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The double-edged role of point-of-care testing in modern medicine

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ABSTRACT

Point-of-care testing (POCT) has emerged as a transformative force in clinical diagnostics, enabling rapid, near-patient testing that can expedite decision-making, improve patient outcomes, and expand access to care. This review critically examines the double-edged nature of POCT, balancing its clear clinical and operational advantages against persistent challenges of accuracy, quality assurance, governance, and cost-effectiveness. The scope of POCT technologies ranges from simple lateral-flow assays to advanced molecular platforms, increasingly integrated with digital health ecosystems. Their clinical utility is evident in emergency medicine, chronic disease management, and resource-limited settings, where timely results reduce delays, hospital stays, and downstream complications, while supporting personalized and preventive care. The COVID-19 pandemic further highlighted the flexibility and scalability of POCT during public health emergencies. However, these benefits are countered by risks of variable analytical performance, inadequate training of non-laboratory operators, fragmented data integration, and economic trade-offs from high per-test costs and potential overuse. Governance frameworks—anchored in ISO 22870 (and now ISO 15189:2022), rigorous quality management, connectivity solutions, and multidisciplinary oversight—are essential to ensuring safe, effective, and sustainable implementation. Successful programs demonstrate that strong laboratory leadership, continuous training, and robust data integration mitigate risks while maximizing impact. Ultimately, POCT should be viewed not as a replacement but as a complement to central laboratory services, whose value is realized only through thoughtful deployment and governance. With advancing technology and improved oversight, POCT can be harnessed as a powerful adjunct in modern healthcare, turning its double-edged potential into a precise tool for patient-centered diagnostics.

1. Introduction

Point-of-care testing (POCT) refers to diagnostic testing performed at or near the site of patient care, rather than in centralized laboratories [1]. Over the past few decades, POCT has transformed the diagnostic landscape, driven by technological innovations, the push for rapid clinical decision-making, and the pursuit of more accessible, patient-centered healthcare [2] By providing rapid results without the need for sample transport, POCT can significantly reduce turnaround time (TAT), enabling prompt medical decisions and timely interventions that improve clinical outcomes [3].For example, in emergency and critical care settings where minutes matter, immediate bedside test results (such as cardiac biomarkers) can expedite diagnosis and treatment, leading to earlier interventions and potentially saving lives [4]. The growth of POCT aligns with broader trends in healthcare: decentralization of services, patient empowerment through self-monitoring, and digital integration of medical data [2,3].

Recent utilization data underscore how widely POCT has been embedded into day-to-day clinical practice. In a 2025 national survey of all 71 Swedish hospital emergency departments, every site reported access to POCT blood gas analysis and haemoglobin, and POCT was used in up to 80 % of patients in some hospitals [5].Similar expansion is seen in primary care and chronic-disease management, where POCT supports rapid diagnosis, monitoring and stewardship of scarce resources. As POCT becomes ubiquitous, ensuring that these devices are implemented within robust governance and quality-management frameworks is increasingly critical.

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In line with the consolidation of ISO 22870 into ISO 15189:2022, this review considers POCT as an integral component of the laboratory's accredited service, rather than as a separate or optional activity at the clinical interface.

Despite these advantages, the widespread adoption of POCT also raises critical questions about test accuracy, quality assurance, cost-effectiveness, and the changing role of laboratory professionals in healthcare delivery. Many POCT devices are operated by clinicians or patients with limited laboratory training, which introduces variability and potential for error if not carefully managed [2,6]. Inconsistencies in quality control, data management, and regulatory oversight are ongoing concerns that underscore the *double-edged sword* nature of POCT – offering significant clinical benefits while posing new challenges to diagnostic governance. This review provides a detailed, research-oriented examination of the technical scope of POCT, its clinical advantages, the limitations and challenges it presents, and strategies for effective implementation and governance.

2. Technical overview and scope of POCT technologies

2.1. Range of technologies and modalities (Table 1)

Modern POCT encompasses a broad array of technologies, from simple disposable test strips to sophisticated molecular platforms. At the simpler end, qualitative or semi-quantitative tests such as urine dipsticks and lateral-flow immunoassays (e.g. at-home pregnancy tests) detect analytes via chemical reactions or antigen-antibody binding that produce a visual readout [1]. These tests are designed to be easy to use, with results indicated by color changes or line appearances, and have become ubiquitous in settings such as clinics and homes. More advanced POCT devices utilize miniaturized electrochemical and optical sensors, microfluidic chips, and embedded reagents to perform complex assays on small sample volumes [1,7]. For instance, handheld blood glucometers use enzymatic electrochemical methods to quantify glucose from a fingerstick drop of blood within seconds, while cartridge-based analyzers can measure blood gases, electrolytes, or cardiac enzymes at the bedside [1,8]. On the larger end of the spectrum, portable benchtop analyzers (often wheeled between hospital units) are capable of multi-test panels – for example, measuring markers such as haemoglobin A1c, C-reactive protein, or coagulation parameters near the patient [1,8]. The ongoing trend in POCT device development is toward greater integration and miniaturization: lab-on-a-chip systems aim to automate entire laboratory workflows (sample preparation, reaction, detection) on a micro-scale device, bringing laboratory-grade testing to the point of care [8].

2.2. Molecular POCT and emerging innovations

In recent years, there has been rapid progress in molecular POCT. Portable nucleic acid amplification test (NAAT) platforms enable detection of DNA/RNA of pathogens (e.g. influenza, HIV, SARS-CoV-2) within about 15–30 min, bypassing the need for centralized PCR labs [1,9,10]. These molecular POCT devices (such as cartridge-based RT-PCR or isothermal amplification systems) offer higher sensitivity than antigen tests and have been deployed in clinics and even rural areas for infectious disease diagnosis [11,12]. However, they often require battery power or electricity and may have slightly longer turnaround times than simpler antigen kits [1]. Technological advancements such as improved microfluidics, biosensors, and nanomaterials are continually enhancing the accuracy and speed of POCT devices [3,8]. For example, microneedle-based minimally invasive sampling and nanotechnology-enabled biosensors are being integrated into new devices to detect biomarkers with high sensitivity [1,13,14]. Researchers are also exploring novel approaches, such as aptamer-based electrochemical sensors for cancer biomarkers at the point of care, illustrating that POCT is extending beyond traditional uses into oncology and other fields [8,15].

Table 1
Selected diagnostic applications of point-of-care testing (POCT) beyond COVID-19.

