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Review Article

Biomedical Laboratory Practices and Challenges in Digitalisation: A Review

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ABSTRACT

Biomedical laboratory plays an important role in the healthcare system by providing services for medical screening, diagnosis, and treatment selection, which is the backbone of a healthcare system. The growing demand for complex testing has placed biomedical laboratories under heavy pressure, leading to an increase in collaboration and bridging the service gaps among laboratories. During the COVID-19 pandemic, laboratories around the globe struggled to perform a large number of COVID-19 laboratory tests every day, as the country combats through the outbreak. This review provides an overview of biomedical laboratory settings and assurance, and discusses current biomedical laboratory practices and their level of digitalisation in Malaysia and a few other countries, such as the United States, Europe, Saudi Arabia, and Africa, during the outbreak. Despite the variety of laboratory practices in different countries, digitalisation remains important in supporting the healthcare system during the COVID-19 pandemic. This review also highlighted the challenges of current practices, which should be addressed to further enhance the accessibility and reliability of biomedical laboratory services. The suggestion of collaboration within the healthcare system has also been discussed to improve laboratory services for handling outbreak situations.

Keywords: Biomedical laboratory, Healthcare digitalization, COVID-19 pandemic

1. INTRODUCTION

Biomedical laboratories are under heavy pressure owing to the rising demand for higher and more complex test requirements, which has resulted in an increasing number of laboratories collaborating to fill gaps in service coverage, especially during the COVID-19 outbreak (Cornish et al., 2023; Strain and Sullivan, 2019). The COVID-19 pandemic has affected medical testing laboratories worldwide (Holladay, 2020; Mazer, 2021; Binnicker, 2020). Many biomedical laboratories have struggled with requests and demands for solutions to combat outbreaks (Cornish et al., 2023; Mazer, 2021). In Malaysia, biomedical laboratories are under heavy pressure to carry out a high number of COVID-19 tests daily, including an 86% increase in diagnostic laboratory capacity, as the country struggles through the outbreak (Codeblue, 2020; WHO, 2020a). Biomedical laboratory testing is increasingly important in

medical practice, from screening and diagnosing medical conditions to choosing appropriate therapies to treat diseases (Sikaris, 2017).

With the emergence of an outbreak, healthcare has enormous potential for the adoption of digital health solutions as digital technologies have revolutionised society in every aspect of life. The World Health Organization (WHO) has begun harnessing digitalisation in healthcare to meet public care needs and treatment demands. With a steadfast commitment to accelerating global health and well-being, the WHO pioneered efforts to unlock the full potential of digital technologies in healthcare (WHO, 2021). Digitalisation in handling biomedical laboratories can support the testing demand and increase the effectiveness and accessibility of the services provided. This further helps to control and manage the pandemic outbreak in a timely manner. The most recent technological development in the healthcare sector is the use of artificial intelligence to predict a disease and allow for the control of disease development by proactively initiating a better lifestyle guided by healthcare professionals (Kumar et al., 2022). However, the use of artificial intelligence to identify patients at risk of a disease relies heavily on the medical data produced by medical testing laboratories (Alowais et al., 2023; Kumar et al., 2022). The limited accessibility of healthcare services with many biomedical testing requirements in rural areas further challenges the transmission of data; thus, it is crucial to ensure the right environment for digital healthcare.

2. OVERVIEW OF BIOMEDICAL LABORATORY

Biomedical laboratories are important entities in healthcare systems. According to the United States Department of Health and Human Services, 14 billion laboratory tests are ordered annually, and most current medical decisions (~70%) for health diagnosis and treatment are commonly based on the outcome of the biomedical test (CDC, 2018). Biomedical laboratories cater to a wide range of tests, ranging from simple (routine) tests to more complex and sophisticated special laboratory tests that are difficult to perform (Bayot, 2024). Routine tests, such as basic biochemistry and haematology tests, are commonly used in the medical community, including testing for blood cholesterol, glucose, and hormone levels. A special test refers to a complex test that is difficult to perform and rarely requested. Genetic testing and the COVID-19 polymerase chain reaction (PCR) are examples of such special tests. Most routine tests are performed in house; however, special tests can be performed in reference laboratories (Bayot, 2024; Sluss, 2014).

