzania, is not an isolated case. Differences in reported Truenat sensitivity across studies conducted in different contexts preclude unequivocal attribution of the phenomenon to limitations of the technology itself. However, they highlight that diagnostic performance can vary significantly with changing operating conditions, underscoring the complexity of the transition from controlled validation to routine implementation in the field. This discrepancy is well known in the literature on decentralized diagnostics used in resource-constrained settings [40]. The implementation gap should not be interpreted as the consequence of a single causal pathway. Rather, it emerges from barriers operating at distinct but interacting levels, ranging from technological performance to health-system implementation and broader governance structures.

The main point to discuss is the extent to which the difficulties encountered in transitioning the prototype to field use are attributable to the limitations of the technologies underlying the tool's development. At the implementation level, however, technological performance alone does not explain why many promising platforms fail to achieve widespread adoption. Even when analytical validation is successful, substantial barriers arise during technology transfer, large-scale

manufacturing, financing, distribution, workforce training, and long-term maintenance. The transition from the prototype to market introduction constitutes the most challenging point within the entire application path, generating what have been defined as "leaks in the pipeline" [41]. Research funding rarely extends to the industrial and commercial enhancement phase, creating a structural gap that immediately blocks instrumental implementation. The management complexity of large-scale production, distribution, and maintenance often exceeds the technological success achieved in the analytical validation phases.

Economic sustainability, logistics, and workforce development constitute complementary implementation barriers that influence whether diagnostic technologies can be maintained at scale. Economic barriers represent another often-overlooked limitation during the phases of technological development, not so much because of a lack of economic analysis, but rather because of the difficulty of predicting the overall costs required to maintain POC platforms. The cost of purchasing the test is a very important but relatively minor component from an economic point of view; in fact, to analyze the overall expenses, it is necessary to take into account other costs related to the maintenance of the instrumentation, the maintenance of the cold chain, the training of field personnel, and the procurement of consumables. In addition, when donor- and international-organization-funded pilot projects are implemented in low-income countries, there is a lack of continuity and economic stability after the original project concludes [41].

Economic challenges are closely related to logistical ones. A systematic review documented how stock-out situations in the use of malaria, syphilis, and HIV testing were often repeated in the management of the POCT testing supply chain in resource-limited settings [42]. This testifies that theoretical technological availability does not directly imply complete accessibility. In rural contexts, the difference is often made by infrastructures that we consider essential yet often taken for granted, such as stable energy access or grid connection, and which condition the effective operation of platforms that, despite being decentralized, require a minimum level of infrastructure [43].

Staff training is no less important, as it can strongly affect the reliability of the data produced. Although several POCTs were designed for operators without a high level of specialized diagnostic competence, continuous training programs on the use of specific tests are essential. While it is important to develop tools that reduce reliance on highly specialized skills, basic staff training remains a strategic element. This is essential to ensure appropriate use of diagnostic technologies, especially in contexts where some tools still require more advanced interpretive skills.

Beyond implementation barriers, broader governance and regulatory structures also influence the successful deployment of POCT platforms. These barriers concern the coordination of diagnostic activities across human, animal, and environmental health systems within the One Health framework. To these problems is added another structural gap, linked to the inability to generate a truly unambiguous vision and an efficient management system between the health systems of human and animal medicine. The rhetoric of the One Health paradigm has now permeated the scientific literature, and government and institutional documents applying this paradigm are increasingly common [44]. Certainly, this represents an important step forward towards a systematic and holistic vision of health systems, but the lack of truly integrated governance between the human, animal, and environmental health sectors is holding back this process. This limitation represents a concrete obstacle to coordinating diagnostic and surveillance strategies and impedes the translation of the principles of health interconnection into shared operational practices [45]. This inability is even more limited in POCT platforms designed from the outset for use across human and veterinary clinical contexts.