Clinical area/setting	Example POCT analyte(s) or panel	Clinical application	Key clinical impact (s)
Acute coronary syndrome in ED and chest-pain units	Cardiac troponin I/T POCT, ± basic chemistry	Rapid rule-out/rule-in of myocardial infarction within structured protocols	Shorter time to treatment decision and discharge; potential reductions in re-attendance when embedded in validated pathways [26,39]
Sepsis and critical illness (ED/ICU)	Lactate, arterial/venous blood-gas, electrolytes, haemoglobin	Early risk stratification, optimisation of resuscitation, guidance of ventilation and haemodynamic support	Faster recognition of life-threatening derangements; improved protocol compliance for sepsis bundles; supports safe treatment in resource-constrained settings [5,32,34,35]
Respiratory infections and antimicrobial stewardship (primary care, ED)	C-reactive protein (CRP), procalcitonin, rapid influenza/RSV antigen tests	Differentiation of likely viral vs bacterial infection, triage for antibiotics and hospital referral	Reduced inappropriate antibiotic prescribing; improved targeting of antivirals; cost-effective reduction in antibiotic use in several settings [25,27]
Diabetes and metabolic disease (primary care, specialist clinics)	Capillary glucose, HbA1c, capillary ketones	Diagnosis and monitoring of diabetes, detection of diabetic ketoacidosis	Immediate therapy adjustments; improved glycaemic control when HbA1c POCT is linked to treatment intensification at the same visit [33]
Haemostasis and anticoagulation monitoring	INR, activated clotting time, anti-Xa assays	Peri-procedural management, warfarin monitoring, assessment before thrombolysis	Enables rapid risk–benefit decisions in emergency settings (e.g. stroke thrombolysis); supports decentralized anticoagulation clinics [39]
Infectious diseases in remote and low-resource settings	HIV, hepatitis B/C, syphilis rapid tests; molecular POCT for STIs and TB	Decentralized diagnosis and linkage to care close to the patient	Improved case detection and earlier treatment; in some programmes, facilitated by national connectivity for automated reporting and surveillance [28]

2.3. Connectivity and data integration

A critical technical aspect of modern POCT is the integration of devices with data management systems. Unlike the closed-loop of a central laboratory information system, POCT results historically were often recorded manually, leading to risks of transcription error or loss of data [16]. Today, many POCT devices feature connectivity (wired or wireless) that can automatically transmit results to electronic medical records (EMRs) or laboratory information systems. Standards such as the CLSI POCT1-A data protocol and device management middleware allow multiple devices and testing sites to feed into a unified database

[17].This ensures that POCT results are immediately available to the care team and become part of the patient's permanent record, improving continuity of care. However, implementation of connectivity is uneven – it is estimated that historically only around 10 % of POCT results were being captured electronically, owing to the siloed and decentralized nature of POCT programs [17].As health systems adopt dedicated POCT data management solutions, the goal is to close this gap so that point-of-care results are as integrated and traceable as central lab results, complete with quality control information and clinician notifications for critical values [16].

In summary, the scope of POCT technologies ranges from simple, low-cost tests to complex diagnostic instruments, all characterized by their proximity to the patient and rapid output of results. This breadth of technology enables POCT to be used in diverse settings including hospitals, outpatient clinics, physician offices, pharmacies, ambulances, nursing homes, and even patient households [1,8]. The technical evolution of POCT continues to blur the line between laboratory and bedside, offering increasingly powerful diagnostic capabilities at the point of need.

3. Clinical advantages of POCT

POCT offers multiple well-documented clinical advantages that can improve patient care and system efficiency (Table 2). Key benefits include:

3.1. Rapid turnaround time and clinical impact

The most frequently cited advantage of POCT is the significant reduction in turnaround time (TAT) for test results, which can translate directly into improved clinical decision-making and outcomes [3,18]. By delivering results within minutes rather than hours or days, POCT enables immediate therapeutic interventions. In emergency departments and intensive care units, this speed is often critical. For example, rapid bedside measurement of cardiac troponin in patients with chest pain allows clinicians to diagnose or rule out myocardial infarction much faster than waiting for central lab results [19]. Studies have shown that using point-of-care troponin assays in the ED can lead to faster diagnosis of non-ST elevation myocardial infarction (NSTEMI), enabling earlier initiation of appropriate treatment and improving emergency department flow [4]. One preliminary report from 2025 demonstrated that implementing a high-sensitivity troponin POCT in pre-hospital and ED settings significantly shortened the patient's length of stay in the ED (by over two hours on average) compared to the usual lab-based protocol [4].Similar impacts are seen in critical care scenarios such as sepsis management, where immediate lactate or blood gas results guide urgent interventions.

Beyond acute care, rapid results improve efficiency in various settings. In outpatient clinics, on-site POCT (for example, a fingerstick HbA1c for diabetes or D-dimer for suspected thrombosis) can allow diagnosis and management to occur in the same visit, avoiding delays or the need for follow-up appointments. [20] The prompt availability of results prevents the loss of patients to follow-up and reduces anxiety from waiting [21]. Randomized trials and meta-analyses provide evidence that using POCT in appropriate scenarios can indeed improve patient outcomes. A review of multiple trials found that integrating certain POCT into clinical pathways led to more timely treatment adjustments and, in some cases, better health metrics for patients (e.g., improved glycaemic control in diabetes, faster antibiotic administration in sepsis) [1]. Overall, the ability of POCT to produce rapid, actionable results is a cornerstone benefit that underlies many of its other advantages.

Table 2
Clinical Advantages of Point-of-Care Testing (POCT).

Domain	Examples	Impact
Rapid turnaround	Cardiac troponin, lactate, blood gases	Faster diagnosis, earlier intervention, reduced ED stay
Accessibility	Malaria rapid test, GeneXpert TB, glucose meters	Improved care in rural/underserved areas
Patient-centered care	Home INR monitors, HbA1c in clinic	Empowerment, reduced loss to follow-up
Cost-effectiveness	CRP for respiratory infections, influenza POCT	Fewer unnecessary antibiotics/tests, reduced hospitalization
Public health emergencies	COVID-19 rapid antigen and molecular tests	Scalable outbreak response, faster isolation

3.2. Improved accessibility and patient-centered care

POCT brings diagnostic capabilities closer to the patient, which is particularly beneficial in settings with limited access to traditional laboratories. In rural or resource-limited areas, a central lab may be hours or days away; here, portable POCT devices enable on-site diagnosis that would otherwise be impractical. For instance, in remote clinics without on-site labs, POCT for infectious diseases (like malaria rapid tests or GeneXpert cartridges for tuberculosis) can guide immediate treatment and this has been shown to improve health outcomes by reducing delays [21]. Even in developed healthcare systems, POCT can fill gaps – such as providing after-hours or weekend testing in small hospitals where the main laboratory is closed, or offering on-the-spot testing in primary care practices and pharmacies. By decentralizing diagnostics, POCT improves healthcare accessibility and convenience for patients, aligning with patient-centered care principles [1].

The portability of POCT devices allows testing in non-traditional environments, further extending reach. Paramedics use handheld devices in ambulances to begin critical tests (like glucose, troponin, or haematocrit) en route to the hospital, potentially speeding up treatment upon arrival. [22] Pharmacies and retail clinics employ POCT for quick strep throat swabs or lipid panels, expanding community access to basic diagnostics [23]. Home use POCT – such as home pregnancy tests, ovulation tests, or home INR monitors for patients on warfarin – empower patients to manage their health with greater independence. By eliminating travel and logistical barriers, POCT engages patients in their own care. Studies note that this decentralization and patient empowerment can improve satisfaction and adherence; for example, chronic disease patients who can perform certain tests at home report feeling more in control and are more likely to follow through with management plans [21].

