

How agile laboratories enable healthcare systems to innovate new models of care

A report by The Economist Intelligence Unit

Key points:

- Clinical laboratories are an integral part of the healthcare continuum with the majority of healthcare decisions supported by diagnostic testing.
- The covid-19 pandemic has tested the adaptability and agility of clinical laboratories and exposed vulnerabilities in the current healthcare system.
- The healthcare landscape is rapidly changing with increasing pressure on cost containment and efficiency gains, evolving reimbursement practices, shifting research priorities and health system consolidation.
- The clinical laboratory must be integrated into the wider health system for healthcare organisations to achieve their full benefit.
- Advancements in laboratory technology including automation and informatics position the clinical lab to provide health systems with the data and insights they need to support public health efforts and lead the transition to value-based healthcare.

Introduction

Clinical laboratories are an integral part of the healthcare continuum. Sometimes defined as the “nerve centre of diagnostic medicine”,¹ the role of the clinical laboratory transcends beyond processing diagnostic tests, to providing vital information, to informing screening, prevention, early diagnosis, tailored treatment, and monitoring and management of human diseases and population health.

The clinical laboratory touches the entirety of the human condition and course of life. The activity of laboratory professionals interconnects with all medical disciplines. Accurate lab test results enable physicians to make appropriate and informed clinical and diagnostic decisions across all levels of healthcare.

The majority of healthcare decisions are supported by diagnostic testing. In the United States, an estimated 13 billion tests are performed annually, driving approximately two-thirds of medical decisions.² In the United Kingdom, the National Health Service (NHS) estimates that 95% of clinical pathways rely on pathology services with 500 million biochemistry and 130 million haematology tests performed annually, averaging at 14 tests for each person in England and Wales per year.³

Clinical laboratories generate and hold the most data on patient and population health within the healthcare ecosystem.⁴ How laboratories use this data to create value could place them at the forefront of patient care.

The impact of laboratory services on clinical pathways and patient outcomes is evident.



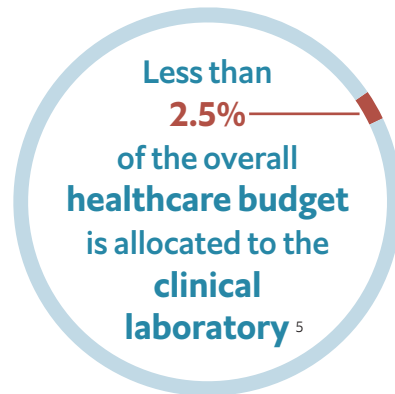
Clinical laboratories are essential for the delivery of healthcare. They are at the centre of medical decisions and prognosis. In many circumstances, they provide the most crucial information for a patient’s health.

*Dr James Crawford,
Executive director and senior vice president of Laboratory Services at Northwell Health in the United States*



Laboratory testing is one of the most important interventions for preventing and treating diseases. Clinical laboratories should therefore have an active role in managing patient care.

*Mr Nqobile Ndlovu,
Chief executive officer for the African Society for Laboratory Medicine in Ethiopia*



Accurate and timely diagnostic testing leads to early disease identification and enables better management of economic resources. However, the importance of the clinical laboratory in the delivery of healthcare is not reflected in funding and resource allocation. Clinical laboratory or diagnostic testing constitutes less than 2.5% of the overall healthcare budget, and laboratories are under increasing pressure to produce greater volume at lower cost.⁵ Traditional laboratory systems, often with an emphasis on cost control, leave little flexibility for laboratories to adapt to the changing healthcare landscape and conditions or acute disruptions, such as the covid-19 pandemic, when the laboratory is increasingly relied on to play an even greater role in driving quality and efficiency in healthcare delivery.



Clinical laboratories are the very basis of the starting point of any patient care. It is the foundation; everything we do is based on evidence that comes from the clinical lab.

*Dr Prabal Deb,
Head of operations at Aster Clinical Labs in India*

The importance of agility: covid-19 and the clinical laboratory

The covid-19 pandemic has had a devastating impact on global health and continues to challenge healthcare infrastructure and delivery. Praised as ‘the unseen frontline’ of the covid-19 pandemic, clinical laboratories have visibly demonstrated their vital role and value in public health and patient management.⁶ Covid-19 testing is the keystone of effective testing, tracing and treatment strategy, informing many clinical, infection control, and public health decisions.