Biomedical laboratory setups can be broadly categorised into hospital and non-hospital laboratories. Hospital laboratories are attached to the hospital, while non-hospital or peripheral laboratories, better known as free-standing or community laboratories, perform testing for follow-up patients referred to by general practitioners, clinical research sites, and other clinics. Most biomedical laboratories are located in or close to hospital buildings, which allows access to physicians and patients (Bayot, 2021). These laboratories may be funded by the government or by private equity. Furthermore, a biomedical laboratory can also offer subspecialty testing services such as biochemistry, haematology, serology, microbiology, histology, cytology, and molecular and genomics. Each biomedical laboratory is designed with a distinct laboratory setup, instrumentation, and skill set, depending on the type of service. In Malaysia, most public and private healthcare centres offer a wide range of biomedical testing services (HKL, 2024; Pantai Hospital, 2024).

3. ASSURANCE OF BIOMEDICAL LABORATORY PRACTICE AND QUALITY

Biomedical laboratories worldwide have faced an unprecedented demand for laboratory tests during the COVID-19 pandemic (Jit et al., 2021; Binnicker, 2020). This surge in demand

has overburdened laboratories, making it challenging for them to process tests within the expected timeframe. The lack of accreditation among many biomedical laboratories is a significant issue. In Malaysia, out of 200 registered biomedical laboratories, only 65 have ISO15189 accreditation (DOSM, 2024). This highlights the need for more stringent measures to ensure that all laboratories can provide accurate and timely test results, thereby supporting the overall healthcare response during the pandemic.

A well-practiced biomedical laboratory would have accreditation of internationally recognised standards, such as ISO 15189:2012, which monitors their performance competence and assesses their management system quality. The standard is used by regulators, accreditation bodies, and customers to confirm and recognise laboratory competence in laboratory practice (Tzankov and Tornillo, 2016; Zima, 2017). A biomedical testing laboratory with one or more accreditations demonstrates its commitment to quality assurance. Laboratory qualities were measured based on test accuracy, reliability, and service constancy (WHO, 2024).

Laboratory accreditation, which is accredited by a third-party authority, is a formal recognition of a laboratory's ability to perform biomedical testing. In Malaysia, ISO 15189 accreditation is certified by Jabatan Standard Malaysia (JSM) under the Ministry of International Trade and Industry (MITI) (DOSM, 2024). An accreditation body in the United Kingdom, the United Kingdom Accreditation Services (UKAS), is recognised by the British government to assess the competence of laboratories and provide ISO 15189 certification, testing, and inspection services (UKAS, 2023). College of American Pathologists (CAP) accreditation is a prestigious certification and accreditation program awarded to medical laboratories and facilities in the United States and internationally. The CAP is a professional medical organisation composed of pathologists and is one of the leading organisations responsible for setting standards and ensuring the quality of laboratory testing and pathology services (CAP, 2024). The biomedical laboratory accreditation demonstrates its commitment to quality assurance.

Biomedical laboratory test quality is not as straightforward as test costs, which can be easily compared based on fee values because the metrics used to measure test quality may vary between laboratories, leading to ISO 1589 accreditation and the College of American Pathologist (CAP) standard. An accredited laboratory must comply with the regulations by reporting all aspects of laboratory operations in a reliable clinical and health setting from time to time and ensure the accuracy and consistency of all biomedical tests performed. For laboratories to retain high-quality lab services in house, one of the underlying reasons that may have put laboratories in such a predicament is the low volume of esoteric or specialised tests, making it financially and technically inviable for in-house performance (Plebani, 2018; Sluss, 2014). The lack of specialised technicians with knowledge and experience in handling specific biomedical special tests as well as limited equipment in the house are also the reasons for sending out laboratory tests to the reference laboratory. Through outsourcing, a laboratory can access specialised skills or resources, which is particularly useful in cases of low demand for laboratory tests that require specialised instruments, facilities, and personnel, while simultaneously reducing costs (Mrak et al., 2018; Plebani, 2018; Sluss, 2014).

4. PRACTICES IN BIOMEDICAL LABORATORY TESTING SERVICES AND DIGITALISATION

Data-driven algorithms for decision support are widely used in the healthcare industry (Rahman et al., 2020). However, curating datasets for analysis is a labour-intensive process that entails integrating many data sources and discerning pertinent attributes, including laboratory data from multiple systems and results from outside laboratories (Pan and Cimino,

2015; Rahman et al., 2020). Data integration within medical data pipelines frequently entails the incorporation of data originally obtained for objectives unrelated to the specific research enquiry at hand. This indicates that data are sometimes not collected in a format suitable for analysis (Pan and Cimino, 2015), and the absence of essential metadata information further complicates the data integration process. Manual data processes in the present implementation of laboratory test-outsourced activities at the NIH Biomedical Translational Research Information System (BTRIS), United States, poses a significant challenge and is increasingly burdensome for laboratory personnel. Findings derived from the analysis of data in electronic health records (EHRs) indicated that most of the outsourced biomedical test results were found to be labelled as "outside the testing" or a similar generic label (Pan and Cimino, 2015). Consequently, these outside laboratory tests with nonspecific labels are difficult to differentiate, which further impedes other tasks such as patient care, data sharing, integration, analysis, and decision support (Pan and Cimino, 2015).