Importantly, improved access through POCT also helps address healthcare inequities. Marginalized or vulnerable populations (such as those in remote indigenous communities or underserved urban areas) benefit when diagnostic services are brought to their vicinity. Evidence from international programs has shown that implementing POCT in community clinics or via mobile health units increases screening and diagnosis rates for conditions like HIV, diabetes, and hepatitis, which in turn facilitates earlier treatment [21]. Thus, POCT serves as a tool for widening healthcare access and delivering more equitable care.

3.3. Potential for reduced healthcare costs

Although individual POCTs often have a higher per-test cost than identical assays run in bulk on automated lab analyzers, POCT can be cost-saving at the system level by improving efficiency and preventing unnecessary expenditure [3,8].The economic benefits of POCT derive from multiple factors. First, rapid results can shorten hospital stays and reduce inpatient days. For example, quicker rule-out of myocardial infarction via POCT troponin or quicker identification of low-risk chest pain patients can lead to earlier discharge from the emergency department or observation unit, translating to cost savings in bed occupancy

[4]. A modelling study on implementing POCT in an ED chest pain pathway found that even if the test cost was higher, the overall cost was offset by reduced use of hospital resources and staff time.

Second, POCT can prevent downstream costs by enabling timely intervention and avoiding complications. In diabetes management, point-of-care HbA1c testing during clinic visits allows immediate intensification of therapy for patients with poor control, potentially reducing long-term complications (and their associated costs) by improving glycaemic control faster than conventional lab testing which might take weeks for feedback [21]. In primary care, using a POCT C-reactive protein (CRP) test in patients with respiratory infections has been shown to safely reduce unnecessary antibiotic prescriptions, which not only curbs drug costs but also helps prevent antibiotic resistance and medication side effects [2]. Similarly, rapid identification of influenza or RSV via POCT in emergency settings can reduce costly ancillary testing (like chest X-rays or blood cultures) and unnecessary antibiotic use for viral illnesses. [24]. A review of studies in paediatric ERs reported that in the majority of analyses, availability of rapid viral test results was associated with lower antibiotic use and fewer additional diagnostic tests, contributing to both clinical and economic benefits [24].

Third, by providing results on the spot, POCT can reduce the need for return visits or referrals. For example, immediate INR (blood coagulation) results from a portable coagulometer allow anticoagulation clinics to adjust warfarin doses in one sitting; this minimizes repeat clinic visits and phlebotomy, which is both cost-effective and convenient. In aggregate, while POCT reagents are more expensive, the improved operational efficiency (shorter visits, reduced follow-up testing), avoidance of adverse events, and better allocation of healthcare resources can lead to a net reduction in healthcare costs in appropriate scenarios [8]. Indeed, economic analyses and trials in primary care and hospital settings have identified specific use-cases where POCT is cost-effective or cost-saving (such as managing chronic conditions and triaging emergency patients) [3,8].It should be noted, however, that realizing these savings depends on thoughtful implementation – indiscriminate use of high-cost POCT where it is not clinically indicated could conversely increase costs, a point addressed later in the section on challenges.

Formal health-economic evaluations provide quantitative support for these cost-related benefits. A systematic review of POCT health-economic studies reported that approximately three quarters (77 %) of evaluations concluded in favour of implementing POCT strategies once both direct and downstream costs were considered, although the magnitude of benefit was highly context-dependent [25]. In the emergency department, a secondary analysis of a randomized controlled trial showed that an ‘upfront’ POCT workflow reduced treatment time and, once personnel time savings were accounted for, was cost-saving compared with standard laboratory-based workflows [26]. For antimicrobial resistance, a 2024 systematic review found that several POCT strategies—particularly C-reactive protein testing for respiratory infections—are cost-effective in reducing unnecessary antibiotic prescribing at commonly accepted willingness-to-pay thresholds [27]. Together, these data support the view that POCT may offer good value for money when thoughtfully integrated into care pathways, even when the per-test analytical cost is higher than that of central laboratory testing.

3.4. Support for personalized and preventive medicine

POCT is a key enabler of personalized medicine and preventive healthcare strategies. By allowing frequent and convenient monitoring of health metrics, POCT empowers patients and providers to tailor treatments to an individual's dynamic condition and to intervene early when problems arise. A prime example is in diabetes care: home glucose meters and newer continuous glucose monitoring (CGM) systems give patients real-time feedback on their blood sugar levels, which helps them and their clinicians personalize insulin dosing and diet/exercise plans. Studies have found that such patient-driven POCT improves glycaemic control and reduces emergency visits for hypoglycaemia or hyperglycaemia. The same principle applies to other chronic diseases—portable blood pressure monitors, INR testers for coagulation, and home lipid testing kits let patients participate in their own care and observe the effects of therapy, leading to more personalized management.

Beyond self-monitoring, POCT devices are increasingly integrated into digital health ecosystems. Many modern POCT devices (glucose meters, blood pressure cuffs, pulse oximeters, etc.) can synchronize with smartphone applications or web platforms. This connectivity enables longitudinal data collection and remote sharing of results with healthcare providers. For instance, a patient's home blood pressure or glucose readings can be automatically uploaded to a clinic's system, where clinicians can remotely monitor trends and adjust medications without requiring an in-person visit. Such data-driven preventive care has been shown to improve outcomes; for example, remote monitoring programs using POCT data have reduced hospital readmissions for conditions like heart failure and diabetes by detecting early warning signs and prompting timely interventions. In the context of personalized medicine, POCT can also guide therapy choices on the spot – consider pharmacogenomic POCT devices (currently emerging) that might determine a patient's genetic metabolizer status from a cheek swab, informing medication selection or dosing during a clinical encounter.

Additionally, POCT contributes to preventive public health by facilitating widespread screening. Rapid tests for HIV, hepatitis C, and other infectious diseases allow opportunistic testing in community settings, identifying asymptomatic cases that can then receive early treatment and counseling to prevent disease spread [2,21]. Home-based screening POCT (such as faecal occult blood tests for colon cancer or home HPV test kits) have increased screening uptake among populations that face barriers to traditional screening services, thereby aiding early detection of disease. All these uses position POCT as a cornerstone of personalized medicine, enabling care that is more continuous, customized, and proactive.

Beyond simple data upload, modern POCT platforms are increasingly embedded within digital-health ecosystems. National programmes for decentralized infectious-disease POCT in remote primary-care clinics have implemented dedicated connectivity solutions that automatically transmit encrypted results from cartridge-based molecular platforms (e.g. GeneXpert) to electronic medical records, laboratory information systems and public-health databases [28]. Such architectures enable real-time clinical decision-support, automated quality-management alerts (e.g. QC failures, out-of-range results) and near-real-time surveillance of outbreaks. In telemedicine and remote-monitoring models, POCT results obtained at home or in community clinics can be combined with physiological and symptom data from apps or wearables to support virtual reviews, illustrating how POCT is becoming an integral component of broader digital care pathways rather than a stand-alone device at the bedside.