From a governance perspective, regulatory harmonization remains one of the most persistent obstacles to large-scale deployment. A significant barrier, especially in the field of POCT for monitoring zoonoses, is the regulatory framework. The EU, through the IVDR Regulation 2017/746, has adopted a harmonized regulatory framework for *in vitro* diagnostic medical devices for human medicine, whereas the application of this regulation to veterinary medicine is not homogeneous. In the EU, as highlighted by Potockova et al. (2020), there is no specific harmonized regulatory framework for veterinary POCTs, leading to fragmentation among Member States and low standardization of quality and marketing requirements [46]. In the United States, regulation is entrusted to the Food and Drug Administration (FDA) and is more structured while remaining risk-based. The products in this case are divided into different categories based on the level of pre-market control, and many POCTs are not subject to authorization based on overly stringent criteria, often relying on post-market surveillance. On the global scene, Japan adopts a more centralized and rigorous approach to veterinary POCTs, assimilating them to the regulation of devices used in human medicine. Japan also has a high degree of regulatory scrutiny and more stringent pre-market requirements than the United States.

In Asia, the picture is also heterogeneous: in China, although a national One Health governance architecture has been formally established, recent assessments report that diagnostic technologies remain unevenly distributed across regions and that interdepartmental data-sharing is

hindered by bureaucratic delays and inconsistent standards, despite stated policy commitments [6]. In Latin America, veterinary public health authorities in several countries have begun aligning national zoonotic surveillance strategies with the regional One Health policy launched by PAHO in 2021, although harmonized regulatory pathways for POC veterinary diagnostics remain in an early stage of development [7].

Overall, a regulatory pattern emerges ranging from a fragmented and indirect system in the EU, through intermediate models in the United States and Latin America, to a more centralized and policy-driven yet unevenly implemented framework in China, up to a highly structured and restrictive set-up in Japan, highlighting a persistent lack of international standardization in the sector [46]. The main implementation gaps are summarized and illustrated in Figure 1.

Gaps in current approaches

Since the main limitation of POCT platforms for zoonoses appears to lie in organizational fragmentation and the lack of effective health governance systems, it is legitimate to ask why these problems persist despite being widely documented and discussed in the scientific literature. Understanding how the results of technological innovation are transformed into operational applications, and the processes by which these technologies are validated, financed, and brought to market, can help explain why they have failed to generate lasting systemic change. The criteria for defining characteristics during the analytical and clinical evaluation of tests, even in cases of greater rigor, are often established a posteriori, bypassing communication between those who develop the technology and those who use it in specific contexts.

The Target Product Profile (TPP) approach defines the characteristics and minimum performance requirements of a diagnostic tool to address specific public health needs. In particular, it specifies critical parameters such as analytical sensitivity and specificity, ease of use, turnaround time, and cost-effectiveness. By establishing clear, evidence-based specifications early. The TPP facilitates alignment among developers, manufacturers, policymakers, and end-users, thereby accelerating product innovation and ensuring that newly developed diagnostic tools effectively meet operational requirements. It outlines the profile or desired characteristics of a target product designed for one or more specific diseases. TPPs indicate the intended use, target populations, and other desired product attributes, including safety and efficacy-related characteristics [47]. This approach is systematically adopted by WHO through the Diagnostics Technical Advisory Group for Neglected Tropical Diseases, which has coordinated the definition of disease-specific TPPs and, more recently, has updated them for diagnosing tuberculosis in peripheral settings

[48, 49]. This approach should also be implemented in a structured way in platforms dedicated to the control of zoonoses and, more generally, in the management of the main diseases considered within the One Health

paradigm. WHO initiatives in the construction of TPPs for swine cysticercosis and tapeworm were important but remain isolated initiatives around specific diseases rather than practice methodologies [50].