Additionally, the decision on the distribution of laboratory testing, whether it should be conducted on-site or outsourced to an external laboratory, depends heavily on cost considerations (Pentella et al., 2020; Sluss, 2014) and an evaluation of the specimen's ability to endure the logistics process (Pentella et al., 2020; WHO, 2020b). For example, certain bacterial or viral specimen's exhibit poor viability during transit, regardless of the preventive measures implemented (Procop and Winn, 2003). The sending laboratory was obligated to guarantee send-out specimen integrity, as stated by The Clinical Laboratories Improvement Act agency and the Joint Commission on Accreditation of Healthcare Organizations in the United States (Procop and Winn, 2003). Biomedical tests that possess a high level of complexity, rendering them unsuitable for on-site execution, as well as those that are infrequently requested (low volume) should be outsourced to a reference laboratory that provides testing services (Plebani, 2018; Sluss, 2014). These factors could be used to improve healthcare services when facing outbreaks, such as the recent COVID-19 outbreak.

A decade ago, the configuration of hospital laboratory medicine in Belgium, as in most European nations, was denoted as fragmentation, redundancy, and surplus capacity, which are deemed difficult to sustain in the contemporary competitive global economy (Schmidt et al., 2022). Currently, Europe is one of the most advanced countries in terms of healthcare growth, with a notable increase in the use of external or reference laboratories for esoteric tests and the practice of laboratory collaboration. Hospital laboratories opt to outsource esoteric testing to external reference laboratories. However, hospitals also consider outsourcing non-esoteric tests, which can be performed more often and at a lower cost, to offsite facilities (Langlois & Wallemacq, 2009; Mrak et al., 2018). However, there is a significant challenge to the distance between the laboratory and hospital, including lengthier turnaround times and a significant reduction in the effectiveness of communication between the laboratory and clinical staff. Laboratory efficiency and economic considerations (cost savings) are significant factors and advantages associated with collaboration and consolidation of laboratory services in Europe (Atkins et al., 2019; Kricka et al. 2015).

Lamovsek and Klun (2020) evaluated the costs of biomedical laboratory services in different Slovenian laboratories and investigated the impact of cost on test pricing. Based on their findings, it was determined that the provision of laboratory services at lower levels incurs significant costs and that laboratory productivity is positively influenced by their concentration and size. A survey was conducted in the form of a questionnaire completed by 31 country delegates to investigate the perspectives on the future of European clinical laboratories, revealing that the effective execution of demand strategies, interpretation of medical testing reports, and preanalytical analysis are among the challenges faced by biomedical laboratories. The study also indicated that, despite the anticipated rise in the number of tests performed, information technology and novel scientific discoveries will have

the greatest effects and that laboratory operations will be impacted by economic pressure (Kricka et al., 2015). The Royal Society of Clinical Chemistry of Belgium stated that outsourcing biomedical laboratory tests to referral laboratories posed significant challenges to hospital laboratories (Kricka et al., 2015; Langlois & Wallemacq, 2009). The COVID-19 pandemic has prompted increased collaboration and coordination between laboratories across Europe and worldwide (Jit et al., 2021).

During the COVID-19 pandemic, hospital physicians, particularly in the emergency departments of Saudi Arabia, rely heavily on prompt laboratory test results and turnaround times to make informed clinical decisions, indicating laboratory operational efficiency (Rabaan and Al-Tawfiq, 2021). Laboratory test results play a pivotal role in guiding physicians regarding patient admission, discharge, or the need for further diagnostic investigations. The daily observations of research conducted by Alshieban and Al-Surimi (2015) at King Abdul Aziz Medical City, Saudi Arabia, revealed that the most delayed tasks in laboratory testing were slide allocation and delivery by pathologists, slide inspection by pathologists, transcriptionists amending reports, and test report verification by pathologists. Their improvement focused on obtaining updated information on biomedical progress by sending reminder emails, followed by phone calls, to ensure workflow efficiency. Improvement was performed by using multiple PDSA cycles to examine these aspects during the intervention (Alshieban and Al-Surimi, 2015). Simsim et al. (2021) investigated the contemporary utilisation of technology in the delivery of healthcare services in Saudi Arabia. Their findings indicate that the use of technological advancements in healthcare provision in Saudi Arabia is increasing, albeit at a relatively low level. It highlights several challenges, such as inadequate facilities, limited awareness regarding the importance of these technologies, scarcity of skilled professionals, absence of a comprehensive information management strategy, lack of a national framework for medical data exchange, and absence of a national regulatory authority (Simsim et al., 2021).