3.5. Flexibility during public health emergencies

The COVID-19 pandemic unmistakably demonstrated the value of POCT in an emergency public health context. When faced with a highly infectious disease spreading rapidly, healthcare systems worldwide turned to POCT—specifically rapid antigen and molecular tests for SARS-CoV-2—to vastly expand testing capacity and speed [3]. These tests, deployable at testing sites, clinics, nursing homes, and even at home, provided results in minutes and became crucial tools for screening, triage, and outbreak control. Studies estimate that billions of COVID-19 POCT kits (both professional-use and home-use) were produced and utilized globally, illustrating how POCT can scale up in a crisis to meet surging demand [1]. By identifying contagious individuals quickly, POCT helped isolate cases faster and reduce transmission in communities and congregate settings.

In situations where laboratory infrastructure was overwhelmed or inaccessible due to surges in testing volume, the portability and simplicity of POCT proved indispensable. Moreover, POCT did not require complex supply chains (e.g. transporting specimens to labs) and thus offered a degree of resilience when lockdowns and logistical challenges disrupted normal lab operations. The pandemic experience also highlighted the importance of integrating POCT results into public health reporting systems for effective response, a task that many regions accomplished by rapidly establishing digital reporting apps for at-home tests or connectivity for clinic-based kits [21].

Beyond COVID-19, the general lesson extends to other public health emergencies: in outbreaks of emerging infectious diseases (Ebola, Zika, etc.) or in natural disasters that incapacitate labs, POCT can fill the diagnostic void. For example, during humanitarian crises or remote field operations, portable POCT devices for key tests (like electrolyte measurement, haemoglobin, or pathogen detection) enable continued medical care when standard labs are not functioning. In summary, POCT offers flexibility and rapid deployability that strengthen health system responsiveness in emergencies. Its role in pandemic preparedness is now recognized, with calls for establishing protocols and stockpiles for rapid point-of-care diagnostics as part of future outbreak response frameworks [21,29].

4. Limitations and challenges of POCT

Despite its many benefits, POCT also presents several important limitations and challenges that must be addressed to ensure its safe and effective use (Table 2). The key challenges include:

4.1. Variable analytical accuracy and reliability

POCT devices, while improving in quality, often have lower analytical sensitivity or precision compared to central laboratory instruments for the same tests. The convenience of rapid, bedside testing can come at the cost of small trade-offs in accuracy. Multiple factors contribute to this: simplified device design (to enable quick use by non-experts), smaller sample volumes, and environmental influences in non-laboratory settings can all impact test performance [8]. For example, many handheld glucometers are known to have measurement variability; studies have found that individual glucose meters can vary by 10–20 % (or more) between devices or compared to the laboratory standard [2,30].One analysis noted coefficients of variation ranging from ~4 % up to 33 % among different hospital glucose meters, and even a modest 5 % analytical error rate could lead to insulin dosing errors in nearly a quarter of cases in tight control protocols [2,31]. Such variability means a POCT result might occasionally misclassify a patient's status (e.g., a glucose reading high or low enough to alter insulin dosing). Likewise, rapid antigen tests for infections (like COVID-19 or influenza) sacrifice some sensitivity for speed and ease of use, leading to more false negatives than gold-standard lab PCR tests [8].False positives can occur too, as seen with certain rapid infectious disease kits that cross-react or pick up residual antigens.

Operator technique and user error are also significant factors in POCT reliability. Unlike a controlled lab environment with skilled technicians, POCT may be performed by a range of personnel (nurses, physicians, paramedics, or patients themselves) who might not always follow the exact protocol. Variations in sample collection (insufficient sample or improper handling), timing (reading a lateral flow test too early or too late), or device operation can introduce errors. A study in a neonatal unit, for instance, found that one operator's POCT glucose results had a much lower bias compared to lab values than three other operators, indicating that human technique was influencing the accuracy [16]. Environmental conditions such as ambient temperature or humidity can further affect some POCT devices (for example, extreme cold or heat can impair chemical reactions or reader optics). All these issues underscore the tension between **convenience and accuracy**: while POCT provides speed and access, clinicians must remain aware of the performance limits. They should confirm critical or unexpected POCT results with laboratory testing when appropriate, and manufacturers as well as oversight bodies must continue to improve and validate the analytical performance of point-of-care devices [8].

4.2. Quality control and regulatory oversight

Ensuring consistent quality in decentralized testing environments is a major challenge. In traditional laboratories, rigorous quality control (QC) procedures, proficiency testing, maintenance schedules, and regulatory standards (e.g., ISO 15189 accreditation or CLIA certification in the U.S.) are in place to guarantee test reliability. In the POCT setting, such controls are harder to enforce across many devices and operators scattered throughout a hospital or across clinics [2].POCT is often performed by non-laboratory personnel with limited training in laboratory techniques, which increases the risk that QC protocols (like running control samples daily or calibrating devices) may be under-prioritized or performed incorrectly [2]. For example, many CLIA-waived tests (considered simple enough for bedside use) do not legally require routine proficiency testing, so a clinic might use a glucometer or rapid strep kit for years without an external performance check [1]. If operators skip even manufacturer-recommended QC (such as running control solution for a glucometer with each new test strip lot), errors can go unnoticed until they affect patient care.

Regulatory oversight frameworks for POCT exist but can be inconsistently applied. CLIA in the United States classifies most POCT as "waived" (low complexity), but still mandates basic elements like following manufacturer instructions and perhaps some minimal training [1]. Many institutions voluntarily impose stricter oversight: for instance, hospital laboratory departments may run an internal QC program for all POCT devices used in their institution, including periodic competency assessments for every operator [1]. Internationally, the ISO 22870 standard provides specific requirements for POCT as an extension of the medical laboratory quality system [2]. Achieving ISO 22870 accreditation requires demonstrating control over method validation, training, QC, and quality assurance for all POCT devices – a challenging task, but some large hospitals have successfully done so, improving their POCT performance as a result [2]. Studies and experience highlight critical areas for POCT quality management: rigorous method verification when implementing a new POCT device (to ensure it correlates with laboratory method), daily internal QC and periodic external quality assessment, documentation of all results and QC, and continual training and competency checks for staff [2,16]. When these elements are neglected, the risk of diagnostic error increases, potentially undermining patient safety. For example, an investigation in one hospital found that operators who rarely performed QC on their glucose meters produced results with significantly greater imprecision, directly linking poor QC compliance to poorer test accuracy [16].

In summary, maintaining laboratory-level quality in a point-of-care context requires strong governance. Without robust oversight, including clear protocols, training, and accountability, POCT can yield erroneous results that may lead clinicians astray. This challenge calls for establishing dedicated POCT coordinators or committees (often led by laboratory professionals) to oversee all POCT activities within an organization – a theme expanded upon in the governance section of this article.

4.3. Fragmentation of data and information systems

A less obvious but significant challenge of widespread POCT is the potential fragmentation of laboratory data. Central laboratories typically feed all results into a unified laboratory information system (LIS), which interfaces with the hospitalelectronic medical record (EMR).

This integration allows for longitudinal tracking of patient results, cumulative reporting, and inclusion in health record summaries, all of which facilitate continuity of care, clinical auditing, and public health surveillance. POCT results, however, have historically often been siloed – recorded only in a patient's paper chart or a device memory, and not always transmitted to the central record systems. Inconsistent documentation is a known issue: if a nurse performs a bedside test and communicates the result verbally without entering it into the EMR, that data point might never be captured formally. Manual transcription errors are another risk when POCT results are written down and later input by hand into records. For example, a glucose result of "2.5" could be accidentally charted as "25" or a positive/negative could be misrecorded, with potential clinical consequences.