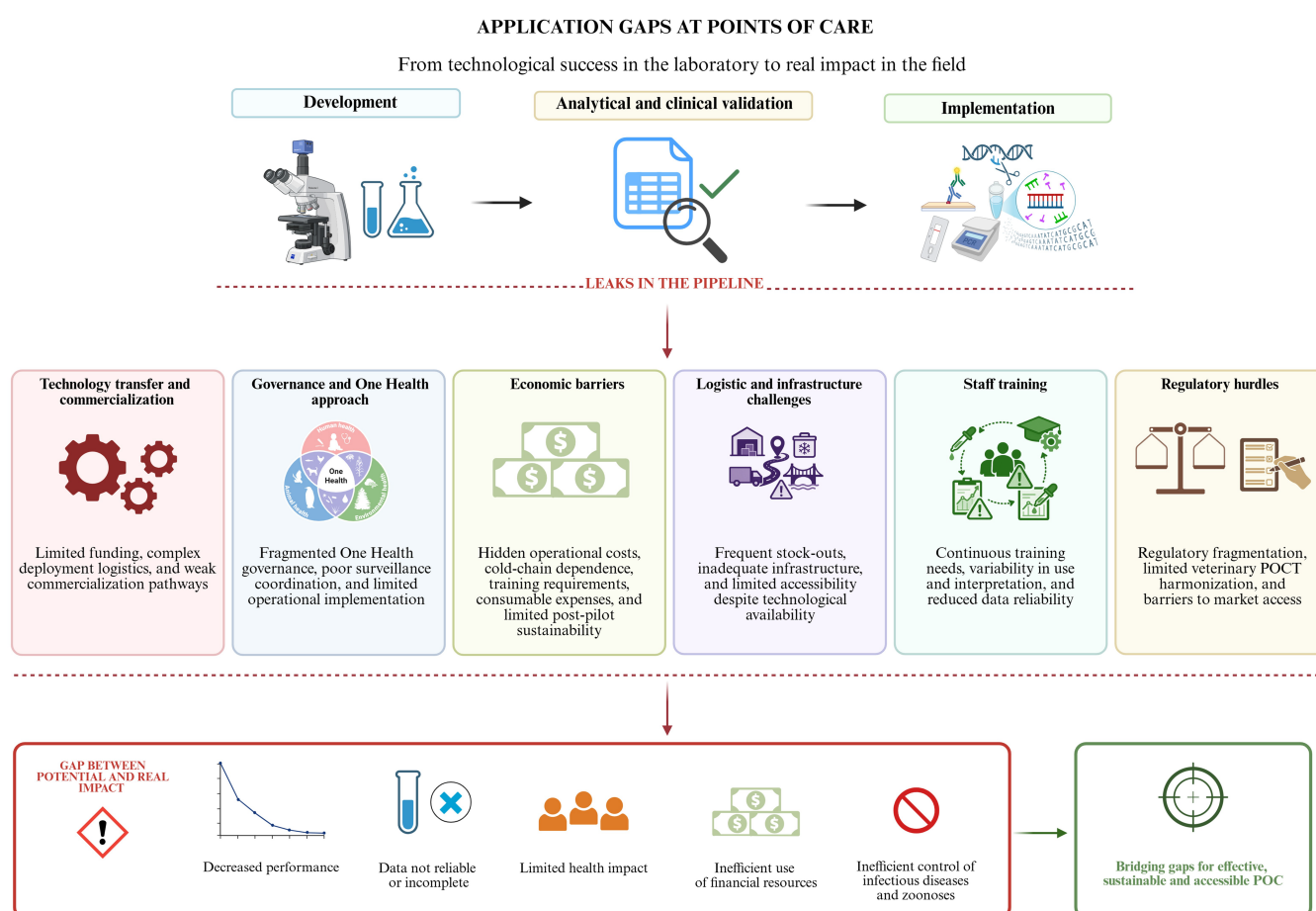


Figure 1: Key implementation gaps in the technology transfer process for POC platforms. Despite successful technological development and analytical and clinical validation, POC diagnostics may encounter multiple barriers before achieving effective implementation, including challenges in commercialization, One Health governance, financing, infrastructure and logistics, workforce training, and regulation. These interconnected “pipeline leaks” can compromise diagnostic performance and data reliability, limit the assessment of health impacts, increase inefficient use of resources, and weaken control over infectious and zoonotic diseases. Bridging these gaps is essential for sustainable and accessible POC implementation.

A recent article, cross-referencing the main international databases on veterinary diagnostics, found that for a significant number of high-priority animal diseases, there is still no commercial diagnostic test available, including several of zoonotic relevance such as Nipah virus, anthrax, West Nile fever, porcine cysticercosis, leptospirosis, leishmaniasis, and Crimean-Congo hemorrhagic fever [51]. The generative capacity of diagnostic innovation is closely linked to economic and organizational limits and is often linked to processes of scientific production and patent protection rather than to an operational demand formulated by the field health and veterinary systems [52].

