VIEWPOINTS

Innovation in Clinical Biochemistry: Gaps and Future Opportunities

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ABSTRACT

Clinical biochemistry is the foundation of modern healthcare, influencing almost every diagnostic and therapeutic decision made inside hospital systems. Despite global technical advancements, countries like as Nepal continue to face challenges in diagnostic access, quality control, automation, data integration, and expert workforce development. The COVID-19 pandemic has pushed the deployment of molecular platforms and point-of-care testing (POCT), but sustainability and standardization remain a challenge. This viewpoint examines persistent inadequacies in clinical biochemistry infrastructure and provides a realistic innovation roadmap for developing health systems. In contrast, new technological innovations—such as near-patient molecular diagnostics, biosensor-driven point-of-care platforms, advanced automated immunoassay systems, and AI-enabled quality assurance—open powerful possibilities for modernizing clinical biochemistry services. Achieving lasting progress, however, depends on investing in skilled human resources, reinforcing regulatory and accreditation mechanisms, promoting collaborative public–private models, and developing robust national reference laboratories to guide proficiency and standardization efforts. Strategic progress in clinical biochemistry has the potential to enhance diagnostic speed, improve disease detection, support rational antibiotic use, strengthen maternal care, and bolster national surveillance systems. For Nepal context, technological innovation must be accompanied by stronger quality systems, governance structures, and local production capacity. This paper calls for a phased, evidence-based modernization of laboratory services to ensure equitable and future-ready diagnostics.

Keywords: *Clinical Biochemistry, Diagnostic Innovation, Nepal, Point of Care Testing*

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INTRODUCTION

Healthcare delivery is a collaborative process between physicians and laboratory specialists, with correct diagnosis as the foundation of patient care. This technique has progressed from simple examinations to complex diagnostic systems. Throughout this journey, laboratory medicine has made significant progress. A well-functioning laboratory meets quality requirements, which include both internal and external quality control procedures (Niraula & Bataju, 2020). Clinical biochemistry is a key pillar of laboratory medicine, helping clinicians understand disease by analyzing blood, urine, cerebrospinal fluid, and other body samples. By profiling metabolites, hormones, enzymes, and electrolytes, it delivers insights that guide treatment, enhance patient care, and enable personalized approaches. The discipline encompasses both conventional biochemical analyses and advanced molecular diagnostics (Cao et al., 2025). The fundamental purpose of clinical biochemistry is to create precise and reliable data to help healthcare professionals make educated decisions, guide therapy, and predict patient outcomes (Olver et al., 2023).

Although value-based medicine and laboratory practices are well-known concepts, the COVID-19 epidemic has emphasized the critical need to alter clinical and laboratory workflows to provide safer, higher-quality, and more sustainable healthcare. Nepal has made progress in strengthening its laboratories, especially since the pandemic, but obstacles remain in areas such as quality assurance, personnel skills, access to current technologies, and digital integration (Plebani et al., 2024). Nepal can strategically modernize its laboratories and guarantee wider, more equitable access to diagnostics by implementing technologies like regulated POCT, AI-assisted quality monitoring, and near-point-of-care molecular tests.

While high-income nations are quickly incorporating automation, AI-driven interpretation, and personalized biomarkers into healthcare, nations like Nepal still struggle with issues including manpower shortages, uneven quality control, reagent shortages, and poor laboratory connectivity. With technology progressing so swiftly, poor

nations now have a significant chance to improve their laboratory infrastructure for modern, future-focused diagnoses.

Existing Gaps in Clinical Biochemistry Laboratory of Nepal

1. **Quality and Accreditation Deficiency**
   In Nepal, oversight of tertiary hospitals and major clinical laboratories is given by the NPHL and, in certain instances, by Indian institutions, whereas EQA initiatives rely on regional networks and private enterprises. Independent quality assurance is hampered by the lack of a national accrediting organization. Creating a specialized accrediting organization would help Nepal to raise laboratory standards, boost patient care, and assure sustainable, self-reliant quality management (Niraula & Bataju, 2020). Outside the capital, very few laboratories comply with ISO 15189 standards. Quality assurance programs are irregular, internal auditor expertise is limited, and participation in external proficiency testing remains low.
2. **Workforce Limitations**
   A survey of clinicians and laboratory specialists in nine European nations examined their views towards test selection and interpretation. The findings revealed that 85.6% of respondents supported efforts to encourage proper test utilization, and all respondents expressed a need for information on test indications to improve collaboration with laboratory specialists. (Plebani et al., 2024).
   There is a significant scarcity of skilled biochemical scientists, particularly those who specialise in molecular diagnostics, immunoassay troubleshooting, internal audits, and laboratory automation management. A survey of clinicians and laboratory specialists in nine European nations examined their views towards test selection and interpretation. The findings revealed that 85.6% of respondents supported efforts to encourage proper test utilization, and all respondents expressed a need for information on test indications to improve collaboration with laboratory specialists. (Plebani et al., 2024).
   There is a significant scarcity of skilled biochemical scientists, particularly those who specialize in molecular diagnostics, immunoassay troubleshooting, internal audits, and laboratory automation management.
3. **Fragmented Procurement and Supply Chains**
   Managing the supply chain in clinical laboratories emerges as a critical concern encompassing various parameters integral to the process. Effective supply chain management can enhance the service quality, making the laboratory more cost-

efficient and affordable, thereby improving the organization's functional capacity and competitiveness. Additionally, A well-structured logistics supply chain stands as a crucial factor in ensuring a consistent provision of high-quality laboratory materials throughout the entirety of clinical laboratory processes (Mitra et al., 2024). In Nepal, many Laboratories face frequent supply disruption, lack of reagent standardization, and dependence on imports raises cost and compromises result accuracy.

