https://doi.org/10.48047/AFJBS.6.10.2024.7190-7203

African Journal of Biological Sciences

Journal homepage: http://www.afjbs.com

Research Paper Open Access

EXPLORING THE CHALLENGES AND PROSPECTS IN HEALTHCARE INDUSTRIES: NAVIGATING FUTURE TRAJECTORIES

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Article History
Volume 6 issue 10, 2024
Received: 15 May 2024
Accepted: 15 June 2024
doi:
10.48047/AFJBS.6.10.2024.7190-7203

Abstract

The Biopharmaceuticals, biotech, and diagnosticsindustries are critical in healthcare and industrial settings. These industries have faced several challenges in recent years, including the need for improved diagnostic technologies, regulatory hurdles, data management and analysis, and supply chain disruptions. In the diagnostics industry, there is an increasing demand for more accurate and reliable diagnostic tools, particularly in the face of emerging infectious diseases and chronic illnesses. This has led to a need for new and improved diagnostic technologies and more efficient and scalable manufacturing processes. Regulatory requirements for diagnostic products can be time-consuming and expensive to navigate, and there is ongoing debate regarding the appropriate level of regulation for new and innovative diagnostic technologies. In process monitoring, the volume of data generated by IoT (Internet of Things) devices can be overwhelming, leading to a need for advanced analytics tools to manage and analyze the data effectively. Additionally, the kit manufacturing industry faces challenges related to supply chain disruptions and material shortages, particularly in the wake of the COVID-19 pandemic. This has highlighted the need for more resilient and adaptable supply chains and a greater emphasis on inventory management and risk mitigation strategies. Addressing these challenges will require collaborative efforts between industry stakeholders, regulatory bodies, and technology providers. Innovations in diagnostic technologies and manufacturing processes and improvements in data management and supply chain resilience are critical for ensuring the accuracy, efficiency, and accessibility of diagnostic testing and process monitoring. It is essential to recognize and address these challenges to enable the continued growth and success of the healthcareindustry.

Keywords: Healthcare, Diagnostics, Process monitoring, data analytics

1.0 Introduction

Diagnostics, process monitoring, and kit manufacturing are crucial parts that play an essential role in healthcare, biotechnology, and other industrial sectors(1). However, these industries face several challenges that must be addressed to ensure they can continue functioning efficiently and provide accurate results mentioned in fig 1(2). This reviewdiscusses the challenges faced by the diagnostics process monitoring and kit manufacturing industries.

