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SPECIAL FOCUS PAPER

Understanding the Role of Portable Medical Devices in the Healthcare System: A Systematic Literature Review

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ABSTRACT

Portable and mobile biomedical devices (MBD) are an important part of modern healthcare. This is due to their ability to perform continuous monitoring, early diagnosis, and personalized treatment even outside the conventional clinical settings. Advancements in the healthcare domain are driven by high-tech sensor technology, wireless communication, and data analytics, which help identify, analyze, and interpret these devices' applications in telemedicine and remote patient monitoring. A systematic literature review was conducted in accordance with established protocols. Peer-reviewed articles published in English during 2015–2025 were identified through a Boolean search string using the related keywords across leading scientific databases. The article selection procedure was guided by Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020. Relevant data were extracted and thematically synthesized. The study is also supported by manual keyword analysis. The review finds four major types of dominant devices, which include wearable sensors, handheld diagnostic devices, smartphone-based medical devices, and implantable portable monitors. They have been used for cardiovascular monitoring, diabetic treatment, neurology, respiratory, and rehabilitative purposes. Besides, there is an improvement in patient engagement, as demonstrated in this research. The barrier to healthcare services access, on the other hand, is reduced. Indeed, portable and mobile biomedical devices are a welcome change that will bring the healthcare system to decentralized and patient-centered care. It should be developed in the future using standardized validation procedures, secure data infrastructures, and regulatory balance. The current review also emphasizes some of the measures that can be adopted to ensure that mobile biomedical technologies can be integrated into digital health ecosystems to benefit the researchers, device designers, and doctors.

KEYWORDS

portable devices, mobile biomedical devices, diagnosis, technology, wireless

1 INTRODUCTION

Portable biomedical devices encompass all small, self-contained systems that can collect physiological or biochemical data outside the traditional laboratory and

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hospital [1], [2]. Examples of these devices include wearable physiological sensors, handheld biochemical analyzers, smartphone-integrated diagnostic tools, and platforms for remote exams [3], [4]. Unlike traditional hospital equipment, portable biomedical devices are designed for mobility, quick deployment, real-time data collection, and ease of access to end-users [5]. The advent of portable biomedical devices parallels major trends toward care delivery in decentralized environments, the growth of telemedicine, and the increasing demand for continuous health monitoring.

An important factor contributing to the increased use of portable/MBD is improved access to health care and greater service delivery efficiency. Factors such as a lack of laboratory infrastructure, a shortage of trained personnel, and long turnaround times for results lead to higher morbidity/mortality rates in low-resource areas [6], [7]. Portable devices help fill these gaps by providing near-patient diagnostics and continuous monitoring without the need for centralized facilities. In addition, portable devices are intended to alleviate overcrowding in emergency departments, reduce time from treatment to delivery, and improve chronic disease management through remote monitoring in higher-resource environments [8], [9].

Clinical uses of portable biotechnology are now diverse. Emergency departments and infectious disease treatment units continue to use wearable biosensors to monitor vital signs continuously [10], [11]. Wearable technologies (e.g., acoustic) with artificial intelligence (AI) have been developed to allow for automatic diagnosis of ailments like obstructive sleep apnea [12]. With the increased availability of smartphone-compatible echocardiograms (ECGs) and electrocardiograms (EKGs), earlier referrals for interventions in people with structural heart disease have become possible [13]. Microfluidic, isothermal amplification Point of Care (POC) viral detection systems enable rapid viral detection [14]. Portable biochemical analyzers provide laboratory-comparable results for numerous conditions (e.g., diabetes and neonatal jaundice) [6], [15]. Clinicians can perform structured telemedicine evaluations using remote physical exam tools and achieve measurable concordance with in-person exam results [16].

Despite the rapid progress made in technology, many key questions still exist with respect to the accuracy of these devices, validation intensity, usability, and feasibility of implementation [17]. Most portable scientific instruments are highly sensitive and specific and are considered a gold standard in experimental research. However, it is crucial to understand the impact of real-world implementation, as practical issues often exist with respect to connectivity, data integrity, user compliance with the device, regulatory issues, and workflow implementation. Moreover, although several narrative and scoping reviews have explored the use of consumer wearables and the traditional use of devices in the healthcare setting, a systematic synthesis of portable and mobile biomedical devices that are clinically validated for use in the clinical setting has not been performed. The purpose of this systematic review is to offer a comprehensive view of portable/MBD and to understand the common issues. This study also aims to provide recommendations for future research directions for the safe and effective use of these devices in the healthcare delivery system by combining technical performance characteristics with real-world implementation data. The research questions that this study aims to answer are:

RQ1: What categories of portable and mobile biomedical devices are currently being evaluated in clinical and near-clinical environments?
RQ2: How do these devices perform relative to gold-standard comparators in terms of sensitivity, specificity, concordance, correlation, and precision?