In underdeveloped nations, establishing functional biomedical laboratories at all levels of the health system is extremely difficult. Non-digital laboratory referral networks are employed in African countries, Ethiopia, and Haiti, based on centralised and decentralised models (AACC, 2017; Fojungo et al., 2017). Both models work well for patient management in programs with low funding. Both models were found to have fast turnaround times, while maintaining the flexibility to integrate various laboratory tests (Fojungo et al., 2017). The number of patients engaging in HIV treatment programs within 6 months increased by 182% in Haiti as a result of the decentralised model. Using a centralised model, cost savings of up to 62% were achieved in Uganda. These models can be replicated in other healthcare settings as well. However, careful coordination and planning will be needed, including situational analysis, adaptation to the specific scenario, use of new technologies, and participation of all laboratory community members, including public-private partnerships, throughout the entire process (Fojungo et al., 2017).

Additionally, the Republic of Guinea government recognised the opportunity to expand its national laboratory system due to the emergence of the West African Ebola virus disease (EVD) outbreak from 2014 to 2016 (Standley et al., 2019). Most healthcare services are limited by funding for disease control programs under the World Health Organization (WHO) and the government for vaccine-preventable illnesses (Kiyaga et al., 2021). To strengthen national laboratory services, the government seeks assistance from international partners in the development of a non-digital referral system that focuses on priority diseases with confirmatory diagnoses. The developed system is required to follow national disease detection and surveillance guidelines and meet international frameworks (e.g., International Health Regulations (IHR)) to accommodate local needs while sustaining resource availability and system maintenance (Kiyaga et al., 2021; Standley et al., 2019).

In Malaysia, the National Strategic Plan for Non-Communicable Diseases (NSP-NCD) 2016-2025 developed by the MOH Department of Prevention and Control, Malaysia, addresses non-communicable diseases (NCDs), which are the main cause of mortality and morbidity among the adult population in Malaysia (KKM, 2020). An increase in screening and conducting NCDs laboratory testing can help people with NCD risk. PeKa B40, which is a free health screening, including biomedical laboratory testing, is one of the Malaysian Ministry of Health initiatives that intends to sustain low-income groups' healthcare needs by focusing on NCD laboratory testing (KKM, 2023). Eligible people can undergo general health screening at any partnered biomedical laboratory facility in Malaysia, including government or private facilities. However, poor collaboration between the private and government sectors has become a challenge in the development of Malaysia's healthcare system (Ahamed et al., 2017). The COVID-19 pandemic has further emphasised the importance of technology in handling laboratory tests and making the laboratory workflow more efficient.

5. CHALLENGES IN BIOMEDICAL LABORATORY TESTING SERVICES

Providing biomedical laboratory services can be challenging and laborious for laboratory professionals. Financial considerations for certain laboratory tests have compelled laboratories to outsource laboratory tests to minimise costs. Outsourcing services, as a potential cost-saving measure, have spread to healthcare services, including biomedical laboratories (Plebani, 2018). However, the absence of readily accessible centralised information regarding the availability of tests or a comprehensive list of laboratories that offer outsourcing services is one of the primary difficulties that they face. The lack of standardised and easily accessible information further complicates the decision-making process of laboratory professionals. In the absence of comprehensive information, some laboratories resort to selecting their preferred outsourcing partners based solely on financial considerations. For example, community hospitals outsource specialised tests to maintain competency and ensure accurate results (Mrak et al., 2018).