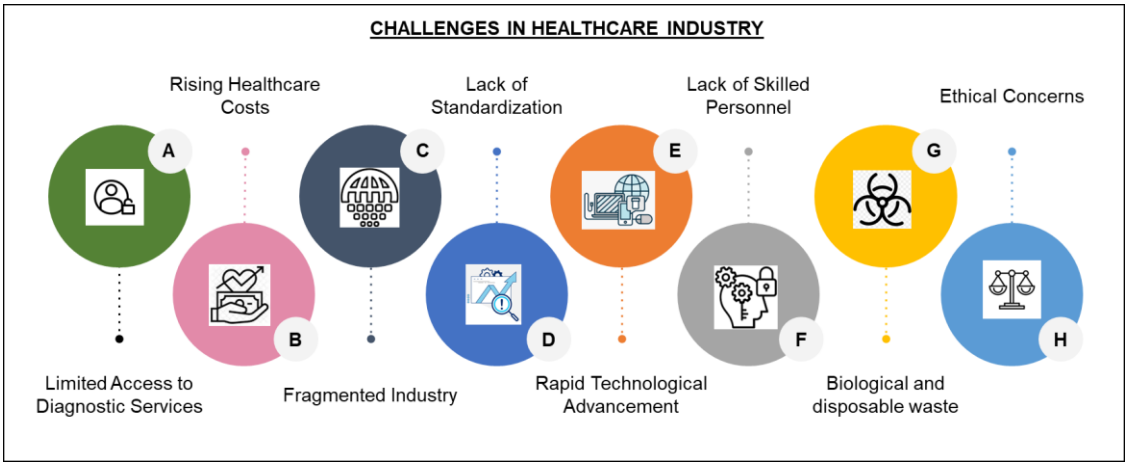

Figure 1 Challenges in the healthcare industry

2.0 Limited Access to Diagnostic Services

A significant challenge faced by the global diagnostics industry is limited access to diagnostic services(3). This challenge is especially prevalent in low-income countries, where access to healthcare is often limited. Inadequate infrastructure, including a shortage of trained personnel and diagnostic equipment, can also limit access to diagnostic services(4). Additionally, the cost of diagnostic tests can be prohibitively expensive, particularly in low-income countries(5).Limited access to diagnostic services remains a significant challenge in many parts of the world, particularly in low-income countries(6). However, significant progress has been made in recent years to improve access to diagnostic services in some regions.The World Health Organization (WHO) launched the Global Health Observatory in 2012 to track progress toward universal health coverage, including access to diagnostic services. Through this initiative, WHO has worked with governments and other stakeholders to develop strategies for improving access to diagnostic services in low-income countries(7). The advances in technology have enabled the development of low-cost diagnostic tests that are easier to use and require less infrastructure, making them more accessible in low-income settings. In 2016, a team of researchers developed a low-cost device that can diagnose HIV and syphilis in under 15 minutes, which has the potential to revolutionize diagnostic testing in low-income settings(8).However, despite these advances, access to diagnostic services remains a significant challenge in many parts of the world, particularly in low-income countries. Improving access to diagnostic services will require continued investment in infrastructure, personnel, and technology, as well as efforts to reduce the cost of diagnostic tests and treatments(9).

3.0 Rising Healthcare Costs

The rising cost of healthcare is a significant challenge faced by the global diagnostics industry. The cost of diagnostic tests and treatments can be prohibitive for many patients, particularly those with chronic illnesses. The high cost of healthcare can also strain healthcare systems, particularly in low-income countries. Governments and healthcare providers must find ways to make healthcare more affordable while maintaining high-quality care(10).Rising healthcare costs continue to be a significant challenge globally. Healthcare costs have been

rising at a faster rate than general inflation in many countries, including high-income countries like the United States and low- and middle-income countries. The COVID-19 pandemic has also put additional strain on healthcare systems and led to increased healthcare costs(11).The rising healthcare costs in the United States is the cost of prescription drugs. According to a report by the Government Accountability Office (GAO), the prices of prescription drugs in the US increased by an average of 33% between 2010 and 2015. This increase in drug prices has led to higher healthcare costs for patients and has strained healthcare systems(12).In response to rising healthcare costs, some countries have implemented measures to control costs. In France, the government sets the prices of prescription drugs and medical devices, which helps to control costs. Additionally, some countries have implemented universal healthcare systems, which can help to reduce healthcare costs by providing more affordable access to healthcare services for all citizens(13). Higher healthcare spending was made by high-income countries, but access to care was still restricted in low-income areas due to persistent imbalances as per figure 2.

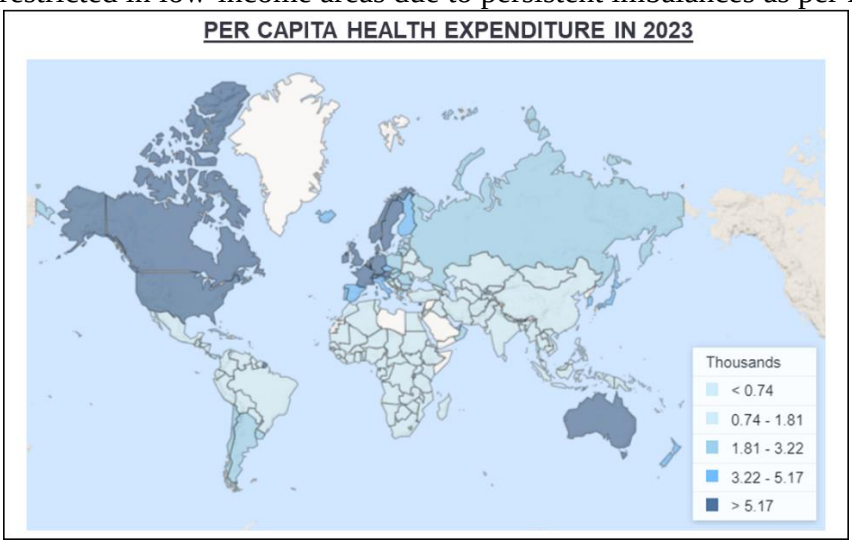

Figure 2 Per capita health expenditure in 2023(14)