Even when documentation is done, lack of integration means POCT results may not be readily visible to all providers or included in cumulative lab reports. This fragmentation complicates patient care – clinicians might overlook a critical POCT result if it resides in a separate system or on a paper log. It also hinders clinical decision support tools that rely on complete data. Furthermore, from an institutional perspective, data silos make it difficult to monitor test utilization patterns, quality trends, or to gather statistics for epidemiological purposes. In the era of big data and health informatics, having 10–20 % of diagnostic data floating outside the main databases is a lost opportunity for analysis and population health insights [17].

Connectivity solutions are mitigating this issue by automating data capture from POCT devices. Modern POCT device management systems can achieve near-real-time transfer of results into the LIS/EMR, greatly reducing the problem of undocumented results and transcription errors [16]. In fact, guidance from professional bodies strongly recommends that institutions use electronic data management for POCT wherever possible, noting that manual documentation of POCT results is prone to error and often incomplete [16]. One guidance document pointed out the serious risk that *"clinical staff may act based on a [POCT] result that is never recorded in the patient's chart"* if manual processes fail [16]. Surveys have indicated that inadequate data management is one of the most frequently cited barriers to effective POCT implementation [21] Therefore, solving the data fragmentation challenge is a high priority: through middleware and interface standards, the goal is to ensure POCT results are seamlessly integrated just like central laboratory data. Until this is universally achieved, fragmentation remains a challenge that can impact continuity of care and the ability to oversee POCT usage at scale.

4.4. Cost considerations and economic trade-offs

From a health-system perspective, the economic impact of POCT is nuanced. On a per-test basis, many POCT assays are more costly than equivalent tests run in high-throughput central laboratories. In addition, decentralized device fleets incur ongoing costs related to connectivity, consumables, maintenance and staff training. These factors have led some stakeholders to label POCT as 'expensive'. However, when time savings, avoidance of downstream complications and reductions in unnecessary admissions or referrals are taken into account, POCT can be cost-effective or even cost-saving in specific settings [25–27]. In the emergency department, for example, upfront POCT panels have been shown to shorten time to treatment decision and decrease length of stay, with economic models demonstrating favourable incremental cost-effectiveness once personnel time and capacity constraints are accounted for [N4]. Conversely, indiscriminate use of POCT without governance—such as routine ordering of extensive panels with little clinical justification—can increase costs, encourage duplicate testing and contribute to overdiagnosis. The economic 'edge' of POCT thus depends critically on careful test selection, protocol design and alignment with clinical pathways. [8].

Healthcare administrators must consider these economics: implementing POCT widely requires not just purchasing devices, but also ongoing costs for consumables, quality control materials, device maintenance, and training of staff. Unfocused expansion of POCT without clear clinical justification may lead to redundancy (doing a rapid test and a lab test for the same analyte), thus duplicating costs. Moreover, reimbursement policies sometimes lag behind – not all point-of-care tests are reimbursed at rates that cover their costs, especially in outpatient settings, which can disincentivize their appropriate use or, conversely, burden providers who use them heavily.

Overuse of POCT is a related risk: because POCT is convenient and quick, clinicians might be tempted to order tests more liberally, including in cases with low pre-test probability or marginal utility. This could lead not only to unnecessary costs but also to potential downstream consequences of false positives (e.g., a false positive rapid test prompting more expensive confirmatory testing or treatment). Evidence from primary care in some countries has shown dramatic increases in POCT utilization; for instance, one report noted that in Denmark – an early adopter of primary care POCT – the use of POCT grew by 45 % over 10 years, and nearly half of all antibiotic prescriptions were preceded by a POCT by 2013 [2].Such trends raise concerns that widespread availability may spur testing even when not clinically indicated, highlighting the need for stewardship. If every clinic were to perform extensive panels of POCT on every patient "just in case," the costs would balloon without proportional health benefits, and the risk of incidental findings or false positives would rise.

Therefore, a challenge for health systems is to **identify where POCT truly adds value** and to restrict use to those scenarios. Economic evaluations recommend that POCT implementation be *carefully targeted* to situations where it offers a clear clinical or workflow advantage (e.g., in emergencies, or when immediate treatment decisions hinge on the result). Widespread adoption without such targeting can lead to inefficient resource allocation [8]. In practice, hospitals often create guidelines or protocols defining when certain POCT (like D-dimer, troponin, or CRP tests) should be used versus when standard lab testing is sufficient, in order to balance cost and benefit. In summary, the higher unit cost of POCT and the potential for overuse represent challenges that must be managed through policy, education, and oversight to ensure cost-effective deployment of POCT in healthcare.

4.5. Risk of over-reliance and diagnostic oversimplification

The ease and speed of POCT can inadvertently encourage a reliance on testing even when clinical judgment or delayed confirmation might suffice. Some clinicians may become inclined to order a battery of rapid tests for every patient complaint ("just to be sure"), which can **oversimplify diagnostic reasoning** and undermine the judicious use of tests. For instance, in primary care or urgent care settings, having rapid tests at one's fingertips (for streptococcus, influenza, CRP, etc.) might lead practitioners to swab and test nearly every patient with a sore throat or cough, rather than first using clinical criteria to assess pre-test probability. Over-reliance on POCT results without considering the broader clinical picture can be problematic. No test is perfect; a negative rapid test does not completely rule out disease if the clinical suspicion is high (false negatives occur), and a positive test in a low-risk patient could be a false positive. Good clinical practice demands that test results be interpreted in context, but the "quick answer" allure of POCT might sometimes short-circuit this process.

There is also a risk that clinicians may bypass critical thinking in favour of what the device says – for example, treating a patient solely based on a POCT result that could be erroneous, without confirming or correlating with symptoms. An illustrative concern is the use of POCT CRP in general practice. Studies have shown that while CRP testing can reduce antibiotic use in some adult respiratory infections, its indiscriminate use in low-risk paediatric cases did not improve outcomes and

could even distract from proper clinical evaluation [2]. In fact, an editorial noted that adding a CRP POCT in children with mild infections provided little benefit and raised questions about its utility in that population [2]. This underscores that more testing is not always better; using POCT outside of evidence-based indications can complicate decision-making or lead to unnecessary treatments.

Another aspect of oversimplification is the **potential devaluation of laboratory expertise**. As testing shifts to the point of care, some clinicians may not fully appreciate the limitations of these tests (for example, the impact of a high haematocrit on glucose meter accuracy, or the proper technique needed for a good throat swab). They might take a POCT result at face value without the caution a laboratory specialist would advise. This could result in missed confirmatory tests – for instance, relying on a single negative rapid HIV test in a high-risk exposure when follow-up testing is actually required, or trusting a single point-in-time INR from a handheld device without recognizing a possible error. Over-reliance on POCT could also reduce the habit of consulting laboratory professionals for difficult diagnostic questions, thereby isolating POCT from expert input and potentially reducing overall diagnostic quality [32].While POCT is a powerful tool, there is a human factor challenge in ensuring it augments rather than replaces sound clinical reasoning. Healthcare providers must be educated on the proper use of POCT, including understanding its performance characteristics and the importance of confirmatory testing when appropriate. Guidelines often stress that POCT should be used to complement clinical assessment, not as a standalone arbiter in cases where clinical judgment or additional tests are needed. Avoiding diagnostic oversimplification is part of the cultural shift required when integrating POCT into practice.

