

Perspective

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Operational challenges and mitigation strategies in preparing malaria quality control panels

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Over the past decades, rapid diagnostic tests (RDTs) have become the most widely deployed diagnostic tool, enabling timely treatment in resource-limited and remote settings[1]. Their reliability, however, depends on rigorous quality assurance frameworks, with the World Health Organization (WHO)-endorsed quality control panels serving as the cornerstone for monitoring RDT performance and ensuring diagnostic fidelity across diverse epidemiological landscapes[2]. Quality control panels are standardized, parasite-based reference materials used to evaluate antigen detection by RDTs under controlled conditions. They play an essential role in detecting lot-to-lot variations, guiding procurement decisions, and safeguarding programmatic confidence in RDTs[3]. Despite this centrality, the practical and operational realities of quality control panel preparation in malaria-endemic regions remain underexplored.

Field-derived knowledge and practical experiences gleaned from endemic or targeted settings offer invaluable insights for guiding future research endeavors. By effectively disseminating and leveraging these practical lessons, researchers can foster collaborative knowledge exchange and equip themselves with a more nuanced understanding of the unique challenges and opportunities present in these specific contexts. The invaluable insights gleaned from field-based research in endemic/targeted settings illuminate the path for future research endeavors. This enriched understanding empowers the development of targeted research strategies and interventions that are meticulously tailored to the unique needs and realities of the endemic/targeted population[4]. This study aims to provide field-based insights into the operational challenges of malaria quality control panel preparation and proposing practical, scalable solutions.

The WHO has set the standard protocol for preparing the quality control panel; however, this standard protocol may be impacted by the local setup[5]. The development of robust malaria quality control panel presents several significant challenges. The conceptual framework of malaria quality control panel preparation—operational bottlenecks and mitigation strategies are given in Figure 1. The arrangement of AB+ positive blood type, fresh frozen plasma, and O+ positive whole blood, at the remote field preparation site poses a significant logistical challenge as there is a limited ability to prepare representative panels, causing delays in preparation. This limited availability of essential blood components could potentially impede the development of a comprehensive and representative quality control panel. Ensuring the quality of fresh blood samples during their journey from patient recruitment to the central preparation site presents a critical challenge in field-based quality control panel development. Long transport distances or inadequate handling practices under challenging field conditions can compromise the integrity of these samples, potentially jeopardizing the accuracy and reliability of the resulting quality control panel as there is risk of thawing and antigen loss during long-distance travel.

Accurate parasite detection during field sample screening hinges on the availability of skilled microscopists and reliable microscopy equipment because inaccurate parasite density quantification increases the risk of false quality control results. However, limited access to such expertise or resources in remote settings can introduce errors and compromise the overall quality of the quality control panel data. Securing community mistrust or poor

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participation in recruitment in the quality control panel development proved challenging. Difficulties in effectively communicating the research program to residents, cultural barriers, mistrust, or lack of understanding among the target population hindered recruitment, potentially limiting the representativeness of the quality control panel and affecting the generalizability of the results. The preparation of malaria quality control panels commences with parasitized blood dilution in O+ positive whole blood, followed by mixing with AB+ fresh frozen plasma to achieve targeted parasite densities of 200/μL (low) and 2000/μL (high). Negative controls are prepared to ensure test specificity and adhere to establish dilution calculations[3]. Maintaining single-digit precision is crucial, as even minor errors can significantly alter parasite levels. Access to deep freezers (–80 ℃) and reliable electricity at the field site posed additional logistical challenges.

Transporting the quality control panels from the preparation site to the ICMR-NIMR laboratory in New Delhi presented significant hurdles, primarily due to the limited availability of high-quality dry ice and the lengthy travel distance. Upon arrival and proper storage, mono-infection is confirmed using genus and species-specific PCR assays according to protocol published[6]. All samples undergo ELISA testing for HIV, HBV, and HCV infections, with