RQ3: What measurable impacts do portable biomedical devices have on clinical workflows, time-to-treatment, hospitalization rates, or mortality outcomes?
RQ4: What usability, connectivity, infrastructure, and regulatory challenges are consistently reported across studies?
RQ5: How are artificial intelligence and advanced analytical models integrated into wearable and mobile systems, and what implications does this integration have for reliability and trust?
RQ6: What thematic and keyword patterns emerge across the literature, and how do they reflect the maturation of the field?

2 LITERATURE REVIEW

The reviews on wearable devices have focused only on the consumer and lifestyle dimensions of wearable devices, specifically monitoring physical activity and promoting general health [18]. Although potential clinical applications were identified, the focus of the reviews is on three areas: technical limitations, lack of industry standards, and privacy concerns. Furthermore, more focused scoping assessments of wearable adherence technologies revealed major methodological limitations related to having small cohorts of participants and insufficient regulation [19]. Hubbard et al. [20] explored challenges in the long-term monitoring of seizures and revealed issues with patient compliance and signal reliability in the ambulatory setting.

Portable technologies provide more than just diagnostic capabilities because they serve as additional resources for healthcare professionals in doing their job. For example, a smartphone-connected mHealth application in India has diagnosed 253 patients with structural heart diseases (SHD). It demonstrated a reduction from 180 days to 83 days in therapy referral time (valve replacement) and a reduction in hospital stays, along with the death rates during the following year [13]. An emergency department feasibility study conducted with 44 patients demonstrated that the wireless biosensor technology was both effective and user-friendly [8]. Organizations face ongoing difficulties with their work implementation efforts. The study on Lassa fever patients found that more than 80 percent of wearable sensor data were discarded due to connectivity and sensor adhesion issues, demonstrating that technological capabilities exceed current infrastructure capacity [21].

The research statistics show significant clinical equivalence between different studies. The POC HbA1c measuring device evaluation demonstrated that device measurements reached high accuracy with 97.1% of NGSP (National Glycohemoglobin Standardization Program) reference values between ±6% measurement range [15]. An acoustic sensor-based wearable device diagnosed Obstructive Sleep Apnea (OSA) with 95.24% diagnostic accuracy, 92.86% sensitivity, and 97.14% specificity when compared to results from in-laboratory polysomnography testing [12]. The COVID-19 pandemic advanced portable diagnostic technology because people needed to diagnose viruses more quickly. A microfluidic isothermal RT-LAMP (Reverse Transcriptase Loop-Mediated Isothermal Amplification) device capable of differentiating SARS-CoV-2 variants achieved a sensitivity greater than 90% and a specificity of 100% in clinical saliva samples [14]. Portable platforms exhibit flexibility to address new public health emergencies according to these advancements.

The existing works provide valuable insights, yet research remains disjointed because it spans multiple disease categories and different types of medical devices. The key findings synthesized from the SLR are shown in Table 1.