CRISPR-based diagnostics offer a concrete example of the discrepancy between patent-driven innovation and

field-level operational demand. In the United States, in 2020, the test developed by Sherlock Biosciences received Emergency Use Authorization from the FDA for COVID-19 diagnosis, marking the world's first regulatory approval for a CRISPR-based diagnostic technology [53]. The company's case is nonetheless paradigmatic precisely because, despite this leading position and a strong intellectual-property portfolio in the field, Sherlock Biosciences was acquired by OraSure Technologies in December 2024 and subsequently redirected its commercialization strategy, moving away from its original focus on pathogen surveillance toward a self-administered test for sexually transmitted infections [54]. This highlights how a patent position with potential applicability across infectious diseases was redirected, rather than achieving full implementation in the

surveillance context for which it had originally been validated, toward a more commercially profitable clinical market.

This generates a shift of scientific and industrial efforts constantly towards the next most promising platform before the previous one reached full implementation capacity [55]. The real problem is not the lack of valid technical solutions but the lack of design and economic incentives to transfer these solutions at scale to markets perceived as unprofitable [56]. The Lancet Commission on Diagnostics (2021) estimated that between 35% and 62% of the populations in low- and middle-income countries lack access to essential diagnostic resources for some of the most common diseases [57]. This highlights how the lack of private investment in research, production, and distribution is one of the main limiting factors.

A recent example of intervention aimed at correcting this market imbalance is the "advance market commitments" (AMC) for neonatal diagnostics, which reduce manufacturers' economic risk by guaranteeing a minimum future demand and thus favor investment in research and development, even for diseases with limited commercial attractiveness, such as neonatal sepsis [58]. However, the mere introduction of economic incentives may not be sufficient to overcome all the distortions that characterize the global diagnostics sector. According to a recent article, the emphasis on simplicity, cost, and scalability in the "ASSURED" criteria promoted by the WHO could paradoxically highlight some inequalities that they intend to counteract [59]. In fact, this vision could impede the development of technologies tailored to specific clinical and diagnostic needs in small markets, thereby disadvantaging the most disadvantaged populations [59]. More expensive technologies, aimed at small populations and developed for very specific contexts, may be less attractive to financiers and producers.

Even if there were economic incentives or regulatory initiatives, they would clash with the vertical nature of health planning. In fact, there is a tendency to develop well-defined guidelines, budgets, and logistical procedures to address specific, circumscribed problems, which often fail to provide useful tools for addressing transversal needs [60]. The design of multiplex diagnostic platforms conceived according to a One Health logic, capable of addressing complex and interconnected diagnostic problems, fails to find a complete application space within vertical health programs on either the human or animal health side [60, 61]. Overall, the combination of validation models that do not align with contexts of use, supply-based innovation processes, market imbalances, and health systems organized into vertical programs helps explain why many solutions, although technically valid

and widely described in the literature, fail to pass the pilot or experimental phase.

From individual tests to diagnostic ecosystems

The analysis revealed that the implementation gap in POC diagnostics for zoonoses does not stem from a lack of effective technologies but rather from multiple barriers that act simultaneously along the path from research to field application. Economic, regulatory, logistical, and organizational factors combine to determine the success or failure of a diagnostic technology's adoption. Certain strategic approaches could help reduce this gap and promote greater integration of diagnostic innovations into zoonosis surveillance and control systems.

Innovation should not be limited to the platform itself, understood as the technical development of a single platform, but should encompass the network of diagnostic and logistical capabilities within which the platform operates. Creating a "diagnostic ecosystem" would mean integrating the human, veterinary, and environmental sectors through sampling sites and regional laboratories connected by standardized procedures for sample submission, diagnostic analysis, and structured workflows for reporting results. The Generalizable One Health Framework, proposed by researchers at the CDC and the Food and Agriculture Organization of the United Nations (FAO), is a fundamental, cutting-edge document in this regard. The proposed framework identifies laboratory systems as a cross-cutting pillar of zoonosis control and recommends that human, veterinary, and environmental laboratories share methods, equipment, and data wherever diagnostic procedures overlap [62]. Conceived in this way, a distributed network of interoperable tests can absorb the temporary loss of a platform, something that an isolated laboratory or a single POC platform is structurally incapable of doing.

One Health digital diagnostics

A diagnostic ecosystem becomes operationally meaningful only if the results it generates can be shared. Many modern POC platforms already feature readers connected to smartphones and the cloud. This enables near-real-time reporting, geospatial tracking of positive results, and automated quality-control telemetry, capabilities that were leveraged during the surge in OTC and POC testing throughout the COVID-19 pandemic [10]. What is lacking is not the ability to transmit results but the architecture that ensures the interconnection of data flows among the various healthcare sectors within the One Health framework.