High testing volumes, demand for rapid turnaround times, evolving testing algorithms, and continually developing national guidelines have tested the adaptability and agility of clinical laboratories and exposed vulnerabilities in the form of current structures, workforce capacity and integration with the broader health system.⁷

Evolving the laboratory system to meet testing demand

The power of clinical laboratory infrastructure and status within the health system is reflected in the speed of response in many countries. South Korea’s previous experience of the outbreak of severe acute respiratory syndrome (SARS) in 2002/2003 meant that plans were already in place, and public and private laboratories could scale up capacity rapidly. This rapid response was supported by an integrated network of public health institutions, private laboratories and hospitals. At the end of February 2020, 65,000 tests had been conducted in South Korea, while

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the US Centres for Disease Control (CDC) had analyzed less than 500 samples.⁸

As clinical laboratories are usually designed to sustain testing volume appropriate for a local health system, demand above surge capacity or a change in the test mix can overwhelm existing infrastructure. The adaptability of systems and processes within the laboratory, including information technology, laboratory management tools and the speed at which staff can adapt to new workflows and informatics tools, is critical for maintaining operations and responding to the crisis.¹⁰



Covid-19 showed we are unprepared to deal with the next pandemic. At the beginning of the pandemic, Africa had just two countries that could test for covid-19, Senegal and South Africa. We need to build this capacity.

*Mr Nqobile Ndlovu,
African Society for Laboratory Medicine*

Maintaining covid-19 testing capacity while preserving routine operations

Testing requirements over the course of the pandemic are evolving, particularly as new variant strains emerge, and there is a need to maintain testing volumes in the face of surging cases.⁹ Implementing lessons learned during the early stages of the pandemic from integration and coordination among policymakers, laboratories and the broader health system will be critical to support the ongoing response.



As we reopen healthcare and society, testing will continue to be essential.

Dr James Crawford, Northwell Health

The pandemic has majorly disrupted routine diagnostic services and forced many labs to shift attention and resources to covid-19 testing.¹¹ An international survey conducted by the Association for Molecular Pathology looked at the impact of covid-19 tests on molecular testing for cancer. 70% of respondents reported that they have decreased or stopped the development of new tests, and approximately 40% of laboratories have either suspended or cancelled plans to upgrade new equipment. Reasons for the disruption to cancer testing activities were linked to supply chain disruptions, staff shortages and redirection of lab personnel and space to covid-19 testing and a decrease in elective procedures resulting in fewer tests.¹²

National cancer screening programs were temporarily suspended in England in the early stages of the pandemic. In June 2020, Cancer Research UK warned that more than 2 million people could be waiting for tests.¹³ Another study in the UK predicts over 3,000 additional cancer-related deaths within the next five years due to diagnostic delays.¹⁴ As diagnostic testing underpins much of the clinical activity in hospitals, delays in diagnosis cause delays in treatment referrals, leading to further bottlenecks. NHS data from mid-2021 indicates that screening and treatment referrals are now on track with a 32% increase in people starting cancer treatment, compared to the same period last year.¹⁵

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The pandemic has accelerated development in connectivity, communication and digitisation to create space for rapid change while preserving routine operational activities in other areas.¹¹

The immediate challenge for laboratories will be to maintain routine screening and testing levels while also being prepared to meet demands as new variants trigger further waves of covid-19.

Informing the public health response

Beyond testing, clinical laboratories play a vital role in providing data to drive the public health response. Clinical laboratories hold data about comorbidities such as diabetes, asthma, heart disease, and immunosuppression associated with more severe cases of covid-19. This data can be harnessed and applied to demographic and risk data such as age and postal codes to help public health workers and physicians identify patients who would be most at risk from a covid-19 infection.

Information processing and data management have become more critical during the pandemic. However, there are some limitations to unlocking the potential of covid-19 related data, from technical aspects such as analysis methods, data mining and machine learning algorithms and system challenges such as integration and accessibility.¹⁰

In addition to challenges related to the pandemic, the laboratory industry is also facing unprecedented workforce shortages. The US Bureau of Labor and Statistics expects the demand for laboratory professionals to grow by 25,000 jobs per year between 2019 and 2029.¹²



We need unified data; the UK and Israel were able to quickly produce covid-19 public health data owing to their national health care structure.