Table 1. Key findings synthesized from the SLR

Author (Year)	Study Design	Device Type	Clinical Application	Key Findings	CASP
Cook et al. (2015)	Engineering validation	Wearable biopotential logger	Physiological monitoring	Open wearable data platform	Moderate
Yang et al. (2015)	Experimental study	Portable respiratory device	Respiratory monitoring	Stable low-power monitoring	Moderate
Keahey et al. (2017)	Clinical evaluation	Neonatal POC device	Jaundice diagnosis	Effective in low-resource settings	High
Bhavnani et al. (2018)	Randomized trial	Pocket echocardiography device	Structural heart disease	Improved diagnostic workflow	High
Im et al. (2018)	Clinical validation	Microholography POC device	Lymphoma diagnosis	High diagnostic accuracy	High
Sobolesky et al. (2018)	Multicenter assessment	HbA1c POC device	Diabetes diagnosis	Comparable to laboratory testing	High
Tzouvadaki et al. (2018)	Prototype validation	Memristive biosensor	Cancer diagnostics	Effective POC detection	Moderate
Zeng et al. (2018)	Experimental validation	Plasmonic biochip	Cancer detection	High-sensitivity detection	Moderate
Atee et al. (2018)	Technical evaluation	PainChek™ mobile device	Dementia pain assessment	Reliable structured assessment	Moderate
Garbern et al. (2019)	Clinical validation	Wearable biosensor	Sepsis monitoring	Accurate ED vital monitoring	High
Li et al. (2019)	Pilot clinical study	Wearable respiratory monitor	ED respiratory rate	Comparable to capnography	Moderate
Constantinescu et al. (2019)	Usability study	mHealth therapy device	Swallowing therapy	Positive usability outcomes	Moderate
Goodlad et al. (2020)	Clinical validation	POC biomarker device	Peritonitis diagnosis	Rapid immune marker detection	High
Saif et al. (2020)	Feasibility study	Wearable biosensor	Alzheimer's monitoring	Acceptable feasibility	Moderate
Wong et al. (2020)	RCT protocol	AI wearable biosensor	COVID-19 detection	AI-based early detection framework	Moderate
Lu et al. (2020)	Narrative systematic review	Wearable health devices	General healthcare	Broad clinical potential	Moderate
Miller et al. (2021)	Feasibility study	Wearable biosensor	Emergency department deployment	Technically feasible	Moderate
Abbadessa et al. (2021)	Pilot clinical study	Wearable biosensor	Multiple sclerosis	Disability tracking feasible	Moderate
Hubbard et al. (2021)	Landscape analytical study	Mobile epilepsy device	Epilepsy monitoring	Development challenges identified	Moderate
Recktenwald et al. (2022)	Clinical application study	Lab-on-chip POC device	RBC flow evaluation	Multi-condition usability	Moderate
Farahi et al. (2022)	Experimental study	Portable fetal monitor	Fetal heart rate	Reliable analysis	Moderate
Lim et al. (2022)	Experimental validation	Microfluidic POC device	SARS-CoV-2 detection	Variant detection capability	High
Xu et al. (2023)	Prototype validation	Smartphone-based POC device	Blood coagulation testing	Low-cost rapid testing	Moderate
Atalor et al. (2023)	Technical study	Wearable chemo monitor	Cancer care	Remote chemotherapy monitoring	Moderate

(Continued)

Table 1. Key findings synthesized from the SLR *(Continued)*

Author (Year)	Study Design	Device Type	Clinical Application	Key Findings	CASP
Arif et al. (2023)	Technical study	IoHT security framework	Wearable cybersecurity	Improved anomaly detection	Moderate
Marengo & Barberato-Filho (2023)	Scoping empirical review	Wearable adherence devices	Medication adherence	User involvement critical	Moderate
Wagner et al. (2023)	Controlled trial	Mobile telemedicine device	Pediatric remote exams	Concordance with in-person exams	High
Sanchez Gomez et al. (2024)	Validation study	Wearable OSA device	Sleep apnea diagnosis	High agreement with PSG	High
Gonzalez Utrilla et al. (2025)	Development study	Wearable motion sensor	Body motion tracking	Continuous motion monitoring	Moderate
Page et al. (2025)	Clinical monitoring study	Wearable biosensor	Lassa fever monitoring	Continuous monitoring feasible	High

Source: Constructed by author.

3 THEORETICAL FRAMEWORK

The study will concentrate on three key theories: the technology acceptance model (TAM), the Diffusion of Innovation Theory, and the Socio-Technical Systems Theory. The TAM states that people will adopt new technology if they find it useful and easy to use. This model is validated by research that tests the usability of the model and how easy it is to use. In one research study [8], the users were satisfied with the emergency biosensor systems. Still, in another study [22], the swallowing therapy systems required a new interface because users found it difficult to connect the devices and interpret the information. The findings from the study demonstrate the impact of usability on the adoption of such technologies in terms of feasibility and time. The Diffusion of Innovation Theory illustrates how the portable biomedical device goes from the testing phase to being used in the healthcare environment. In the healthcare environment, new ideas begin with feasibility studies, which include the testing of wearable devices. These initial studies are essential in spreading innovation since they determine if something will work before proceeding to the next step, which includes randomized trials based on outcomes and has shown a reduction in hospitalizations [13]. Socio-technical systems theory examines the relationship between technology and the organizational structure that supports it. The fact that the Lassa fever surveillance program has a high rate of data discarding due to connectivity problems [21]. The degree of diligence in testing the wearable technology shows that the efficiency of the technology is highly dependent on the preparedness of the whole system. The theoretical models help to understand the dynamic healthcare setting as a complex technical system included in portable biomedical devices.