The One Health data integration framework, recently proposed for real-time pathogen surveillance and applied genomic epidemiology, demonstrates that combining laboratory diagnostic data with epidemiological and environmental data from different sectors can generate

early warning signals that would not be produced by any single data stream [61]. Evaluating interoperability standards during the POCT design phase, rather than adding connectivity after the product is brought to market, would allow diagnostic results to automatically feed into surveillance systems.

Integration of machine learning into the proposed digital diagnostic ecosystem

Machine learning (ML) could further strengthen One Health digital diagnostics by enabling the integrated analysis of data generated by decentralized point-of-care (POC) platforms alongside epidemiological, environmental, climatic, genomic, and animal health datasets. Such integration is particularly relevant to One Health surveillance because the emergence of infectious diseases and antimicrobial resistance are shaped by interactions among human, animal, and environmental populations, while ML approaches can accommodate heterogeneous, high-dimensional data across these domains [63, 64]. This could allow surveillance systems to move beyond retrospective reporting towards predictive and adaptive surveillance, including the identification of transmission patterns, spatial and temporal risk prediction, and the generation of early warning signals to support targeted interventions [63, 65]. Climate- and environment-informed ML models may be particularly valuable where environmental conditions influence pathogen transmission and geographic risk [66].

Moreover, ML algorithms could facilitate the automated interpretation of diagnostic outputs and genomic data, while supporting the analysis of sequencing data for antimicrobial resistance prediction. ML-based approaches have demonstrated potential for predicting phenotypic AMR from whole-genome sequencing data, including the application of Random Forest, XGBoost, and other algorithms across multiple bacterial pathogens [67, 68]. More recent work has highlighted the potential for integrating AI with genomic and rapid diagnostic technologies to support pathogen characterization, resistome profiling, outbreak investigation, AMR prediction, and genomic surveillance [69].

Embedding these analytical capabilities within interoperable diagnostic and surveillance networks could therefore transform POC platforms from isolated diagnostic tools into components of a connected, real-time, data-driven surveillance ecosystem. This vision is consistent with global genomic surveillance strategies that emphasize connectivity among sample collection, diagnostics, data sharing, analysis, and public health response, as well as One Health guidance advocating integrated surveillance across human, animal, and environmental sectors [70, 71].

Task shifting and decentralization of diagnostic competences

The training barrier cannot be addressed solely by designing tests that require progressively fewer skills. Effective decentralization requires personnel who possess not only the operational knowledge needed to perform a test but also sufficient technical understanding to recognize errors, respond to unexpected conditions, and troubleshoot problems when specialized support is unavailable. This capacity is particularly important in rural and remote settings, where operators may work independently and under variable infrastructural conditions. “Task shifting” defined as the structured transfer of diagnostic tasks from specialized personnel to appropriately trained healthcare workers, has already been shown to be feasible in point-of-care settings in low- and middle-income countries. A systematic review showed that targeted training of healthcare workers without ultrasound experience enabled them to acquire and interpret diagnostic images with significant clinical impact [72]. The recurring constraints identified by the authors were poor connectivity for remote supervision, training costs, and an unstable power supply [72]. Successful decentralization therefore requires more than simplified diagnostic platforms; it requires a sustainable workforce-development model that combines standardized training, competency assessment, continuing supervision, technical support, and streamlined workflows for healthcare and veterinary personnel, particularly in resource-limited rural and remote settings.

Modular and adaptable diagnostic platforms

The so-called “pipeline losses” reflect a recurring pattern in which research and industry shift attention and resources to a promising new platform before the previous one has been fully implemented in the field [55]. This phenomenon is partly due to modular and reconfigurable platforms, because many diagnostic devices are designed to identify a single, specific target. In contrast, modular and reconfigurable platforms that can adapt to new pathogens by replacing reagents, cartridges, or primer sets, while keeping the hardware, sample preparation procedures, and readout systems, could extend the operational lifespan of diagnostic technologies and preserve investments in infrastructure, equipment, and workforce training. A single adaptable platform could therefore address multiple and changing public health priorities without requiring replacement whenever a new pathogen emerges, or diagnostic priorities shift.