In the United States, efforts are underway to address rising healthcare costs(15). The Affordable Care Act (ACA), passed in 2010, includes provisions designed to reduce healthcare costs and increase access to healthcare services. These provisions include incentives for healthcare providers to deliver more efficient care, increased funding for preventive care, and the establishment of accountable care organizations (ACOs), which are groups of healthcare providers that work together to improve the quality and efficiency of care(16). The Malaysian government provides public healthcare services through the Ministry of Health, but private healthcare services are also available and often preferred by Malaysians due to perceived better quality of care and shorter waiting times(17). One of the main drivers of rising healthcare costs in Malaysia is the increasing burden of non-communicable diseases (NCDs) such as diabetes, hypertension, and heart disease. These conditions require long-term management and treatment, which can be expensive, particularly for those who do not have health insurance or access to public healthcare services(3). Additionally, the introduction of new medical technologies and treatments, such as new drugs and medical devices, can also contribute to rising healthcare costs in Malaysia. These technologies often come with a higher price tag, and as demand for them increases, so does the overall cost of healthcare. The government also provides financial assistance to those who cannot afford to pay for medical treatment through various social welfare programs(18).

4.0 Fragmented Industry

The healthcare industries are highly fragmented, with numerous players operating in different regions and sectors(19). This fragmentation can make it challenging to ensure the quality of diagnostic tests and treatments. Additionally, smaller companies may lack the resources and expertise to develop high-quality products, leading to the production of substandard products(20).The healthcare industry is often described as fragmented, as it is made up of various stakeholders, including healthcare providers, pharmaceutical companies, medical device manufacturers, insurance companies, and government agencies(21). The Global Health Delivery Project (GHD), a global health debate forum, has been used to examine the variables influencing diagnostic supply and demand in low- and middle-income nations. To guarantee that patients receive the appropriate diagnosis at the appropriate time, the platform which has over 19,000 members from 185 countries discussed the creation of delivery systems, commercial models, new technologies, interoperability standards, and governance structures. Strengthening health systems, expanding the body of knowledge, harmonizing regulations, and guaranteeing capacity and quality are some of the solutions(3) . Efforts are underway to address fragmentation in the healthcare industry. For example, initiatives such as the Health Information Technology for Economic and Clinical Health (HITECH) Act in the United States and the European Union's General Data Protection Regulation (GDPR) aim to improve the interoperability of EHRs and protect patient data privacy. Additionally, there are ongoing efforts to standardize drug pricing and increase transparency in the pharmaceutical industry(22).

5.0 Lack of Standardization

The lack of standardization in the biopharmaceutical and biotech industries is a significant challenge(23). The absence of clear regulations and guidelines can lead to inconsistencies in the quality of diagnostic tests and treatments(24). Additionally, a lack of standardization can make it difficult to compare diagnostic tests and treatments, limiting the ability of healthcare providers to make informed decisions.Lack of standardization is a significant challenge in the healthcare industry, particularly in terms of healthcare delivery and medical product development. Without standardization, there can be significant variation in the quality of care provided, leading to inefficiencies, safety concerns, and barriers to innovation(25).One example of lack of standardization is in medical device development. Different countries may have different regulatory standards and requirements for medical devices, making it difficult for manufacturers to develop products that can be sold globally. Additionally, without standardization in the design and manufacturing process, there can be significant variation in the quality of medical devices, which can compromise patient safety(26).Another example is the lack of standardization in healthcare data. Different healthcare providers may use different systems and data formats, making it difficult to aggregate data and analyze it on a larger scale. This can hinder efforts to improve population health outcomes and develop more effective treatments(21). Efforts are underway to address the challenge of lack of standardization in the healthcare industry(27). Organizations such as the International Organization for Standardization (ISO) develop and promote standards for healthcare products and services, while regulatory agencies work to harmonize regulatory requirements across different countries.