4 MATERIALS AND METHODS

The study is based on synthesizing key ideas and patterns related to portable medical devices. The methodology used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) approach for the selection of suitable studies. A focused search was conducted on electronic databases such as PubMed, IEEE Xplore, Scopus, Google Scholar, and Web of Science. The Boolean search string used is

as follows: ("portable biomedical device" OR "wearable medical device" OR "mobile health device" OR "Point of Care device") AND ("clinical validation" OR "sensitivity" OR "specificity" OR "accuracy" OR "gold standard" OR "comparison"). The search was conducted on peer-reviewed studies published in the English language between 2015 and 2025. The research excluded studies that focused on conceptual designs, narrative reviews, editorials, or non-clinical prototypes without any validation data. The screening process began with the evaluation of titles and abstracts for relevance, followed by a full-text evaluation that applied eligibility criteria. After the removal of duplicates and screening, only 30 studies were left for the final analysis, as shown in Figure 1. The study used the Critical Appraisal Skills Programme (CASP) in order to analyze the quality of the studies considered, the strength of the methods used, the validity and clarity of the results, and bias in them. The studies were grouped into high quality (clear methodology, low risk of bias, strong validity), moderate quality (minor methodological limitations but acceptable rigor), and low quality (significant bias, unclear ways of doing things, or weak validity). The information is gathered about the type of devices and study design, validation, clinical use, implementation challenges, and advanced analytics integration. The qualitative analysis approach was used to answer the research questions.

