Research Article

Ethical Challenges in Point-of-Care Testing for Cardiac Biomarkers: Balancing Rapid Diagnosis with Clinical Responsibility

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Abstract

The rapid expansion of point of care testing (POCT) has significantly transformed clinical decision-making, particularly in acute care settings. Cardiac biomarkers such as troponins (conventional and high sensitivity) and natriuretic peptides are increasingly being deployed at the bedside to expedite diagnosis and guide timely management [1]. While the clinical advantages of POCT are well recognized, its widespread implementation raises important ethical considerations that remain insufficiently addressed [2]. We aim to project that the rapid expansion of cardiac biomarker POCT has outpaced the development of practical ethical guidance for its implementation. In particular, challenges related to analytical reliability, accountability, quality oversight, equitable access, patient autonomy, and environmental sustainability require a structured ethical framework to support safe and clinically responsible use of POCT in cardiac care. One of the primary ethical concerns relates to the trade-off between speed and analytical accuracy. Although POCT offers faster turnaround times, variability in analytical performance compared to central laboratory assays may compromise diagnostic certainty [3]. This is particularly critical in the context of cardiac biomarkers, where even minor inaccuracies can lead to misclassification of myocardial infarction. In cardiac care, such errors carry particularly significant ethical implications because troponin results may directly influence urgent decisions regarding admission, invasive procedures, discharge, or withholding of treatment. This underscores the necessity of an ethical framework to ensure rapid testing does not compromise diagnostic integrity and patient safety.

Unlike conventional laboratory testing, POCT is often performed in environments where critical factors such as temperature, humidity, time to analysis, and oxygen exposure are less controlled and may fluctuate significantly, thereby affecting assay performance [4]. Furthermore, the pre-analytical phase represents a major source of error in POCT. The use of whole blood samples, particularly in capillary (fingerstick) testing, increases susceptibility to hemolysis, while improper specimen handling can introduce errors such as air bubbles, micro clots, or gross clotting [5, 6].

Another important issue is the question of accountability and diagnostic testing acumen. POCT is often performed by non-laboratory personnel, which may lead to variability in test execution and interpretation but also in the level of technical competence compared to trained laboratory professionals [2]. While non-laboratory personnel may be willing to accept responsibility for performing and interpreting tests, this does not necessarily ensure adequate proficiency or adherence to standardized procedures. This concern is particularly relevant for cardiac biomarkers, where high-sensitivity assays are increasingly integrated into established rule-in and rule-out algorithms developed and verified primarily in central laboratory settings in collaboration with specialties such as emergency medicine and cardiology. However, the direct applicability of these interpretive pathways in POCT environments remains incompletely established because POCT testing may be more vulnerable to preanalytical variables, operator-dependent factors, and analytical variability. Although recent studies have begun evaluating point-of-care high-sensitivity troponin assays and accelerated diagnostic pathways in emergency care settings, evidence remains comparatively limited when compared with well-established central laboratory protocols [7]. Further multicenter validation studies are therefore needed before these algorithms can be universally adopted across diverse POCT settings. From an ethical and clinical perspective, cardiac biomarker POCT may be most appropriate in settings where rapid triage and timely decision-making are critical, particularly when central laboratory access is delayed or unavailable. However, for complex clinical scenarios requiring highly standardized serial testing, comprehensive diagnostic interpretation, or confirmatory evaluation, central laboratory testing may remain the preferred approach. An ethical framework is therefore essential to clearly define roles, responsibilities, and oversight while also ensuring appropriate training and competency assessment to safeguard the quality of patient care.

Quality assurance represents an additional challenge. POCT environments may lack standardized oversight compared to central laboratories, raising concerns related to patient safety and non-maleficence [8]. This highlights the need for ethical and operational guidance including the implementation of standardized algorithms, training programs, regular competency assessments, and clearly defined governance frameworks with laboratory oversight. In addition, harmonization of test results between POCT devices and central laboratory assays remains a significant challenge, particularly in ensuring comparability and consistency of results for patients managed within the same healthcare setting [8]. In the interim, it is imperative these two types of measurements be clearly delineated from clinical interpretations to avoid harm.