6.0 Rapid Technological Advancement

The rapid pace of technological advancement is a significant challenge faced by the global diagnostics industry(28). New technologies are continually emerging, leading to the development of new diagnostic tests and treatments. However, keeping up with these technological advancements can be challenging, particularly for smaller companies with limited resources(29). Data scientists are interested in the data collected by Internet of Things (IoT) devices (30). Data mining and analytics show enormous promise for developing

successful healthcare apps, but this is dependent on the availability of reliable information; there is no foolproof approach for implementing such methods(31). The success of data analytics-based applications depends on the record-keeping, preparation, and mining processes. However, when dealing with many complicated data, chemical analytics presents various challenges. Some of the issues that need to be addressed are data complexity, access, regulatory compliance, information security, effective analytics methodologies, interoperability, manageability, security, development, reusability, open data, missing data, and data heterogeneity (32). Additionally, new technologies may not always be effective or affordable, limiting their usefulness in clinical settings.The healthcare industry has experienced rapid technological advancement in recent years, with new technologies and innovations emerging at an unprecedented pace(33). These advancements have the potential to transform healthcare delivery and improve patient outcomes, but they also present new challenges and opportunities for healthcare providers and stakeholders.Rapid technical improvements have been a defining feature of the diagnostic sector, pushing innovation, efficiency, and accuracy in diagnostic testing. Key technological advances such as Next-Generation Sequencing (NGS), Advanced imaging techniques, and lab-on-a-chip technologies have transformed diagnostics, allowing for faster, more precise, and cost-effective testing methods mentioned in figure 3.The rapid technological advancement in healthcare is the rise of telemedicine and digital health technologies(34). Rapid technological advancement also presents challenges in terms of privacy and data security, as well as potential ethical concerns around the use of AI and other technologies. Addressing these challenges will require ongoing efforts to develop and promote responsible use and regulation of technology in healthcare.