Dr James Crawford, Northwell Health



People now understand the value and importance of automation. Automation was implemented into lab systems during the pandemic. As we advance, health systems will be overwhelmed with chronic diseases, oncology cases etc., clinical labs will be better equipped to meet the demand.

Dr Prabal Deb, Aster Clinical Labs

The covid-19 pandemic has raised the importance of the clinical laboratory in the pandemic response and population health and spurred the acceleration and adoption of new technologies within the lab. Increased automation of common lab tasks and workflows will continue, driven by their accelerated use out of necessity during the pandemic.

The covid-19 pandemic has tested the agility and adaptability of laboratory systems, structures, and processes. Lessons learned have equipped clinical laboratories with a roadmap for future pandemics and health crises. However, the pandemic is not the only force testing laboratory systems. The healthcare landscape is rapidly changing with increasing pressure on cost containment and efficiency gains, evolving reimbursement practices, shifting research priorities and health system consolidation. Healthcare systems need to anticipate these changes and enable the clinical laboratory to respond to new challenges through the adoption of flexible laboratory design strategies and operations, new diagnostic approaches, and advanced laboratory technology.

Emerging trends: evolving role of the clinical laboratory to meet current health challenges

Growth in older population segments, the increasing burden of chronic diseases and government investment in healthcare is driving the demand for clinical laboratory services. These demand drivers combined with the rising adoption of digital pathology platforms and the increasing pace of research and development in diagnostics, thrust the clinical laboratory to the forefront of the future of healthcare.¹

Laboratory integration and consolidation

Mergers, acquisitions, outsourcing and consolidations, with the goal of improving efficiency, increasing volumes and reducing the cost per test, are standard in the current clinical laboratory environment.

Value-based care, a delivery model in which providers are compensated based on health outcomes, is a topical concept in many healthcare systems as all stakeholders are looking to optimise value and build a more sustainable health system. In the clinical laboratory space, we are starting to see a shift in focus from volumes and cost per test to the effectiveness of laboratory information in improving diagnostic and therapeutic pathways and clinical and economic outcomes.¹⁷

The clinical laboratory is at the heart of this shift towards value-based care. The laboratory should not be viewed in isolation but at the centre of coordinated care as health systems move to

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lower costs while achieving optimal patient outcomes. To optimise the clinical benefit of laboratory and diagnostic services, the laboratory must be represented in the integration efforts of the wider health system.



The clinical laboratory needs to be integrated in the current healthcare infrastructure or healthcare network. In-system labs place lab experts closer to the local medical team, supporting medical decision-making. Many things are lost if the laboratory is outside the health system, but we know that this is not always financially sustainable. We gain a lot of economy of scales with big lab centres, but risk losing proximity to clinical care.

Dr James Crawford, Northwell Health

Advanced testing capabilities

The move from standardised medicine towards preventive and personalised care with a high degree of patient centricity necessitates more complex and specialised tests. Advances in genomics, automated technologies, informatics and big data's potential in combination with increasing consumer expectations and demand for individualised treatment options are driving innovation in clinical diagnostics.

The introduction of more advanced and effective tests, including genetic tests, non-invasive tests and new forms of cancer screening, should position the clinical laboratory to play a more central role in the patient's journey.

Developments in biomarkers are leading to improved diagnosis and management of cardiovascular diseases (CVDs) and traumatic brain injury (TBI).



Advancements in biomarkers such as high-sensitivity cardiac troponin, while not yet widely available, including in the US, have the potential to optimise screening and risk stratification for CVDs, helping to identify patients at high-risk of heart disease earlier, prioritise treatments and prevent unfavourable outcomes.¹⁷ Recent developments in biomarkers for TBI are helping to create a more holistic view of the condition, transforming how TBI is managed, improving diagnosis, predicting the rate of severity and supporting personalised treatment.^{18,19}

The adoption of automation and informatics supported by machine learning

Automation and the application of machine learning (ML) in informatics are among the leading technological innovations shaping the role of the clinical laboratory.²⁰

Automated equipment allows robotic systems to rapidly and efficiently perform processes that

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laboratory assistants or technologists would have previously done. Recent developments shaping laboratory automation include robotics and the use of custom built robots to automate DNA extraction from blood and saliva, increasing sample processing throughput and improvements in the integration of different types of testing, such as chemistry, haematology and immunoassay onto a single analyser, helping to optimise laboratory space.²¹

Informatics can be applied to mine and interpret the information from large databases, rapidly analyse laboratory results and compare patient data to existing datasets, enabling more informed treatment decisions and optimising patient outcomes.