Existing multiplex POC devices, capable of simultaneously detecting multiple respiratory viruses from a single cartridge by modifying the amplification targets, demonstrate that this approach is already technically feasible [73]. Extending this principle to

zoonotic surveillance would favor platforms built on flexible detection architectures rather than a single priority pathogen, allowing assays to be reconfigured in response to evolving epidemiological needs. This would help reduce the costs of designing new devices for each emerging threat and limit the tendency to prematurely abandon technologies that are still potentially useful.

Toward a unified regulatory framework through policy integration

Within the Quadripartite alliance of FAO, UNEP, WHO, and WOA, although diagnostic regulation does not yet constitute a dedicated line of action, the “One Health Joint Plan of Action” already assigns this collaboration a clear coordinating role across the human-animal-environment interface [74]. A model of what a unified approach might look like was developed by the EFSA through a multi-criteria decision analysis among Member States to classify zoonoses with a view to establishing a coordinated, cross-sectoral surveillance system. Pathogen- and surveillance-related criteria were defined in an integrated manner for both the human and animal health sectors, rather than developed separately. The priority list includes diseases such as Crimean-Congo hemorrhagic fever, echinococcosis, hepatitis E, avian and swine influenza, Lyme disease, Q fever, and West Nile fever. This list serves to guide surveillance strategies by considering the overall health of humans and animals, rather than focusing solely on the rules of a specific sector [75]. This logic should be extended to the diagnostic field towards a single, jointly evaluated authorization pathway for zoonotic POC platforms.

Globally, national and regional frameworks are emerging that could lead to a unified approach. The NOHF program in the United States and PAHO’s regional “One Health” policy, discussed previously, respectively identify laboratory capacity as one of seven coordination objectives [5] and map veterinary public health and surveillance initiatives in Latin America and the Caribbean [7]. Incorporating a dedicated diagnostic workstream into the existing Quadripartite architecture, rather than creating a parallel governance body, would be the most realistic path toward the unified authorization process outlined here.

Discussion

What has been discussed so far points to the need to view diagnostics not as a supplementary tool for enhancing health systems’ capabilities, but as the operational hub linking surveillance, early detection, and pandemic preparedness in practice. Within a One Health framework, efforts to strengthen disease surveillance and management are incomplete and ineffective if diagnostic capacity, understood as logistical, structural, and managerial infrastructure, remains limited and fragmented. The broadly defined ecosystem model

discussed thus far is particularly valuable in rural and peripheral contexts, where connectivity, decentralization, adaptability, and joint regulation make all the difference (Figure 2).

The importance of strengthening diagnostic capacity in these settings extends beyond local disease management. Rural and remote areas may combine frequent interactions among livestock, wildlife, and humans with limited diagnostic infrastructure and surveillance coverage, creating conditions in which zoonotic threats can remain undetected or be recognized only after substantial spread. In an increasingly interconnected world, however, geographic remoteness does not equate to epidemiological isolation. International trade and the continuous movement of people, animals, food products, and other goods can rapidly connect locally emerging infections to distant populations. Consequently, gaps in zoonotic disease detection in underserved or geographically remote areas should be regarded not only as local surveillance weaknesses but also as vulnerabilities in global health security.

Although many of the examples discussed in this manuscript are drawn from European and international contexts, the gap between diagnostic innovation and effective implementation spans diverse geographic, socioeconomic, and regulatory settings. Bridging this gap, therefore, requires a globally coordinated strategy rather than a regionally limited one for developing the diagnostic ecosystem.

Geographic isolation does not, however, imply epidemiological isolation: transportation networks, international trade, and the movement of people, animals, and goods can rapidly transform a localized emergence event into a cross-border threat, with consequences for public health, food safety, and economic stability. Strengthening diagnostic capacity and epidemiological surveillance in resource-limited settings should therefore be viewed not only as a means of improving local disease control, but as an integral component of global preparedness and prevention of future public health emergencies [41, 43].

Trade-offs and feasibility constraints

None of the approaches proposed in this manuscript, nor those that will be proposed and integrated in the future, is sufficient on its own. The true value of the proposed approach lies in viewing them as goals to be achieved collectively and as interacting components within the same system, rather than as independent solutions. The proposed strategies also present challenges that must not be overlooked; widespread digital diagnostics within a One Health framework require reliable connectivity and adequate electrical infrastructure, conditions that remain lacking in many rural and resource-poor areas. Similarly, task shifting can be an effective solution only if

accompanied by ongoing investment in staff training, supervision, and continuing education. Without stable support, there is a risk of perpetuating dependence on

external funding, which has already limited the sustainability of numerous pilot projects [41].