Urgency may arise from the limited survival time of the specimen after it has been collected, necessitating quick and efficient testing (WHO, 2014; Procop and Winn, 2003). This is also one of the challenges usually faced by laboratories with limited facilities or technical expertise to perform biomedical testing, particularly highly complex tests, resulting in the decision to outsource (Plebani, 2018; Sluss, 2014). Special or esoteric tests for very rare diseases require special equipment and facilities for diagnosis. The low demand for esoteric tests necessitates the use of specific equipment in the laboratory. However, there is a shortage of available outsourcing laboratories in nearby locations with the ability to provide a broad range of services, particularly in emergencies, or when the time for conducting tests on a specimen hinders the process of laboratory services. The extent of the geographic distance offered by an outsourcing laboratory is also a crucial consideration (Mrak et al., 2018). Laboratories that are easily reached, adjacent to other facilities, or have wider and more comprehensive service coverage tend to be the preferred outsourcing options.

The imprudent selection of a reference laboratory for outsourcing can provide significant ramifications for laboratory services. A laboratory that neglects customer services, such as the quality of care exhibited by laboratory staff during testing, proper handling of samples, prompt responses from laboratory professionals, and responsiveness of outsourcing laboratories to any issues or concerns raised by the customer, could also affect the overall quality and performance of laboratory services. Such problems can compromise the quality of patient care, making it essential for laboratories to approach the selection process diligently. Laboratories with good customer service value outsourcing partnerships by maintaining high-quality turnaround times for high-quality tests. Efforts are being made to address this challenge and enable medical

professionals to easily and objectively make informed decisions when selecting their preferred outsourcing laboratories (Plebani, 2018; Mrak et al., 2018; Sluss, 2014).

6. CONCLUSION

The COVID-19 pandemic has led to a surge in telehealth and virtual visits (Koonin et al., 2020; Li and Carayon, 2021). These factors have contributed to a wide range of transformative advancements in healthcare, particularly in biomedical laboratory services. The global health crisis has heightened the imperative for effective global governance and has expedited the implementation of digital solutions for laboratory services. This study provides an overview of biomedical laboratory settings and assurance, and reviews current biomedical laboratory practices and their digitalisation development. The transition from COVID-19 swab testing at healthcare facilities to antigen self-testing kits at home represents a significant shift in pandemic management. Initially reliant on centralised testing centres, the availability of self-test kits empowers individuals to promptly assess their status, facilitating quicker detection and isolation of cases. This decentralisation not only eased the burden on healthcare facilities, but also enhanced accessibility, particularly in remote or underserved areas. Moreover, it reflects healthcare's embracing of technology to optimise services. By leveraging advancements in diagnostics and telemedicine, healthcare systems can offer more efficient and convenient solutions, ensuring timely intervention while promoting public health. This evolution underscores the adaptability of healthcare in integrating innovative tools, ultimately enhancing the resilience of pandemic response strategies. The pandemic has highlighted the importance of sharing information, resources, and expertise to effectively manage and respond to a global health crisis. The widespread implementation of telemedicine by numerous nations during the pandemic has served as an initial impetus for the expansion of digital healthcare.

A comparative study between Malaysia and other countries (i.e., the United States, Europe, Saudi Arabia, and South Africa) highlighted that some countries employ non-digital systems, whereas others have limited evidence of biomedical laboratory collaboration and current practices. Despite non-digital advantages, there are opportunities for improvement through digitalisation, especially due to global advancements in technology. The use of digital systems has the potential to improve communication across many tiers in the healthcare system. Digitalisation plays a crucial role in enhancing laboratory services and collaboration among different laboratories. The implementation of digitalisation has the potential to improve and transform the working methods. Thus, the results and discussion of this study indicate that there is significant variation in laboratory practices among the studied countries. There are prevalent issues associated with the specificity of turnaround time, process speed, and sample transportation. This research highlights the need to enhance and standardise laboratory practices to improve patient care, minimise delays, and optimise the utilisation of resources. Through the utilisation of technology, these nations have the ability to capitalise on the advantages provided by automation, real-time tracking, and standardised communication in order to optimise their biomedical laboratory services.

Evaluation of the efficiency of medical laboratories is of mutual concern to both health service users and health policymakers. It was determined that digitalisation plays a crucial role in laboratory services, particularly in facilitating collaboration among different laboratory services. The analysis findings can assist public healthcare institutions in identifying existing gaps in practice and subsequently optimising the processes. The results of the study emphasise the significant benefits of implementing digital laboratory procedures in all nations studied. The implementation of digitalisation in laboratory workflows has the potential to significantly transform the efficiency, performance, and coordination of processes in respective countries. These examples illustrate that the results of laboratory practices suggest that the adoption of a

platform strategy, characterised by a structured workflow, might generate an interconnected impact that will yield advantages for various disease programs.

Declaration of Interest
The authors declare that they have no conflict of interest.

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