The potential for applying machine learning to laboratory data will revolutionise efficiencies in throughput capacity, accelerate the adoption of advanced and complex testing, help mitigate workforce shortages and position the laboratory as the data hub for the healthcare system, leading the change from reactive to proactive medicine. The efficiencies generated through automation and informatics will empower laboratories to better serve the needs of clinicians and patients and ultimately be a more productive resource supporting the broader objectives of the health system.

Implementing automated technologies and advanced informatics is highly challenging and requires investment and robust implementation strategies to deploy these complex systems. Existing laboratory infrastructure often needs

to be remodelled and the workforce upskilled to operate new systems.^{20,22}

Role of the laboratory as a partner in public health

Advancements in automation and artificial intelligence (AI) provide an opportunity to leverage clinical laboratory data to support public health. Laboratory data and analytics can contribute to clinical decision support, support health plans and monitoring of chronic diseases, and inform disease surveillance at a population level. Data generated from the laboratory can help predict and understand public health risks, enabling physicians and policymakers to customise interventions, including prevention measures, screening and treatments for specific subpopulations.²⁰

In the example of chronic disease, population health data can identify at-risk or pre-diabetic stage individuals, enabling interventions to slow and ideally prevent disease progression. Laboratory test results can help monitor changes in diet and blood glucose levels in at-risk individuals, preventing complications such as heart disease, stroke, blindness and kidney disease. Prevention and early treatment will also generate cost savings in the health system.²³

The covid-19 pandemic has clearly demonstrated the role of the clinical laboratory in supporting public health with data generated through diagnostic testing supporting surveillance, identifying vulnerable population groups, informing health policy, and monitoring vaccine efficacy.

There is an opportunity for clinical laboratories to play an advanced role as a critical partner

in population health management by building on partnerships with health and government stakeholders. The clinical laboratory can have an active role in designing and implementing future care delivery models that are rooted in generating value and best meet the needs of the local population.



The laboratory is the first to see the data. In an integrated healthcare system, laboratories can contribute to timely diagnosis, and better optimization of therapies and better prognosis. If we take the perspective of regional populations, we can translate lab information into programming for population health and work with public health authorities.

Dr James Crawford, Northwell Health

Preparing for the future: Elevating the role of the clinical laboratory in the healthcare system

The covid-19 pandemic has planted the clinical laboratory at the forefront of healthcare. To maintain this elevated role and thrive in a rapidly changing environment, clinical laboratories need a high level of adaptability and agility. Making better use of existing data and resources, building a workforce that can support constant innovation, and strengthening the clinical laboratory to lead the transition to value-based care can validate the clinical laboratory's potential as a strategic force in the future of healthcare.

Making the most of clinical laboratory data

There is potential for the clinical laboratory to become the 'big data hub' of the healthcare system. However, if the data collected cannot demonstrate the impact of the laboratory services to stakeholders involved in the clinical pathway, it is unlikely that the full value of the clinical laboratory will be realised.

The work of the laboratory is not done with the test result. There is the untapped potential of the data generated in the clinical laboratory to inform real-time treatment decisions, target population health interventions and provide insights on cost-effectiveness and risk assessment. Laboratories need to promote more effective utilisation of data and position the laboratory as a steward or central repository of data to prove their potential in enhancing patient and population outcomes,

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reducing the total cost of care, and strengthening the patient and clinician experience.²⁴

It is also necessary to consider supporting infrastructure. As Dr Prabal Deb explains, 'Another important factor is effective IT setup. It is very important because the report may be ready, but if it doesn't reach the clinician/patient at the right time, the test doesn't make any impact.'