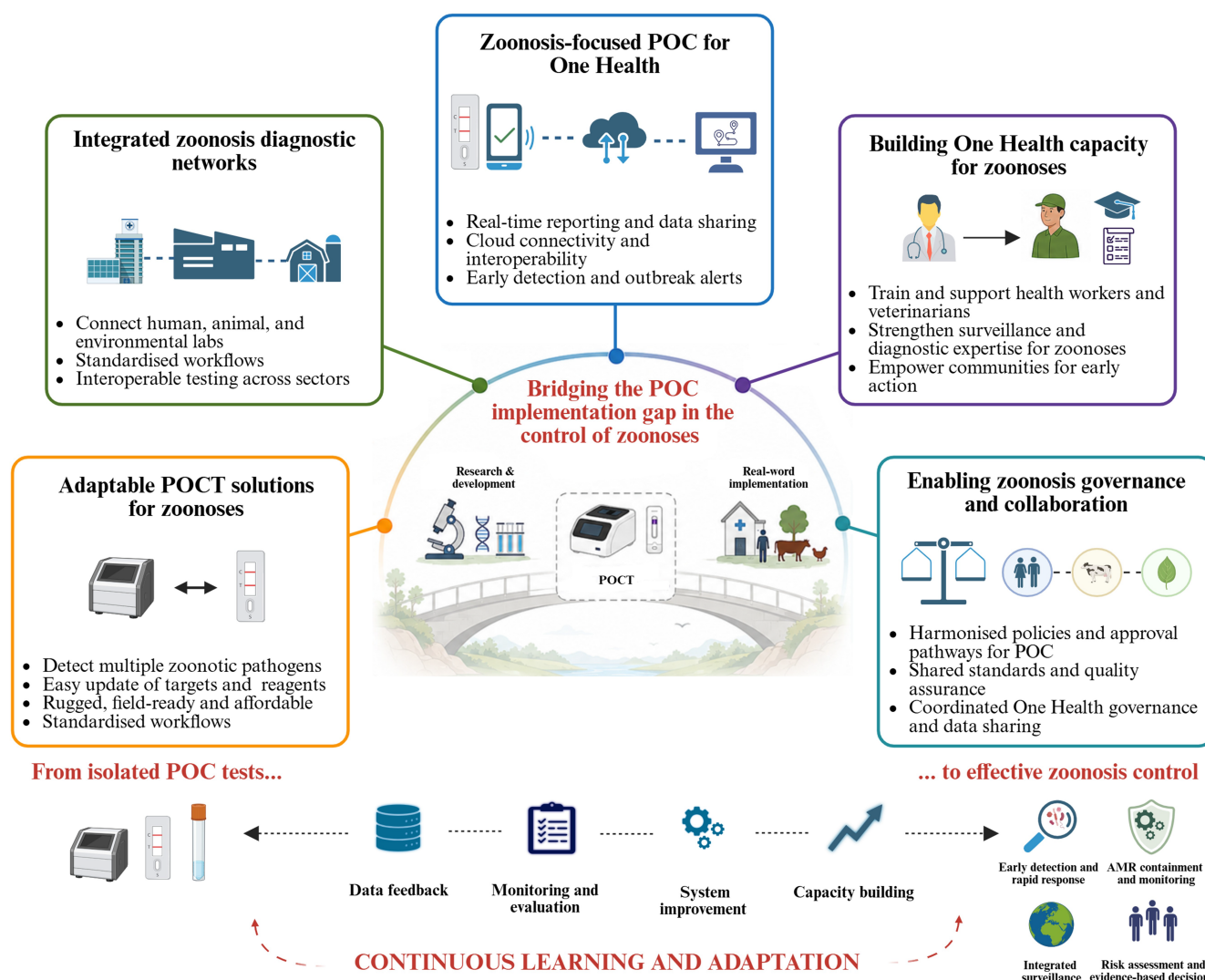


Figure 2: One Health diagnostic ecosystem for implementation of point-of-care testing (POCT) in zoonotic disease surveillance and control. The framework integrates adaptable POC technologies with diagnostic networks, real-time data connectivity, trained human and veterinary personnel, and coordinated governance to bridge the gap between research and real-world implementation. Continuous data feedback, monitoring, system improvement, and capacity building support iterative adaptation and strengthen integrated surveillance, early detection, outbreak response, antimicrobial resistance monitoring, and evidence-based decision-making.