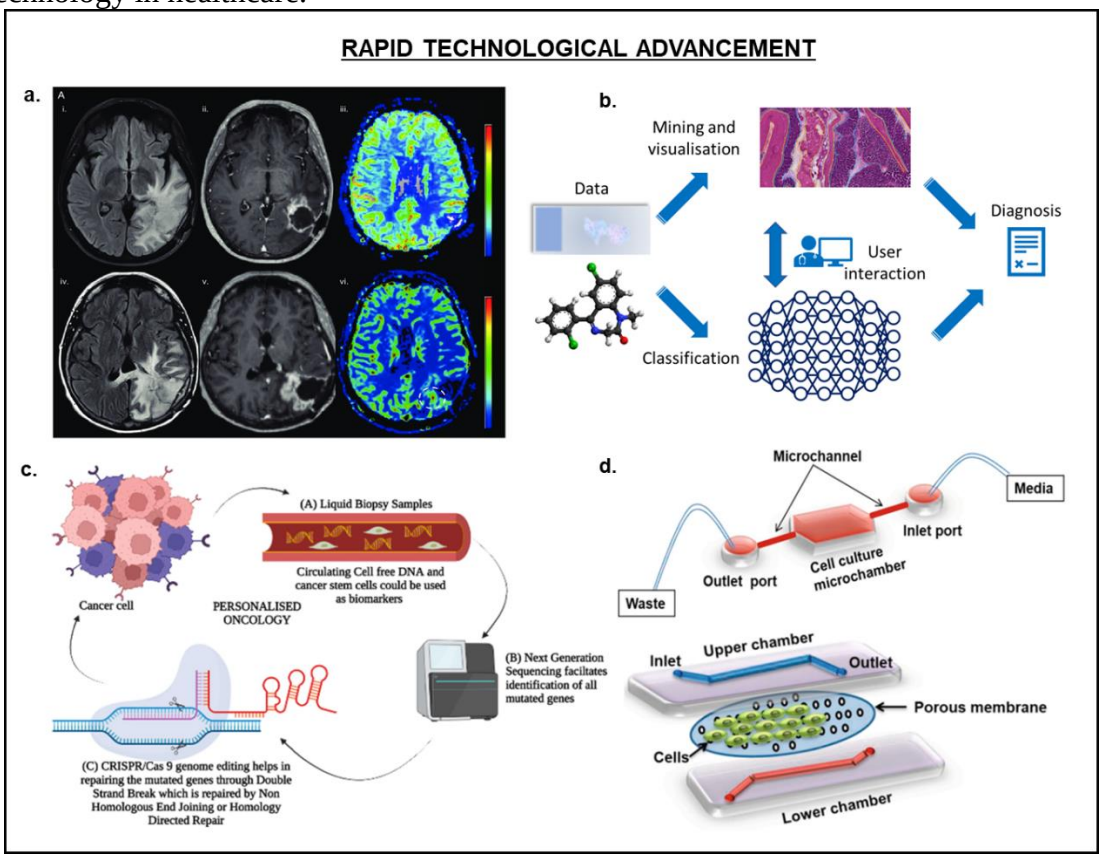

Figure 3 Rapid Technological Advancements in Healthcare a. Advanced Imaging Technique (35), b. Digital Pathology(36), c. Next Generation Sequencing (NGS)(37), d. Lab-on-chip Technologies(38)

7.0 Lack of Skilled Personnel

A shortage of skilled personnel is a significant challenge faced by the global diagnostics industry(39). This shortage is particularly prevalent in low-income countries, where access to education and training programs may be limited. The shortage of skilled personnel can limit the quality of diagnostic tests and treatments and treatments, leading to inaccurate diagnoses and ineffective treatments.The healthcare industry is facing a significant challenge with the lack of skilled personnel, particularly in areas such as nursing, medical technology, and physician specialties. This challenge is affecting healthcare delivery in many countries around the world, and it is likely to worsen as demand for healthcare services continues to grow(40).According to the World Health Organization (WHO), there is a global shortage of 5.9 million nurses, with many countries struggling to recruit and retain nursing staff. This shortage has significant implications for the quality of care provided, as well as the overall cost of healthcare(41).The shortage of medical technologists, who play a critical role in diagnosing and treating patients. In many countries, there is a shortage of medical technologists, which can lead to delays in test results and longer wait times for patients. Additionally, shortages in physician specialties such as primary care and mental health can result in limited access to care for patients(42).Efforts are underway to address the challenge of the lack of skilled personnel in healthcare(43). Telemedicine and digital health technologies can enable healthcare providers to deliver care remotely, which can help to alleviate shortages in certain specialties and improve access to care for patients in remote or underserved areas(44).

8.0 Biological and disposable waste

The use of LOC technologies has increased the volume of diagnostic tests conducted, which has directly contributed to an increase in waste generation(45). Due to their small size, LOC devices frequently require single-use cartridges, adding to the overall waste volume. Most of the consumables and disposable cartridges used in LOC devices are made of plastic. The World Economic Forum reported that the healthcare industry is responsible for around 4% of the world's plastic trash, and that number is predicted to climb due to the proliferation of single-use medical gadgets(46). Plastic waste from diagnostic instruments should be disposed of properly to prevent environmental pollution. Plastics take a long time to disintegrate, and their buildup in landfills or inappropriate disposal in oceans and other bodies of water can affect marine life and ecosystems(47). Significant amounts of raw materials, energy, and water are needed to manufacture consumables like disposable cartridges. The extraction of these resources may result in environmental damage and a pressure on natural resources as the demand for diagnostic testing rises. To maintain safety, infection control, and environmental protection, strict regulatory criteria must be followed in the proper processing and disposal of biological waste produced by diagnostic testing(48). These rules must be followed by diagnostic labs and healthcare facilities, which could result in extra expenses and infrastructure needs. Diagnostic laboratories may incur additional expenses because of putting effective waste management procedures into place. Financial resources may be needed to make infrastructure investments in waste segregation, recycling, and disposal as well as to teach workers on proper waste handling techniques(49).The recent establishment of multiple Biosafety Laboratories (BSLs) in India has substantially improved the laboratory's design, construction, and management skills, allowing it to address public health and biosafety (50). These limitations impede the ability of established laboratories to respond swiftly to public health emergencies. Due to limited biosafety laboratory facilities and the scarcity of industry diagnostic tools, development needs to improve(51). If lab development progresses at this pace, these challenges will be eliminated, and industry will move quickly in these areas. Different types of biological and disposal waste mentioned in table 1.