We need to reframe the lab's product. We must see our product as information that is actionable, not simply data. We need to change our vocabulary from a "sick patient perspective" to a "healthy consumer". Hopefully, in the future, clinical labs will have a greater role in wellness care.

Dr James Crawford, Northwell Health

Preparing the workforce of the future

A critical challenge that clinical laboratories will have to overcome is the widening gap between the demand for laboratory services and the lack of skilled professionals. Many countries around the world are struggling with a significant decline in laboratory professionals.²⁵

The role of the pathologist or laboratory technician is also evolving with greater emphasis on informatics, data science and machine learning (ML). Laboratory professionals have unique expertise and often acute knowledge of the impact of diagnostic testing and on patient prognosis, treatment, and outcomes. This expertise prompts a greater need for

laboratory staff to be integrated into the wider health system through multidisciplinary teams and integration into other areas such as biotechnology and genetics.²⁶

The adoption of automation and informatics should result in fewer resources required for manual operations, freeing laboratory staff to focus on more skilled roles, better integrated within multidisciplinary teams and prepared for future disease outbreaks and health emergencies.

Training of new laboratory staff will need to include a much larger emphasis on informatics and data science. Upskilling and continuing medical education opportunities will need to be developed to enable the current workforce to acquire the necessary skills. Data scientists will also become an integral part of laboratory operations, working alongside pathologists and laboratory technicians in the clinical laboratory of the future.²⁰

More efficient workflows and laboratory processes supported by the increased adoption of automation and ML will also promote the consolidation of laboratory services, allowing laboratories to increase volumes and expand services while gradually reducing the demands for laboratory staff.²¹

Leading the transition to value-based healthcare

The impact of the clinical laboratory across the continuum of care, role in public health and insights generated on diagnosis, treatment and outcomes place the clinical laboratory in a prime position to lead the transition to value-based health care.

The laboratory is in a unique position to provide leadership and direction to overcome current health system challenges of spending, quality and increasing complexity and optimise time-to-diagnosis and time to treatment and support prevention, care coordination and cost-effectiveness.

Despite this promise, current systems and structures make it difficult to integrate laboratory insights into existing clinical pathways or provide information for clinical decision support. There is also limited outcomes-based evidence to support laboratory-led innovation.²⁶

There is a need for new standards and methods to measure what matters; quality, costs and outcomes, to stakeholders in the wider health system and for alignment on the goals of a value or outcomes-based system.¹⁹

The laboratory has considerable influence on population health through supporting pre-diagnostic identification, guiding treatment decisions and delivering post-diagnostic computations and longitudinal data to inform public health decisions and reduce the total cost of care.²³

Conclusion

The covid-19 pandemic, in combination with trends in diagnostic demand, innovations in testing capabilities and automation, have shifted how we think about the laboratory; from a volume-driven commodity to a high-value service that can drive better outcomes for patients, providers and the wider health system. When leveraged correctly, the clinical laboratory can greatly assist health systems in attaining better operational efficiency and clinical outcomes. To achieve this elevated role, health systems should:

Position the clinical laboratory to support population health.

Accelerate the adoption of advanced testing capabilities that are cost-effective and support population health. The laboratory is at the core of clinical decision making and should have an active role in designing and implementing future care delivery. Health systems need to facilitate advancements in laboratory technology and testing capabilities to support preventative care and proactive medicine.

Elevate the value of the clinical laboratory by demonstrating its benefit to the entire health system.

For the health system to reap the full benefit of the clinical laboratory, we need a better understanding of the costs and value generated by the laboratory. Laboratory services constitute a promising revenue source for health systems while producing insights to improve outcomes at a lower cost. IT systems should be implemented and integrated to generate data and insights that measure laboratory outcomes. These insights can help health systems structure clinical laboratory services as a valuable economic resource that

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best fits the needs and context of local and national health dynamics.

Invest in agile laboratory infrastructure, technology and professionals.

Covid-19 was the ultimate wake up call for health systems to support flexible clinical laboratory infrastructure and systems prepared for future health challenges. Investment in clinical laboratory infrastructure, technology, and professionals needs to be prioritised to maximise the laboratory's full potential and thrive in a rapidly changing environment. Health systems must proactively anticipate future changes and respond to new opportunities with agility and readiness to adapt laboratory operations.

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- **Dr Prabal Deb,**
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