Even the idea of a shared regulatory framework between human and veterinary medicine, while offering clear advantages in integration and implementation speed, faces challenges due to the complexity of existing regulatory systems. Greater harmonization would, in fact, require a high level of coordination among authorities across sectors and jurisdictions, with inevitable administrative and political implications. These difficulties do not call into question the validity of the proposed approach, but they highlight that its success depends not only on technological innovation but also on the ability to build stable collaboration among disciplines,

institutions, and levels of governance. In other words, progress in One Health diagnostics requires organizational and cultural change at least as much as technical development.

Conclusions and future perspectives

The objective of this study is to understand why POC diagnostic technologies for zoonotic diseases, despite technological advances, have not yet achieved widespread and sustainable adoption in the settings where they are most needed. Technologies already in use in some settings, extensively discussed in recent literature and

considered the most promising, as noted in the previous chapter, have demonstrated their ability to provide reliable results and contribute to epidemic management and surveillance. The problem, therefore, does not seem to lie so much in the performance of technologies as in the conditions that determine their adoption and use. Validation processes that do not adequately reproduce real-world operating conditions, innovation models that do little to address local needs, limited commercial interest in many zoonotic diseases, fragmentation between human and veterinary health systems, frequently underestimated maintenance and training costs, and non-integrated regulatory procedures all contribute to the gap between technological innovation and field implementation.

For this reason, this paper considers zoonotic POC diagnostics as part of an ecosystem in which technologies, people, infrastructure, data, and governance are closely interconnected. Continued scientific and technological innovation remains essential, but innovation alone cannot substitute for a fundamental requirement of effective surveillance: the ability to identify a pathogen early directly influences the effectiveness of epidemiological surveillance, containment measures, and response strategies. Diagnostic capacity should therefore be regarded as foundational infrastructure for preparedness rather than as a downstream product of technological innovation. If decentralized diagnostic capacity continues to be the system's weakest link, especially in regions where the risk of zoonotic spillover is highest, many of the principles of the One Health approach will remain difficult to translate from conceptual principles into operational practice.

This work does not claim to provide an exhaustive analysis of existing gaps or to definitively identify strategies for addressing them; rather, it proposes a framework that situates zoonotic diagnostics within a complex ecosystem. Although this discussion is intended to provide a conceptual foundation for future studies, pilot programs, and regulatory initiatives, its primary objective is to promote an open, interdisciplinary dialogue on the subject. Only through dialogue among the scientific community, institutions, human and veterinary health professionals, and other stakeholders will it be possible to identify shared solutions that bridge the gap between technological innovation and real-world application.

Limitations of the perspective

The cases presented in this manuscript were selected to highlight recurring patterns, not to provide an exhaustive and quantitatively representative survey of technical limitations and implementation barriers. Such an analytical and comparative approach would have been more appropriate for a systematic review. This perspective, however, aims to offer an original viewpoint

and a direction for the future, rather than a detailed analysis or a comparative evaluation of current policies. Although the first part presents recent examples in which the implementation of POC devices was managed efficiently and yielded good diagnostic results, this article is intended to be a critical analysis of the current barriers to implementation. In this regard, unresolved gaps and bottlenecks are discussed in greater detail than the less prominent success stories. The resulting picture may therefore overestimate the prevalence and severity of implementation failures relative to incremental progress that is genuinely occurring but remains underreported in scientific literature, precisely because routine success rarely generates dedicated publications. This does not invalidate the barriers discussed in this manuscript, but it suggests that the picture presented here should be read as an illustration of a structural pattern rather than as an exhaustive account of successes and failures across the sector. The CRISPR case discussed in a previous section was deliberately included for this reason: published literature offers a steady stream of studies documenting analytical validation and proof-of-concept success, while structured accounts of implementation failure remain comparatively scarce. This imbalance risks creating a misleadingly optimistic frame of reference against which the critique presented in this manuscript might otherwise be evaluated.

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