Table no. 1 Diverse Categories of Biological and Disposal Waste

Type of Biological Waste	Disposal Methods	Waste Products	% Distribution	References
Infectious Waste	Inceration, Autoclaving, Chemical, Microwave	Used swabs, bandages, and disposable gloves from patients with infections.	15%	(52)
Pathological	Incineration, Chemical, Burial	Human tissues, organs, or fluids removed during surgery or autopsy.	Very less	(53)
Sharps	Sharps container, Incineration, Recycling	Used needles, syringes, or scalpels.	1%	(54,55)
Chemical	Segregation, Neutralization, Licensed Disposal	Expired disinfectants, solvents, or heavy metals (e.g., mercury from broken thermometers)	3%	(56,57)
Pharmaceutical	Return Programs, Incineration, Landfill	Expired or unused medications.	Very less	(58)
Cytotoxic	Incineration, Segregation	Cytotoxic drugs used in cancer treatment.	Very less	(59,60)
Radioactive	Storage, Disposal, Shielding	Radioactive diagnostic materials.	1%	(61,62)
Non-Hazardous	Landfill, Recycling, Composting	Regular waste from health-care facilities.	85%	(63,64)

9.0 Ethical Concerns

The diagnostics process monitoring, and kit manufacturing industry must also address ethical concerns related to the use of diagnostic tests and treatments(65). There may be concerns related to the privacy and security of patient data, particularly in the era of big data. Additionally, there may be ethical concerns related to the use of genetic testing, including concerns about discrimination and stigmatization(66).The healthcare industry is facing a range of ethical concerns related to patient care, access to healthcare, and the use of technology and data. These concerns are becoming increasingly important as healthcare delivery becomes more complex and as new technologies and treatments emerge(67).Ethical concern in healthcare is the issue of patient autonomy and informed consent. Patients have the right to make decisions about their healthcare, but they may not always have access to the information they need to make informed decisions(68).Healthcare providers and stakeholders have an ethical responsibility to ensure that all patients have access to high-quality care, regardless of their ability to pay or their social status. However, in many countries, there are significant disparities in healthcare access, which can have serious consequences for patients' health outcomes(69).The use of technology and data in healthcare also presents ethical concerns around privacy, data security, and the responsible use of AI and other technologies. The use of AI in healthcare can raise concerns about the potential for bias in algorithmic decision-making, as well as the potential for breaches of patient privacy and security.Efforts are underway to address these ethical concerns in healthcare, through the development of guidelines and best practices for patient care and the responsible use of technology and data.

For example, the World Medical Association has developed ethical guidelines for the use of AI in healthcare, while regulatory agencies such as the US Food and Drug Administration (FDA) are working to establish guidelines for the use of digital health technologies(70).