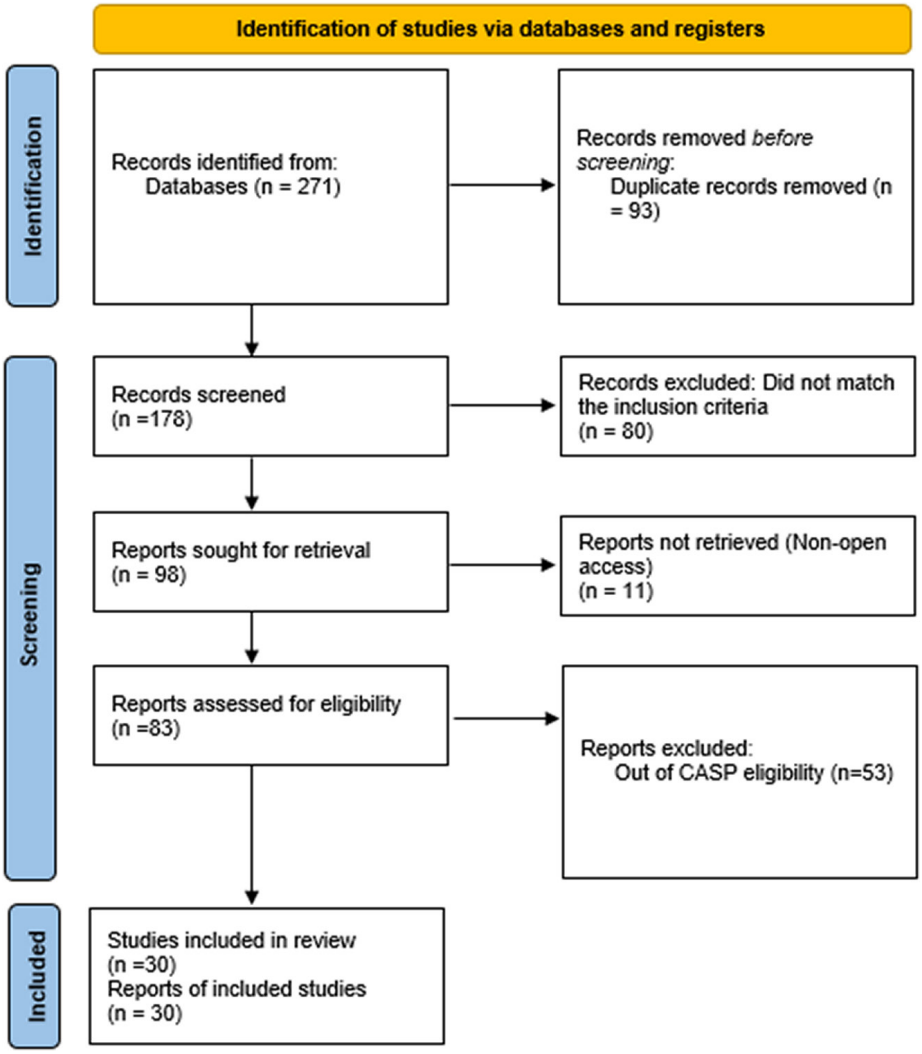

Fig. 1. PRISMA flowchart

Source: Constructed by author.

5 RESULTS

The studies included in this research showed that most of them aimed at validating devices and checking how well they perform in clinical settings. The results were noted in terms of accuracy, sensitivity, and specificity tests and then compared to well-known gold-standard benchmarks. The gold standard benchmarks included laboratory reference assays, polysomnography, conventional echocardiography, standard pathology diagnosis, and in-person clinical examinations. Against these standards, portable devices demonstrated varying levels of concordance and diagnostic accuracy. Many studies have shown how important remote monitoring systems and decentralized healthcare delivery methods are. This shows that researchers are paying more attention to portable technologies that make healthcare services easier to access. Several studies used artificial intelligence for interpreting and classifying signals. AI-assisted systems, still in their early stages, seem to have potential for improving diagnostic accuracy. Researchers are focusing on making sure portable biomedical devices are reliable and practical for clinical use, while also working on making these devices easy for people to access. Figure 2 shows the four main device types found in the studies that were used in this study.

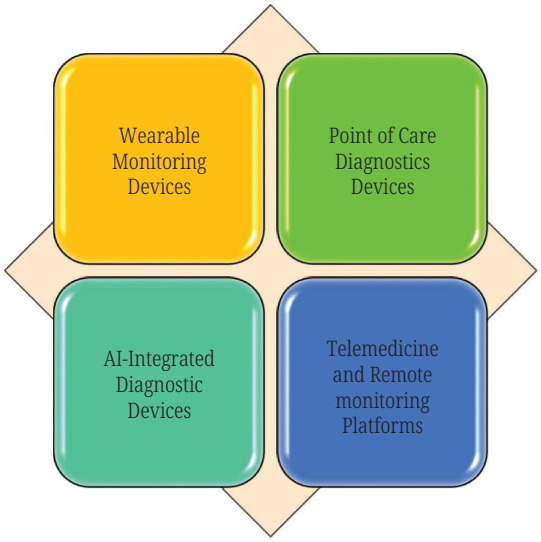

Fig. 2. Distribution of device category

Source: Constructed by author.

Wearable monitoring devices represented the largest number of studies. They were mainly used for continuous monitoring of physiological signals such as heart rate, oxygen saturation, respiration, and sleep. POC diagnostic devices were the second largest in terms of the number of studies. The POC devices were primarily employed for biochemical or molecular analysis and were designed for use in resource-limited settings. AI-integrated diagnostic devices were an emerging trend, where some studies applied machine learning algorithms for improved signal analysis, classification, and diagnosis. Telemedicine platforms, although smaller in number, were primarily employed for distant access to healthcare and electronic clinical assessment. This indicates that the current trend of studies on portable biomedical devices is towards continuous monitoring and decentralized diagnostics.

5.1 Clinical performance outcomes

The studies reported a variety of metrics used to assess device performance across all included clinical trials: sensitivity, specificity, accuracy, correlation coefficients, and agreement with a reference standard from an established laboratory. Most of the POC diagnostic devices showed strong agreement with the laboratory-based 'gold standard' for sensitivity and specificity. They are clinically acceptable based on these values, allowing their use for rapid decision-making based on their diagnostic capability. Wearable technology (e.g., smartwatches) is demonstrating potential to monitor real-time physiological parameters in patients. Examples cited in individual studies included challenges such as excessive signal noise and connectivity interruptions, along with inconsistent long-term data. AI systems outperformed traditional non-AI-based classification systems by achieving superior performance in classifying identifiable patterns. A final observation noted by individual studies was a persistent need for greater volume and diversity of datasets to demonstrate the generalizability of performance. In summary, portable biomedical diagnostic devices are beginning to demonstrate diagnostic performance equivalent to that of traditional clinical laboratory-based devices. Also, the analysis of keywords in the 30 abstracts prominently revealed the themes shown in Figure 3.