A further concern is that, in many settings, front-line clinicians may not fully appreciate the analytical limitations and governance requirements of POCT. Surveys and qualitative studies indicate that ownership of POCT quality is often poorly defined, with uncertainty about who is responsible for calibration, QC review, documentation of errors and corrective actions [33]. At the same time, blood gas analyzers and other POCT devices increasingly provide broad panels of results (e.g. electrolytes, metabolites, haemoglobin), which can be misinterpreted if clinicians are unaware of pre-analytical vulnerabilities such as haemolysis, sample dilution or local reference limits [34, 35]. For instance, apparently minor or undetectable haemolysis can lead to clinically relevant positive bias in potassium results on POCT blood-gas systems, with implications for the diagnosis and treatment of hyperkalaemia [34,35]. When POCT is perceived as ‘simple’ and isolated from the laboratory's quality management system, there is a real risk that misleading results will be accepted uncritically. Addressing this requires explicit communication of responsibilities, feedback on POCT quality metrics and ongoing education tailored to non-laboratory users.

4.6. Training and workforce implications

The decentralization of testing from the lab bench to the patient's bedside shifts certain responsibilities from medical technologists to a broad group of healthcare workers, raising issues of training, competency, and workforce management [2]. Most POCT is performed by individuals who are not trained laboratory scientists, such as nurses, physicians, EMTs, or even patients/family members at home. These users may have limited knowledge of the analytical processes involved in testing – for example, they might not fully understand the importance of patient preparation, correct sample collection, instrument calibration, quality control procedures, or proper result interpretation in context [2].The consequence is that without adequate training, there is a higher risk of user errors leading to inaccurate results (as discussed earlier). For instance, a nurse unfamiliar with the need to mix a sample thoroughly in a cartridge may yield an erroneous result, or a home user might misapply a drop of blood on a test strip. Training every operator is a formidable task, especially in a large hospital with hundreds or thousands of potential POCT operators rotating through shifts [17].

Competency assessment and ongoing education are equally important. Simply training staff once (during orientation or when a device is introduced) is not sufficient for long-term quality. Skills can decay, and new updates or best practices may arise. Accreditation bodies and regulators emphasize competency assessments – in fact, CLIA and other accrediting organizations outline specific competency elements for POCT operators, such as direct observation of their technique, written quizzes, and blind sample testing [1]. Many institutions now have dedicated POCT coordinators or educators who develop training programs, administer annual competency evaluations, and maintain certification records for all POCT [1,17]. This is a significant operational undertaking that effectively creates a new domain of workforce management within healthcare settings.

The expansion of POCT also creates a need for **clear roles and accountability**. Who is responsible for the oversight of POCT in a facility? Best practices suggest forming a multidisciplinary POCT committee (often led by the laboratory department) that sets policies, evaluates new test requests, and monitors quality indicators [1]. On the ground, point-of-care coordinators (often medical technologists) serve as liaisons between the laboratory and clinical teams, ensuring that devices are maintained, QC is performed, and operators are following procedure. However, not all institutions have allocated full-time positions for this, which can strain existing staff. A survey in Canada found that more than half of hospitals cited insufficient staffing to support their POCT programs as the number one problem [16].

From the perspective of laboratory professionals, the rise of POCT can lead to concern that their expertise is being bypassed or undervalued, potentially affecting morale. Conversely, clinicians and nurses might feel burdened by being tasked with lab-like responsibilities on top of their regular duties (“scope creep”). If a nurse has to manage quality control and documentation for a dozen bedside tests, that is additional work that might detract from patient care if not properly integrated into workflow. Therefore, addressing the workforce implications is crucial: it involves adequate staffing (e.g., enough POCT coordinators per number of devices/operators), proper training frameworks, and fostering a team approach where lab and clinical staff collaborate rather than operate in silos [16].

In essence, POCT blurs traditional professional boundaries, making interprofessional collaboration vital. The most successful POCT programs reported in the literature are those with strong governance and communication – where, for example, the laboratory oversees quality and provides training, nursing management enforces compliance on the floors, and physicians support appropriate use of tests [1,16]. Establishing this culture and training infrastructure is a challenge, but it is necessary to fully reap the benefits of POCT without compromising test quality or overloading the workforce. The national Swedish survey of emergency departments, for example, found that although all sites trained nurses for POCT blood-gas analysis, only 30 % had a recurrent training schedule, highlighting a gap between initial training and ongoing competence assurance [5].

4.7. Undetected interferences and matrix effects in POCT (Table 3)

A further, and often under-appreciated, limitation of POCT is the risk of analytically altered results due to **undetected interferences** and matrix effects. Many POCT systems rely on whole-blood samples obtained by non-laboratory staff under time pressure, frequently in high-acuity environments such as emergency departments, intensive care units or operating theatres. Under these conditions, pre-analytical errors – including prolonged tourniquet application, difficult venepuncture, use of small-gauge needles, vigorous mixing and delayed analysis – are common and substantially increase the likelihood of haemolysis, clotting or sample contamination.

Table 3
Examples of POCT technologies and device formats.

Analytical principle/format	Typical example(s)	Common analytes/tests	Main advantages	Main limitations
Lateral-flow immunoassay (LFIA)	Strip-based rapid antigen tests, CRP strips	Viral antigens (e.g. influenza, SARS-CoV-2), pregnancy tests, CRP	Simple, low-cost, no instrumentation; suitable for self-testing and low-resource settings	Semi-quantitative or qualitative; susceptible to user interpretation; limited connectivity unless used with readers
Electrochemical biosensor	Glucose meters, POC creatinine devices	Glucose, creatinine, some cardiac markers	Very small sample volume, short TAT, established workflows	Analytical interference from haematocrit or drugs; need for calibration and lot verification
Cartridge-based molecular platforms	Closed-cartridge PCR systems (e.g. for TB, SARS-CoV-2, STIs)	Respiratory viruses, TB, chlamydia, gonorrhoea, trichomonas	High analytical sensitivity and specificity; minimal hands-on time; increasingly network-connected	Higher cost per test; need for temperature-controlled cartridge storage; maintenance requirements
Benchtop blood-gas and critical-care analyzers	Multi-parameter blood-gas/electrolyte devices in ED/ICU	pH, pCO_2, pO_2, electrolytes, haemoglobin, lactate	Broad panels from small samples; very rapid results; integrate well into ICU/ED workflows	Vulnerable to pre-analytical error (e.g. haemolysis, air bubbles); requires robust QC, training and maintenance [5,32,34,35]
Microfluidic lab-on-a-chip platforms	Integrated cartridges with multiplex capability	Panels for sepsis, coagulation, or metabolic markers	Potential for multiplex testing and automation in a small footprint	Cost and complexity; standardization and regulatory evidence still evolving
Smartphone-enabled readers and digital POCT	Smartphone camera-based readers, Bluetooth linked devices	LFIA strip interpretation, home INR, glucose, some infectious diseases	Enhanced connectivity, automated interpretation and result upload to EHR or apps; suitable for telemedicine models	Dependence on connectivity and software; cybersecurity and data-protection issues; device-phone compatibility

In the central laboratory, coloured interferences such as haemolysis, icterus and lipaemia are usually detected and quantified by dedicated indices, and samples that exceed predefined thresholds are suppressed, repeated or reported with explicit comments. By contrast, many POCT platforms either lack such indices altogether or incorporate only rudimentary flagging, and visual inspection is frequently impossible because samples are contained within closed cartridges or microcuvettes. As a result, clinically significant interferences may go unnoticed and spuriously abnormal or normal results may be accepted at face value.