4. **Fragmented diagnostics ecosystem.**
   Depending on a country's diagnostic infrastructure, patients and providers play different roles in ensuring that a correct and timely diagnosis is made (Yellapa et al., 2017). Public, private and NGO labs use different standards, reporting formats and procurement channels hindering referral testing, supply predictability and surveillance.
5. **Technological Inequity**
   POCT and molecular testing are expanding but often without standard QC linkage, operator training, or integration into referral diagnostic pathways.
6. **Minimal Digital Integration**
   High-quality healthcare in the precision-medicine era requires seamless integration of all clinical information. Structured data offers a powerful foundation for clinical decision-support systems, improving patient safety and overall care outcomes. Laboratory medicine responsible for generating the majority of structured clinical data, holds a key position in achieving this (Shin et al., 2025). Despite this, many laboratories remain disconnected from hospital EMRs and national surveillance networks, hindering the timely and meaningful use of laboratory data.

Future Opportunities for Innovation

1. **Near-POC Molecular Diagnostics and Smart, Quality-Linked POCT**
   Early and accurate disease detection is critical for effective treatment and improved patient outcomes. Microfluidics-based point-of-care testing (POCT) provides a rapid, low-cost, and noninvasive alternative to conventional diagnostics, while also supporting drug development and therapeutic evaluation (Cao et al., 2025; Miesler et al., 2020; Plebani et al., 2024). With infectious diseases spreading faster due to globalization and lifestyle changes, healthcare systems, especially in low- and middle-income regions require accessible, efficient, and affordable diagnostic solutions. Frugal innovations, including POCT, enable bedside or community testing, reducing delays, unnecessary

treatments, and supporting timely public health responses. Portable biosensors, microfluidic platforms, and automated immunodiagnostics further enhance accuracy while maintaining cost-effectiveness.

In Nepal, deploying pilot diagnostic hubs with these technologies could shorten turnaround times, improve patient management, and expand applications such as antenatal care, emergency triage, glycemic monitoring, renal function, and electrolyte assessment, provided operators are trained and robust real-time quality control systems are in place (Miesler et al., 2020).

Compact near-point-of-care molecular assays, biosensor-driven POCT devices, and automated immunodiagnostic platforms now allow highly sensitive diagnosis of infectious illnesses even at district and peripheral health institutions. Establishing prototype diagnostic hubs employing these technologies in Nepal could drastically cut turnaround times for clinical decision-making and enhance patient outcomes. It is both feasible and sustainable to expand biosensor-based POCT for uses like antenatal care, emergency triage, glycemic monitoring, renal function assessment, and electrolyte evaluation as long as operators obtain the necessary certification and labs use real-time QC dashboards to guarantee accuracy and consistency.

2. AI-Assisted Interpretation and QC Monitoring

Artificial intelligence is rapidly transforming quality assurance in healthcare, driving advancements in diagnostics and patient care. Artificial intelligence-based approaches have demonstrated clear superiority over conventional methods. AI can support assay curve interpretation, flag QC deviations, predict analyzer failure, and triage abnormal biochemical panels for specialist review-without replacing human experts (Shin et al., 2025).

3. Workforce Upskilling & Academic Reform

Establish national training centres for molecular biochemistry, QA accreditation, automation handling, and digital laboratory science. Fellowship programmes will develop future leaders.

4. Indigenous QC Serum and Control Material Production

With growing automation in clinical laboratories, the demand for quality control (QC) materials has increased to ensure accurate performance monitoring. Reliance on commercial QC materials is often costly or limited by availability,

making it economically unfeasible for many countries. Developing in-house QC serum from pooled patient samples offers a cost-effective alternative, providing greater stability, reduced variation, and minimal matrix effects compared with commercial controls (Plebani et al., 2024).

Building a domestic QC ecosystem at institutions like Nepal Teaching Hospital would not only enhance laboratory capabilities but also advance national diagnostic self-reliance. With support from academic institutions, government agencies, and innovative startups, Nepal has the potential to become a regional leader in producing affordable, ISO-standard QC systems tailored to local needs within the next decade.

5. **Local Manufacturing and Public-Private Collaboration**

Investment in reagent cartridge assembly, biomedical consumable production and domestic R&D reduces reliance on imports and ensures cost sustainability.

Conclusion:

The greatest challenge is not technology; it is coordination between policy, skilled manpower, quality assurance, and sustainable financing**.**

Advancing clinical biochemistry in Nepal and Asia can bridge diagnostic gaps and improve public health. Adoption of point-of-care testing, population-specific biomarkers, and AI-driven analyses enables early detection, cost-effective care, and equitable access. Strengthened laboratory infrastructure and trained workforce will foster sustainable healthcare improvements and region-specific biomedical research.

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