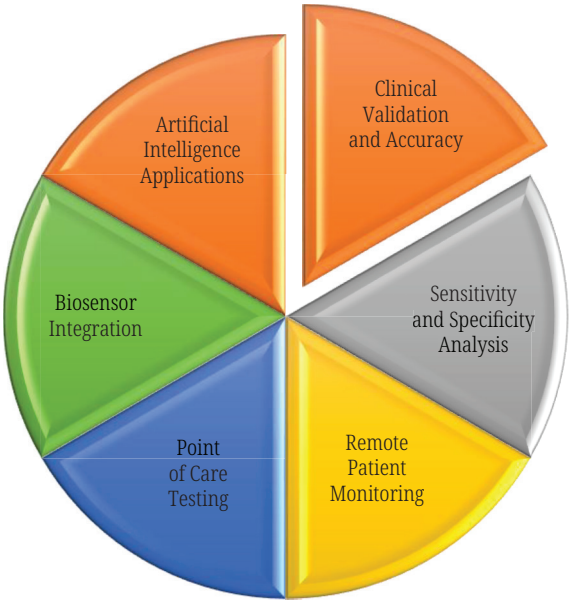

Fig. 3. Major keywords and themes

Source: Constructed by author.

The most prominent theme was the need for validation with reference standards, and this reflects the fact that accuracy is still the most important issue in portable device technology. The second theme was the need to make healthcare more accessible, especially through remote monitoring and POC testing. These trends indicate a shift towards patient-centric healthcare delivery systems enabled by technology.

6 DISCUSSION

This review finds a discernible movement towards decentralizing healthcare via portable biomedical technology, as evidenced by the growth of wearable monitoring

devices with a greater focus on providing ongoing physiological monitoring and preventive healthcare. The fact that there are so many POC systems available for diagnostics indicates an increasing need for rapid and convenient testing in resource-limited settings, as these systems will contribute to improved efficiency of the clinical decision-making process. The newly developed AI-integrated systems also indicate an increasing focus from basic data collection to intelligent data interpretation. Although the initial results are promising, further validation studies will be required before clinical application.

RQ1. Research shows that wearable biosensor systems are the main technology being tested in clinical and near-clinical settings. They help with continuous monitoring of respiratory function [1], [11]; keeping an eye on vital signs in emergency rooms [8], [10]; tracking neurological and chronic illnesses [9], [20], [23]; and watching over infectious diseases [21]. They are often seen in hospitals but also in more decentralized settings, showing how flexible and focused on patients they really are. POC diagnostic devices make up the second-largest group. They offer portable devices that can detect cancer [3], [5], and [17], diagnose diabetes by measuring HbA1c [15]; screen newborns for jaundice [6]; analyze immune system biomarkers [7]; and even detect SARS-CoV-2 [14]. They usually let tests happen quickly and close to the patient by cutting down on the need for big labs. Some platforms combined mobile health and telemedicine, like AI-powered systems to detect COVID-19 [24], tools for checking on kids remotely [16], and digital ways to assess pain [25]. The studies all point to one clear idea: wearable monitoring and POC diagnostics are the main types of devices being tested in clinical settings.

RQ2. A majority of the studies in this analysis used validation against a current gold-standard comparator. For example, the performance of wearable systems used to monitor respiratory status was found to be highly correlated with measured respiratory parameters taken using reference standards [1], [11]. In contrast, systems used to detect obstructive sleep apnea were validated using polysomnography [12]. The strongest example was that multicenter evaluations of POC HbA1c testing devices yielded clinically acceptable agreement with laboratory assays [15]. Microholography and machine-learning-assisted cancer diagnostic technology have demonstrated excellent diagnostic agreement with traditional histopathologic studies [17]. Likewise, POC immune biomarker testing devices had high reliability when assessing for peritonitis [7]. Even though most POCs were found to fall within accepted sensitivities and specificities, several POC devices were studied exclusively as pilot or feasibility trials [8], [9], [23], indicating that further validation is necessary from larger multicenter studies. Overall, the available evidence supports the view that many of the POC biomedical devices reviewed are approaching performance levels equivalent to those currently accepted in clinical guidelines.