Haemolysis is particularly problematic. In whole-blood POCT for blood gases and electrolytes, even modest haemolysis can materially distort key parameters – most notably **potassium**, but also bicarbonate, pH and pCO_2 – with the potential to prompt inappropriate therapeutic interventions [35](e.g. unnecessary treatment for “hyperkalaemia” or erroneous adjustment of ventilator settings). Reported rates of haemolysed samples in emergency and critical-care settings are high, and these errors may be amplified where repeated measurements are performed on the same patient using similarly flawed technique. Because many POCT devices either do not report a haemolysis index or provide only a binary flag at relatively high thresholds, subtle yet clinically relevant degrees of haemolysis may not be recognized by the operator.

Other interferences and matrix effects also affect POCT performance. Examples include lipaemia, hyperbilirubinaemia, high white cell counts, extremes of haematocrit and the presence of exogenous substances such as contrast media or certain drugs. These can variably impact optical, electrochemical or enzymatic signals and may do so differently on POCT platforms than on central laboratory analyzers. Furthermore, manufacturers' interference studies often evaluate a limited range of interferents at relatively high concentrations, and the results may not fully reflect complex real-world combinations of physiological and pre-analytical factors. An important additional example is the interference seen with glucose meters [36,37].

Mitigating these risks requires a **multifaceted governance approach**. The POCT programme should define and enforce minimum requirements for sample collection, handling and timing; ensure that operators receive initial and ongoing training focused on pre-analytical variables; and implement procedures for periodic comparison of POCT results with central laboratory methods in representative clinical scenarios. Where possible, selection of analyzers should favour platforms that provide quantitative or semi-quantitative haemolysis and other interference indices, with clearly defined decision limits and actions. Clinicians should be encouraged to interpret POCT results in the light of the overall clinical picture and to request laboratory confirmation whenever results are discordant, unexpected or inconsistent with prior trends. Failure to address undetected interferences risks converting one of POCT's key strengths – rapid availability of results at the bedside – into a genuine patient-safety hazard.

5. Strategic implementation and governance frameworks

Given the delicate balance of POCTbenefits and risks, a strategic approach to implementation and robust governance frameworks are essential for maximizing its advantages while mitigating downsides (Table 3). Key strategies include:

5.1. Development of clear policies and guidelines

Healthcare institutions should establish formal policies defining *when and how* POCT is to be used. This includes criteria for which tests are approved for point-of-care use, in what clinical scenarios they are indicated, and any requirements for confirmatory laboratory testing. Professional societies and expert panels have published guidelines to assist with this. For example, the National Academy of Clinical Biochemistry (NACB) has developed evidence-based guidelines for POCT that provide graded recommendations on optimal use based on clinical evidence [1]. Likewise, the World Health Organization (WHO) ASSURED criteria (Affordable, Sensitive, Specific, User-friendly, Rapid and Robust, Equipment-free, Delivered to end-users) offer a framework for evaluating appropriate POCT, particularly in resource-limited settings [1]. By adhering to such guidelines, healthcare providers can ensure that POCT devices deployed meet certain standards and fulfill genuine needs. At the institutional level, a POCT governance document typically covers the scope of testing, responsibility assignments, quality and documentation procedures, and integration with the lab's quality management system.

5.2. Quality management systems and accreditation

Historically, laboratories relied on ISO 15189:2012 for general medical laboratory quality requirements and ISO 22870:2016 for POCT-specific requirements, leading to parallel accreditation tracks. The 2022 revision of ISO 15189 fundamentally changes this landscape by incorporating the POCT-related requirements of ISO 22870 into a single, consolidated standard [38]. As a result, laboratories can now work with one accreditation framework that explicitly covers both central laboratory testing and POCT, including governance, competence, risk management and continual improvement. This integration has practical implications: it encourages laboratory-led extension of established quality-management systems to POCT, supports clearer assignment of responsibility for decentralized devices and provides regulators and ac-

creditation bodies with a unified tool to assess POCT programmes [38,39]. However, laboratories that were previously accredited to ISO 22870 will need to carefully map and update their documentation and processes to demonstrate conformity with the new ISO 15189:2022 clauses.

Historically, accreditation requirements for POCT were described in ISO 22870:2006/2016, to be applied in conjunction with ISO 15189 for medical laboratories. The publication of **ISO 15189:2022** has consolidated these provisions by explicitly incorporating the requirements for POCT into a single, integrated standard. ISO 22870 has consequently been withdrawn, and laboratories are now expected to implement and maintain POCT within the same overarching quality management framework that governs central laboratory testing. In practice, this means that all testing sites – including decentralized POCT locations – must comply with requirements for risk management, verification of performance, traceability, metrological alignment, documentation, staff competence, internal quality control and participation in external quality assessment. This shift reinforces the concept that POCT is not an optional add-on operating outside the laboratory's purview, but rather an integral part of the accredited laboratory service that is subject to the same governance, oversight and continuous improvement processes.

Achieving such accreditation means implementing procedures for method validation, routine QC, external proficiency testing, and ongoing monitoring for every POCT analyte, just as would be done in the lab. While challenging, doing so has demonstrated improvements in patient result accuracy and consistency [2]. Regulatory bodies in some countries are also moving toward stronger POCT oversight. In Australia, for instance, national standards (developed by its National Pathology Accreditation Advisory Council) require that laboratories and POCT providers meet the *same minimum standards* for governance and quality in order to receive reimbursement, effectively holding POCT to equivalent quality requirements as central labs [21]. Wherever possible, organizations should pursue at least a subset of formal accreditation or certification for their POCT programs, as this imposes discipline and external auditing that drive quality improvement.

5.3. POCT program governance and leadership

A successful governance framework often involves a POCT steering committee or working group. This interdisciplinary committee usually includes laboratory medicine specialists, point-of-care coordinators, nurses, physicians from key departments, and IT personnel [2]. Such a group can oversee the selection of POCT devices (evaluating new technologies for performance and suitability), develop training programs, and review quality metrics regularly. Many institutions appoint a POCT Medical Director (often a pathologist/clinical chemist) who has ultimate responsibility for the scientific and clinical integrity of the POCT program [16]. In addition, POC coordinators (often medical technologists) handle day-to-day management: training operators, managing inventory of test kits, performing device maintenance, and troubleshooting problems [16]. Empowering these roles and committees is critical. They should be given authority (backed by hospital administration) to enforce POCT policies—such as locking out operators who are not certified, or discontinuing a POCT in a unit if quality standards are not met [17]. Interdepartmental communication is also key: for example, when the laboratory updates a central method or reference range that affects how POCT results should be interpreted, there must be a channel to update POCT users and, if needed, recalibrate devices or software.