10.0 Conclusion

The healthcare industry faces a range of challenges that impact patient care and the delivery of healthcare services. These challenges include limited access to diagnostic services, rising healthcare costs, a fragmented industry, lack of standardization, rapid technological advancement, lack of skilled personnel, and ethical concerns. Addressing these challenges will require ongoing efforts and collaboration among healthcare providers, regulators, policymakers, and other stakeholders. Investments in technology, education and training, and workforce development can help to address challenges such as limited access to diagnostic services and the lack of skilled personnel. Efforts to promote standardization and the use of best practices can help to improve the quality of care and promote efficiency in healthcare delivery. Similarly, the use of telemedicine and digital health technologies can help to improve access to care and reduce costs, while also addressing ethical concerns around patient privacy and data security. Incorporate sustainability principles into diagnostic product design, using eco-friendly materials, optimizing product life cycles, and ensuring easy disassembly and recycling. Implement energy-efficient technologies and processes, waste reduction strategies, and water conservation measures. Engage suppliers and stakeholders to adopt sustainable practices, conduct life cycle assessments, and implement lean manufacturing principles. Addressing the challenges facing the healthcare industry will require a concerted effort to promote collaboration, innovation, and investment in healthcare infrastructure and workforce development. By working together, healthcare providers and stakeholders can help to ensure that all patients have access to high-quality care and that healthcare delivery is efficient, effective, and ethical.

11. Future Prospectives

The diagnostic industry plays a crucial role in healthcare by providing essential tools and services for disease detection, monitoring, and treatment decision-making.The diagnostic industry will continue to benefit from technological advancements, such as artificial intelligence (AI), machine learning, and big data analytics(71). These technologies have the potential to enhance the accuracy, speed, and efficiency of diagnostics, leading to more personalized and precise healthcare.There is a growing trend towards decentralized testing, where diagnostic tests can be performed at the point of care, such as a doctor's office, clinic, or even at home. Advancements in microfluidics herald the fulfillment of the potential inherent in lab-on-a-chip technologies, epitomizing the convergence of precision engineering, biomimetic principles, and miniaturized analytical platforms to revolutionize biological and chemical analysis, diagnostics, and therapeutics on a scale previously unattainable (72).The field of molecular diagnostics is rapidly evolving, driven by advancements in genomics, proteomics, and molecular biology(73). These techniques allow for the detection of genetic mutations, biomarkers, and specific disease-related molecules, enabling early disease detection, precise treatment selection, and monitoring of therapeutic response.Liquid biopsy is a non-invasive diagnostic technique that involves analyzing various biomarkers, such as circulating tumor DNA (ctDNA), circulating tumor cells (CTCs), or exosomes, found in body fluids like blood or urine(74). It has the potential to revolutionize cancer diagnostics by enabling early detection, monitoring treatment response, and detecting minimal residual disease. Personalized medicine aims to tailor medical decisions and treatments to individual patients based on their specific genetic makeup, biomarkers, and other relevant factors(75). Diagnostics will play a critical role in identifying patient characteristics and predicting treatment responses, leading to more targeted and effective therapies.With the advancements in diagnostics, there is a growing trend towards integrating diagnostics with therapeutics.

Companion diagnostics, for example, are tests that help identify patients who are most likely to benefit from a particular therapy. This integration ensures targeted and optimized treatment plans for patients, reducing trial and error in prescribing medications.The rise of digital health technologies and telemedicine has transformed the healthcare landscape. Diagnostic companies are embracing telemedicine platforms, remote monitoring devices, and mobile applications to provide virtual consultations, remote diagnostics, and continuous monitoring of patients' health parameters(40).Overall, digitalization, robotization, and automation are expected to revolutionize diagnostic pathways, leading to smarter laboratories and imaging systems. Key trends include biosensor usage, liquid biopsies, consumer testing, and AI transformation in pathology and radiology. Partnerships with consumer technology businesses can create value-based payment models that reward health outcomes and improve prevention, early detection, and wellness management. These technologies are expected to significantly change the future of diagnostic avenues.

12.0 Funding

The Author would like to thank and acknowledge the financial support from **UniversitiTeknikal Malaysia Melaka (UTeM) Zamalah Scheme**andgrant PJP/2022/FTKEE/S01884**.**

13.0 ConflictsOfInterest

The Authors have no conflicts of interest in this work.

14.0 Ethical Approvals

The study does not involve experiments on animals or human subjects.

15.0 Data availability statement

There is no data for this review.

16.0 Informed consent

None.

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