RQ3. Evidence from various studies indicates measurable effects on clinical workflow efficiency and patient management. The use of rapid POC diagnostic platforms for infectious diseases [14] and for diagnosing jaundice in newborns [6] likely decreases the time of diagnosis and enables earlier intervention. The deployment of wearable biosensors in emergencies has increased the ability to continuously monitor patients without adding to staff workload [8], suggesting that these systems provide some degree of optimization to clinicians' workflows. Remote monitoring systems used in decentralized models of cancer care [26] and for monitoring infectious diseases in West Africa [21] demonstrate how wearable systems can enable clinicians to extend their oversight beyond the hospital setting. Additionally, the use of mobile echocardiograms in clinics treating patients with heart disease improved access to imaging tests [13]. While there may not be universal evidence of the impact

of these devices on reducing direct mortality or hospitalization rates, they are likely indirectly contributing to improvements in patient outcomes by enabling earlier detection, faster turnaround times for diagnostic testing, and improved remote patient monitoring.

RQ4. Portable biomedical devices have been fairly effective, but research continues to demonstrate that individuals continue to encounter enormous issues in the use of biomedical devices. In the testing steps of swallowing therapy systems [22] and the testing-out of wearables in the research with individuals [19], some of the usability problems were detected. In research concerning emergency department deployments, it has been stated that the new systems could not necessarily blend well with the setup of the respective hospitals [8]. The development and regulation of mobile health systems that could monitor epilepsy proved to be particularly tricky [20]. The study focused on connectivity and data security issues, especially with IoHT-based wearable systems, while evaluating anomaly detection [27]. For portable biomedical devices to work well together, it's not enough to show they're just technically solid. It also needs the proper infrastructure, strong cybersecurity, user-friendly designs, and to follow all the regulations.

RQ5. A growing trend of integrating smart analytics and AI in mobile biometric systems exists today. Examples include the use of machine learning in microholography for lymphoma diagnosis [17] and AI-powered wearables for early detection of COVID-19 [24], as well as a study to strengthen supplier security of wearables in the IoHT framework through deep learning techniques [27]. Increased use of signal processing, such as using wavelet transformations to analyze the fetal heart rate, demonstrates the contribution of computational modeling to improved understanding of data through the interpretation process [28]. While these advancements in AI systems/software provide greater accuracy and automation of diagnostic data, there are many unanswered questions regarding the model's applicability, transparency, and trustworthiness. The literature indicates that, while some AI-assisted portable/biometric systems demonstrate promising results, general validation and explanations may also enhance clinician confidence and regulatory acceptance in these systems.

RQ6. The different studies under review share a common central theme, which uses the terms "wearable," "POC," "validation," "sensitivity," "accuracy," "remote monitoring," and "artificial intelligence." The proofing metrics become more essential for validation purposes, which shows that wearable technology has advanced from its initial prototype phase to the point where it undergoes clinical testing through evidence-based methods [1], [10], and [15]. The development of wearable technology shows an increasing trend that combines AI-powered products [17], [24], and [27] with mobile-device diagnostic systems [4] and [14], according to previous research studies. These studies also emphasize that such technical developments have evolved into intelligent healthcare systems that function as a network of interconnected systems. The domain of wearable biomedical devices shows significant development because it is evident from the reviews that research and technical developments are increasing at an accelerating pace. Also, the cumulative effect of all these factors shows that portable biomedical devices have progressed from the experimental phase to become an established healthcare solution that meets performance criteria and functions using digital technology.

7 CLINICAL IMPLICATIONS

Portable biomedical devices prove their effectiveness in enhancing the healthcare system in various medical settings. Using biosensors that are always observing

the body's vital signs helps medical staff detect changes in the body at an early stage [1], [10]. Remote health observation systems allow patients to be monitored at all times, which means they can be observed without being in the hospital, and this helps their medical treatment continue to progress [21], [26]. POC diagnostic tools allow doctors to conduct immediate tests right next to the patient's bedside, and the test results are no less accurate than those of standard tests [6], [15], [17]. Mobile healthcare systems help bring medical facilities closer to people living in remote areas where medical resources are limited [1], [16]. If various devices support the same benchmark standards, it becomes easier to use them in medical procedures.