5.4. Training, competency, and support

As highlighted in the challenges, training and competency assessment are linchpins of POCT governance. A strategic implementation will include developing standardized training modules for each POCT device, which all operators must complete (often with a written test and observed practical demonstration) before being allowed to perform patient testing [1,2]. Competency should be reassessed at defined intervals (e.g., annually), in line with CLIA or accreditation requirements [1]. A useful strategy is leveraging e-learning and certification tracking software to manage the large number of staff involved. Some hospitals have implemented e-learning courses followed by in-person competency check-offs, and use the POCT data management system to restrict device use to certified operators only (via operator ID lockouts) [1,16]. Additionally, it is also strategic to incorporate POCT training into staff orientation and periodic education days.

Providing **adequate support and resources** is equally important: front-line staff should have readily accessible reference materials (quick guides, infographics) for each test, and a help line to contact laboratory POCT specialists if they encounter issues. Regular audit and feedback can reinforce good practices – for instance, the POCT committee can review monthly QC compliance reports by nursing unit and communicate back any deficiencies or improvements. Field experiences such as the QAAMS program in Australia (Quality Assurance for Aboriginal Medical Services) have shown that comprehensive support, including biannual workshops and ongoing management support for remote POCT programs, resulted in test performance equalling that of central labs over time [16]. This underscores that continuous education and support are part of governance.

5.5. Data integration and connectivity solutions

Addressing data fragmentation is a key governance objective. Institutions should invest in connectivity solutions so that all POCT devices either connect directly to the LIS/EMR or through a middleware that consolidates data [17]. A strategic plan might involve phasing out devices that cannot be interfaced. In parallel, governance policies can mandate that no manual result transcription is allowed except under defined downtimes, and even then a procedure for later reconciliation is in place. By ensuring POCT results are captured in the patient's electronic record automatically, patient safety is improved (clinicians have all data available) and the organization can monitor POCT utilization and outcomes. Many hospitals report that once they implemented a unified POCT data management system, they saw reductions in undocumented results and were able to automate billing for POCT (recovering revenue that was previously lost when tests were not documented [17].

5.6. Monitoring and continuous improvement

Strategic implementation is not a one-time event but an ongoing process. Governance frameworks should include regular review of key performance indicators for the POCT program. These might include analytical performance metrics (comparison of POCT vs laboratory results, internal QC statistics, external proficiency testing scores), compliance metrics (percentage of QC checks done on schedule, operator certifications up to date, etc.), and outcome metrics (turnaround times achieved, impact on patient length of stay, etc.). Negative trends (like increasing QC failures or user errors) can prompt interventions such as retraining or tightening of procedures [16]. Positive trends, on the other hand, can justify expansion of POCT services or serve as a model for other departments. A feedback loop is critical: frontline staff should be informed of any issues with their POCT performance (e.g., a certain clinic frequently mislabels patient IDs on results, or a unit's devices often have QC failures) so they can participate in problem-solving. Moreover, any adverse events or significant errors involving POCT should be investigated with root cause analysis, and the lessons learned used to fortify the system (for example, if an anticoagulated patient had a bleeding episode due to an erroneously low INR reading from a device, the investigation might reveal an operator skipped QC; the response might be to implement stricter QC verification before reporting results).

Institutional governance might require that such incidents be reported to the laboratory or POCT committee as part of the quality assurance process.

In summary, effective governance frameworks for POCT revolve around **standardization, accountability, and integration**. By following international and national standards, empowering a multidisciplinary leadership structure, and investing in training and IT connectivity, healthcare organizations can safely harness the benefits of POCT. Literature reviews have noted that where clear regulation and governance models are in place, POCT implementation is more consistent and successful [21]. Conversely, fragmented or lax governance leads to variability in quality and slows adoption due to trust issues. The goal is a streamlined yet rigorous framework that ensures quality results and meets the needs of patients and providers alike [21].

6. Conclusion

Point-of-care testing in clinical diagnostics indeed represents a double-edged sword: it offers unparalleled opportunities for rapid, accessible, and patient-centric care, but it also introduces challenges in maintaining accuracy, quality, and appropriate use. On the positive edge, POCT has revolutionized how and where we can deliver diagnostic services – improving clinical workflow efficiency, supporting timely decision-making in critical scenarios, extending the reach of healthcare to remote and underserved areas, and empowering patients in the management of their health. These advantages, documented in numerous studies and amplified by recent global experiences (such as the COVID-19 pandemic), underscore why POCT is increasingly embraced as a vital component of modern healthcare [1,3].

On the other hand, realizing the full benefits of POCT without compromising care requires overcoming its inherent challenges. Analytical limitations must be acknowledged and countered by rigorous validation and user training; quality assurance must be as uncompromising at the bedside as it is in the lab. Data management and connectivity issues have to be resolved to prevent fragmentation of patient information. Moreover, the healthcare community must guard against overuse and ensure that the convenience of POCT does not supersede sound clinical judgment. In short, **POCT should be integrated thoughtfully, not just added superficially**.

The path forward is one of balance and governance. Effective strategies include implementing strong oversight frameworks that mirror laboratory standards, investing in continuous training and competency evaluation for all POCT operators, and fostering collaboration between laboratory specialists and clinical teams to monitor and improve POCT services [1,2]. Policy-makers and professional bodies are called to provide clearer regulatory guidance and support for POCT – as seen in emerging international standards and national accreditation programs – to ensure consistent quality across diverse settings [1,21]. Technological advancements will no doubt continue to enhance POCT device performance and connectivity, but technology alone cannot address issues of misuse or misinterpretation; hence, education and clinical governance are equally important.

In conclusion, when POCT is employed in the right context with proper quality controls and oversight, it can lead to improved clinical and economic outcomes and becomes a powerful adjunct to centralized testing [3,21]. The experience of institutions that have effectively integrated POCT shows that benefits overwhelmingly outweigh the risks once a culture of quality and collaboration is established [1] [2].POCT is not a panacea or a replacement for the central laboratory; rather, it is a complementary approach that, if managed well, enhances the overall diagnostic capability of the healthcare system. As the healthcare landscape continues to evolve toward more decentralized, personalized, and value-based care, POCT – wielded with care – will remain an integral and growing part of the clinician's toolkit. The double-edged sword can thus be turned into a precise scalpel, improving patient care when guided by the steady hand of good science and governance.

CRediT authorship contribution statement

Tahir S. Pillay: Writing – original draft, Project administration, Formal analysis, Conceptualization. **Ashlin Rampul:** Writing – review & editing, Conceptualization. **Evette L. Subramoney:** Writing – review & editing. **Barbara S. van Deventer:** Writing – review & editing. **Chantal van Niekerk:** Writing – review & editing. **Siphokazi Gwiliza:** Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cca.2025.120770.

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