The ease of access to POCT devices may also contribute to overutilization of cardiac biomarker testing, increasing the chance for false results and unnecessary interventions [10]. However, these devices are also crucial in improving access to timely diagnostics, particularly for patients in resource-limited and rural settings where centralized laboratory services may be unavailable or delayed. By enabling rapid decision-making at the point of care, POCT can facilitate early diagnosis, triage, and management of acute cardiac conditions, thereby potentially improving clinical outcomes. Nevertheless, disparities in implementation and resource allocation may exacerbate existing healthcare inequities if access to POCT technologies is uneven [11]. These ethical challenges are summarized in Table 1. An ethical blueprint is thus crucial to promote appropriate utilization while ensuring equitable access to POCT services.

From cardiac biomarkers perspective, due to their role in high-stakes decision-making ethical concerns become paramount. Addressing these challenges requires strengthening training, ensuring laboratory oversight, implementing robust quality systems, and developing ethical frameworks.

While POCT has clear advantages in improving timely detection of acute cardiac events, it raises important questions about which high-risk conditions are suitable for decentralized testing. It also highlights concerns about how complex, time-sensitive clinical information is interpreted and communicated when testing is performed by non-laboratory personnel outside the central laboratory, even within supervised care settings. At the same time, as patients increasingly access personal health data through electronic records and wearable technologies, an ethical dilemma emerges between promoting autonomy and ensuring beneficence and non-maleficence, underscoring the need for clear safeguards and clinical oversight in the expanding use of cardiac POCT. Figure 1 illustrates the balance between clinical benefits and ethical risks associated with POCT for cardiac biomarkers, emphasizing the need for quality assurance and governance.

Moreover, the increasing use of POCT has also brought attention to an important ethical concern related to environmental sustainability. Many POCT devices rely heavily on single-use plastics, including cartridges, test strips, lancets, and packaging materials. As the use of POCT continues to expand, particularly in high-volume areas such as emergency cardiac care, the amount of biomedical plastic waste generated is also increasing. Previous reports have highlighted that disposable diagnostic materials contribute significantly to healthcare-related plastic waste, which may create environmental and public health challenges, especially in

settings where waste management systems are limited [12]. Although POCT provides substantial clinical benefits through rapid diagnosis and timely patient management, these advantages should be balanced against their broader environmental impact. From an ethical perspective, this relates to the principles of non-maleficence and justice, as healthcare practices should aim to avoid unintended harm to both communities and the environment. Therefore, alongside improving patient care, there is also a need to encourage sustainable disposal practices and support the development of more environmentally responsible diagnostic technologies.

In conclusion, the expanding role of POCT, particularly for high-risk applications such as cardiac biomarkers, necessitates a robust ethical framework to guide its implementation. As also emphasized by the Canadian Society of Clinical Chemists, POCT should be conducted in a manner that prioritizes effective patient care while judiciously utilizing available resources, with financial or personal incentives such as making workflows easier for clinicians, the push to provide faster results, meeting performance targets, or possible influence from industry, not serving as primary drivers [13]. Equally important are the principles of patient autonomy and confidentiality, particularly as POCT becomes increasingly integrated with digital health technologies, wearable devices, and personal health records. In these evolving care models, patients should be adequately informed not only about the purpose and limitations of testing, but also about how their results may be stored, accessed, shared, or integrated across healthcare systems. This is especially relevant as rapid connectivity, and remote monitoring may increase the risk of unauthorized access or unintended disclosure of sensitive health information. Therefore, informed consent processes and robust data protection safeguards are essential to preserve patient trust, maintain confidentiality, and ensure ethical use of POCT-generated data. In this rapidly evolving landscape, the vital and timely role of the IFCC Task Force on Ethics is particularly significant in providing global guidance and standard setting to address emerging ethical challenges in POCT. An ethical framework for POCT in cardiac care should include key elements such as quality assurance processes, protection of patient confidentiality, equitable access to testing, and consideration of environmental sustainability. Such measures may help ensure that the expanding use of POCT remains aligned with patient safety and ethical clinical practice. As access to rapid, decentralized cardiac testing continues to expand, maintaining a balance between accessibility, clinical oversight, and ethical responsibility will be essential to ensure safe, equitable, and patient centered care.