8 CHALLENGES AND LIMITATIONS IDENTIFIED IN THE LITERATURE

The study faced some challenges and limitations; however, the outcomes were good. Studies functioned like pilot studies, testing if they could be done by conducting small-scale research [8], [9], [23]. The research studies had a very short follow-up time, and the researchers could not conclude if the results were sustained or if there were any long-term clinical benefits [11]. The actual working environment of the system brought up problems that affected the system's performance during emergencies and when it was operating in a decentralized manner [8], [21]. Most of the devices still required larger clinical trials, but they had not yet been fully validated in multicenter studies [6], [15]. There is a need for consistent methods to assess and conduct more research in various fields to develop strong evidence for clinical application. Various studies have highlighted the difficulties in implementing these systems regarding their performance. Figure 4 illustrates the most general difficulties that arise. It was also concluded that the approach was feasible and had good prospects of being incorporated into the existing clinical practice, despite some difficulties.

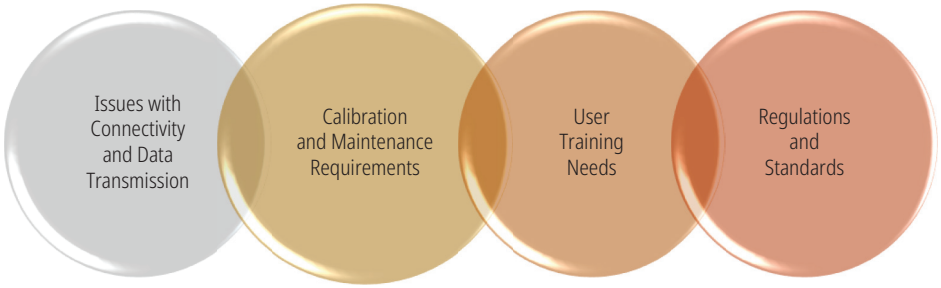

Fig. 4. Identified barriers

Source: Constructed by author.

9 RECOMMENDATIONS

The study presents the following recommendations on the basis of the review conducted.

Conducting Longitudinal Studies: It is evident that existing pilot studies have demonstrated limited generalizability, thus limiting the broader clinical use of these technologies. To increase the reliability and external validity of these technologies and support their use via an evidence-based approach across a diversity of healthcare populations and settings, multi-site, multi-centered, large-scale empirical validation studies are needed [9, 11].

Smooth Governance: Regulatory fragmentation-related issues (e.g., lack of harmonization between the U.S. FDA and European Medicines Agency) and poor interoperability of digital health systems create barriers to standardized approval processes, along with the integration of portable biomedical technologies within existing clinical settings. Harmonizing standards to reduce fragmentation, improving interoperability between health information systems, and facilitating collaboration between agencies would improve safety surveillance of these devices and create pathways for consistent implementation [13], [16], [17], [20].

Strengthen Frameworks: Rising cybersecurity threats, ethical issues, and unpredictability of the economic feasibility of deploying mobile biomedical devices may prevent them from being deployed sustainably. Robustly establishing data protection protocols through regulatory frameworks and defining the costs of mobile biomedical devices in real-world settings (especially in low- and middle-income countries) will enhance the long-term equitable and secure adoption of mobile biomedical devices [6], [27], [29], [30].

The recent proliferation in the use of IoT-enabled medication management and wearable physiologic monitoring systems provides evidence that there are certain viable and low-power, patient-centric remote health care models, which support scalable integration of portable biomedical technology into everyday clinical practice [31], [32]. In addition, by analyzing how service failures occurred during the COVID-19 pandemic, the study supports the argument that responsive governance is required to implement sustainable and resilient digital health solutions through action-oriented quality monitoring [33].

10 CONCLUSION

In a systematic review, mobile and portable biomedical devices used in a clinical setting and near-clinical setting were considered. The results showed that wearable biosensors and POC diagnostic systems are the most extensively studied devices. Wearable biosensors and POC diagnostic systems demonstrated a high level of agreement with gold standard comparators. Evidence exists that mobile and portable biomedical devices can increase the efficiency of the diagnostic process, optimize workflow, and implement decentralization in the healthcare system. The integration of artificial intelligence into mobile and portable biomedical devices has recently increased, and it has improved the analytical accuracy of the devices but also introduced challenges in validation and trust. There are still challenges associated with mobile and portable biomedical devices, such as usability, connectivity, infrastructure, and regulatory aspects. In general, the literature reviewed indicates that there is an emerging marketplace for mobile and portable biomedical devices that will continue to require large-scale validation before these devices can be used to deliver integrated and performance-driven healthcare solutions.

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