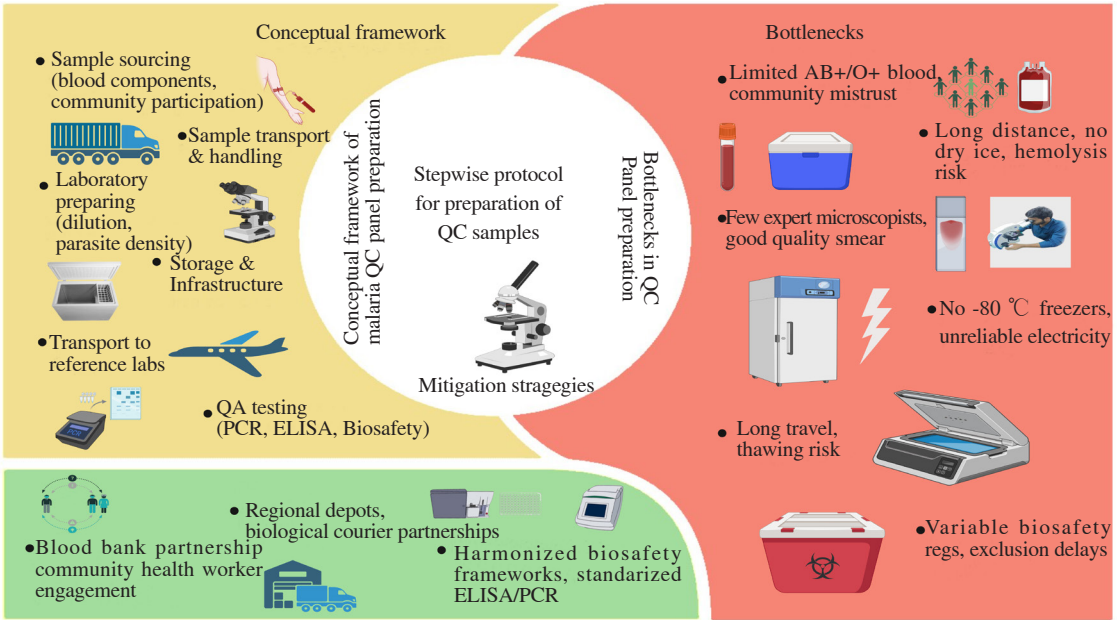


Figure 1. The conceptual framework of malaria quality control panel preparation operational bottlenecks and mitigation strategies. QA: quality assurance; QC: quality control.

Table 1. Challenges in malaria quality control panel preparation and proposed mitigation strategies.

Challenge	Consequence for QC panel integrity	Proposed mitigation strategy	Scalability/policy relevance
Sourcing of blood components (AB+ plasma, O+ positive whole blood)	Limited ability to prepare representative panels; delays in panel preparation	Establish partnerships with regional blood banks; organize pre-arranged mobile collection drives	Feasible through integration with national blood services and donor-supported programs
Maintaining sample integrity during transport (long distances, lack of dry ice)	Hemolysis, antigen degradation, compromised parasite density	Use phase-change materials (PCMs) as dry-ice alternatives; GPS-tracked cold-chain; decentralized preparation hubs	Highly scalable when linked to existing vaccine/biological cold-chain systems
Limited access to skilled microscopists in remote sites	Inaccurate parasite density determination; risk of false quality control characterization	Remote digital slide review *via* tele-pathology; rapid on-site microscopy training	Scalable through WHO microscopy networks and digital health platforms
Community mistrust or low participation during recruitment	Reduced sample availability; risk of non-representative quality control panels	Community health worker engagement; culturally tailored communication; local advisory boards	Scalable through integration with community-based malaria programs
Infrastructure limitations (unstable electricity, lack of –80 ℃ freezers)	Inconsistent storage; antigen degradation; loss of quality control materials	Backup power systems; leverage regional lab networks; centralized cold-storage hubs	Requires capital investment but aligns with national laboratory strengthening plans
Transporting quality control panels to reference laboratories	Risk of thawing and antigen degradation during long-distance transport	Pre-position regional storage depots; partner with specialized biological transport couriers	Scalable through regional centers of excellence supported by WHO/ Global Fund
Regulatory and biosafety requirements (HIV, HBV, HCV screening)	Potential biosafety risks; delays due to exclusion criteria	Standardized ELISA/PCR screening workflows; harmonized biosafety regulations	Scalable with policy harmonization under WHO biosafety frameworks

QC: quality control. HIV: human immunodeficiency virus; HBV: hepatitis B virus; HCV: hepatitis C virus.

any positive results leading to sample exclusion. Further, ELISA analyses quantify *Plasmodium falciparum* histidine-rich protein][and *Plasmodium vivax*-specific *Plasmodium* lactate dehydrogenase antigen levels in the prepared quality control panels. Challenges in malaria quality control panel preparation and proposed mitigation strategies are mentioned in Table 1. Fieldwork, by its very nature, presents an inherent level of unpredictability that necessitates adaptability and resourcefulness from researchers. The challenges encountered during the preparation of the malaria quality control panels, as outlined in this study, serve as valuable insights that can inform and optimize future research endeavors in similar contexts. By openly sharing the practical lessons learned from these obstacles, we can empower fellow researchers and practitioners to anticipate and effectively navigate potential hurdles in their own field-based studies. The conceptual framework of malaria quality control panel preparation—operational bottlenecks and mitigation strategies are given in Figure 1. Furthermore, this experience underscores the meticulous nature of the quality control panel preparation methodology, where even minor deviations from the established procedures can significantly impact the timeline and overall success of the project. Recognizing and mitigating these potential lapses through careful planning and meticulous execution is crucial for ensuring the quality and reliability of the resulting.

In essence, embracing the inherent challenges of fieldwork and actively sharing the practical knowledge gained from such experiences fosters a collaborative research environment that ultimately contributes to the development of more robust and effective research methodologies for the benefit of both researchers and the communities they serve.

From a practical perspective, field-adapted, scalable solutions ranging from blood bank partnerships to decentralized storage hubs can significantly improve the feasibility and reliability of quality control panel preparation in endemic regions. In conclusion, overcoming the operational barriers of quality control panel preparation is not a peripheral technical issue but a strategic priority for global malaria control. Embedding practical mitigation strategies into both research practice and policy frameworks provides a pathway for ensuring robust, reliable malaria diagnostics that underpin elimination efforts worldwide.

Conflict of interest statement

The author declared no conflicts of interest concerning the authorship and publication of this short article.

Ethical approval

The study was approved by the Institutional Ethical Committee of ICMR-National Institute of Malaria Research, New Delhi, vide letter number-NIMR/EC/2009/2 dated 09.01.2009.

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Authors' contributions

Naseem Ahmed: Original manuscript writing, concept development, literature search, editing; Piyush Choudhary: Manuscript editing, literature search; Supriya Sharma: Editing and proof reading; Anupkumar R Anvikar: Overall monitoring, proof reading; Praveen Kumar Bharti: Manuscript development, manuscript editing, overall monitoring, proof reading.

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