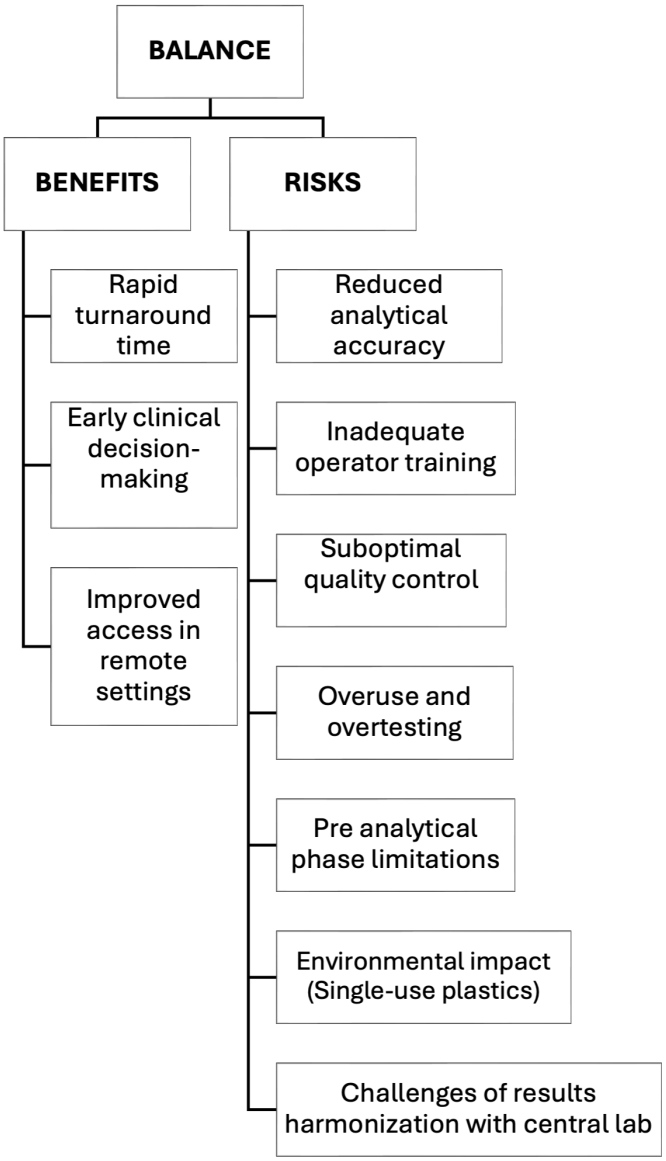
Table 1: Ethical considerations in POCT for cardiac biomarkers and their clinical implications.

Ethical Principle	Ethical Considerations	Description	Clinical Impact
Autonomy (Clinical decision-making responsibility)	**Professional Accountability and Governance** **Informed consent and data confidentiality**	Testing is often performed by non-laboratory personnel	Risk of misinterpretation and inappropriate clinical decisions (e.g., non-lab operators interpreting delta troponins, both absolute and percentage deltas) Patients may not fully understand how POCT-generated data are stored, shared, or integrated with electronic health systems
Beneficence (Act in patient's best interest)	**Improved Access**	POCT expands access to diagnostics, especially in remote or resource-limited settings, enabling earlier identification and triage of acute conditions when central laboratory testing is not readily available.	Timely clinical decision-making, improved patient outcomes, and more appropriate triage of MI cases (e.g., identifying patients requiring urgent versus non-urgent care).
Equity (Fair distribution of care)	**Resource Disparity**	Use in low-resource settings without adequate infrastructure or quality systems; however, POCT can significantly improve access to diagnostic testing in rural or underserved areas where central laboratory services are unavailable.	Potential variability in test quality and accuracy; however, improved access may enable earlier triage and clinical decision-making, particularly for patients distant from healthcare facilities.

Ethical Principle	Ethical Considerations	Description	Clinical Impact
Non-maleficence (Do no harm)	**Accuracy vs Speed**	POCT may have lower sensitivity compared to central lab testing, though newer high-sensitivity assays are improving	Missed or delayed diagnosis of MI (e.g., false negative MI)
	Quality Assurance	Variability due to preanalytical errors and operator dependence; inconsistent QC/ EQA practices	Variable reliability of results, potential patient harm
	Environmental Impact (Single-use plastics)	POCT generates single-use plastic waste (e.g., cartridges, strips), raising environmental concerns	Environmental contamination, long-term public health risks, and ethical concerns regarding sustainability and responsible healthcare delivery
Justice (Fair use of resources)	**Over-testing**	Easy availability may lead to unnecessary or excessive testing (e.g., troponin overuse)	False positives, unnecessary admissions, increased healthcare costs

POCT, Point of Care Testing; QC, Quality Control; EQA, External Quality Assessment; MI, Myocardial Infarction

Figure 1: Ethical balance in POCT for cardiac biomarkers.



Disclosures of Interest

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Ethical Approval

Not required as study does not involve human subjects or data.

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Data Availability

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Author Statement

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