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Editor's Corner

The delivery of healthcare services is increasingly dependent on patient-ready technologies, a trend that shows no sign of slowing. Clinical Engineering professionals (CEs) are at the core of this evolution. Their role in designing, implementing, managing, and optimizing medical technologies is essential to achieving safe and effective patient care.

By integrating knowledge from engineering, life sciences, and management, CEs are uniquely positioned to analyze complex systems and apply technology in ways that improve outcomes. Their independent validation of medical technologies ensures that devices meet stringent safety and quality standards, reinforcing trust in their use throughout the continuum of care.

As healthcare systems around the world evolve, CEs remain at the forefront—driving innovation and maintain high standards across the entire technology lifecycle. Staying current with the latest advancements, research, best practices, and global regulations is not just beneficial; it's imperative.

One of the most impactful ways to support this ongoing development is by participating in global events such as the **6th International Clinical Engineering & Health Technology Management Congress** (**ICEHTMC**). This premier event provides unparalleled opportunities for professional growth, global collaboration, and cultural exchange.

WHY ATTEND THE 6TH ICEHTMC?

1. Knowledge Advancement

- **Trends & Innovation:** Access the latest developments in clinical engineering and healthcare technology.
- **Global Best Practices:** Learn how healthcare systems worldwide address shared challenges in lifecycle management, regulation, and quality assurance.

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6. Cultural and Global Perspective

- **Understand Global Systems:** Gain insights into healthcare delivery models from different regions.
- **Foster Collaboration:** Build relationships across borders and cultures.
- **Experience the Culture:** Enjoy Shenzhen's cuisine, history, and vibrant professional community.

7. Motivation and Inspiration

- **Reignite Passion:** Discover stories of success and innovation that highlight the real-world impact of your profession.
- **Renewed Commitment:** Leave inspired to further contribute to advancing healthcare technology worldwide.

As I pen this editorial, the World Health Organization is convening its World Health Assembly, and it is worth remembering that as far back as 2007, Resolution WHA60.29 emphasized the importance of planning, assessing, acquiring, and managing health technologies responsibly and effectively. The dependency trend makes that resolution more relevant than ever.

It will be my great pleasure to welcome you this October to **Shenzhen, China**, the venue for the 6th ICEHTMC. Your participation demonstrates a steadfast commitment to professional excellence, global collaboration, and the continuous pursuit of better healthcare for all.

Xie Xie

Yadin David

EdD, PE, CCE, FAIMBE, FACCE

Editor-in-Chief

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Original Research Article

Discussing the Clinical Value of Full-Range Autofocus Endoscopic Cameras

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ABSTRACT

Objective: This study aims to explore the potential of full-range autofocus (FAF) technology to improve image clarity and operational ease in endoscopic procedures.

Methods: The paper analyzes the application and development of manual focus, autofocus, manual zoom, and auto zoom technologies in clinical endoscopy. The clinical value of FAF technology in endoscopy, including intelligent scene linkage and continuous optical lossless zoom, is discussed.

Results: The application of FAF technology significantly enhances medical diagnosis and treatment by providing clearer and more flexible imaging. This technology allows for seamless focusing from near to far distances, improving the accuracy and effectiveness of medical procedures.

Conclusions: The FAF technology represents a significant advancement in endoscopic technology. It not only improves diagnostic precision and treatment efficiency but also contributes to safer and more comfortable medical services, which can promote further development in the medical industry.

Keywords—*Manual focus, Autofocus, Manual zoom, Auto zoom, Full-range autofocus.*

INTRODUCTION

In recent years, the medical endoscopic camera system—integration of traditional optical technology with modern computer and microelectronics technologies—has become a widely utilized medical instrument because of increased medical standards and public health awareness.[1] These systems have become increasingly common in clinical diagnosis and treatment, significantly enhancing diagnostic and therapeutic accuracy, reducing patient suffering, and accelerating recovery.

A review of related research reveals that the primary goal of endoscopic camera systems is to assist doctors in "seeing clearly" by obtaining sharp images while maintaining user-friendliness and simplicity. Thanks to advancements in focusing and zooming technologies, endoscopic cameras have evolved from "manual focus to autofocus, manual zoom to auto zoom, and then to full-range autofocus (FAF)," thus greatly facilitating clinical procedures, ensuring the clear vision, reducing surgical risks, improving surgery success proportions, and enhancing the functionality and application experience of endoscopes.

This process not only marks technological advancement but also reflects the broader trend in medical equipment development toward efficiency, precision, and ease of use. The primary objective of this study is to analyze the application of autofocus and zoom technologies in endoscopes, and discuss their positive impacts on medical diagnosis and treatment. Furthermore, we explore the potential future influence of these technologies on the development of endoscopic technology.

TECHNOLOGICAL EVOLUTION IN ENDOSCOPIC FOCUSING

Clinical Requirements for Imaging Precision

Endoscopic surgery is intricate and complex, requiring clear imaging to present the details of the observation area to improve the diagnosis proportion of lesions (especially early and subtle lesions), thereby facilitating the doctor's surgical intervention. For example, when doctors perform gastrointestinal surgery, to prevent unnecessary damage caused by intestinal adhesion, clear images of the lesion are required. This clarity aids doctors in observation and operation, reducing the risks associated with the blindness of traditional surgery, and minimizing organ damage and functional interference.

Manual Focus

In order to ensure a clear field of view in usage scenarios, medical endoscopic cameras initially introduced manual focus technology. This technology requires the operator to rotate manually the focusing ring based on visual judgment. The focusing effect heavily depends on the operator's subjective judgment and precise adjustment, demanding a high level of skill from the operator. In practice, human errors are inevitable, making it difficult to guarantee clarity, and the operation process generally takes about 3 seconds or even more.

Autofocus

In medical scenarios, doctors often need to obtain the clearest images as quickly as possible. Therefore, with the development of electronic technology, autofocus technology has been introduced into endoscopic cameras. This technology uses sensors to detect the distance between the target scene and the lens, automatically adjusting the focus. Operators only need to click a button on the camera, and the lens will automatically adjust to the clearest image based on image clarity and the theoretical focus position, significantly simplifying the use of endoscopes and making them highly suitable for medical applications.

The principle of autofocus is as follows: Optical signals received by the integrated optical lens are transmitted to the image sensor module, where the image sensor inside converts the optical signals into electrical signals that are then sent to the camera's processor. The processor runs an autofocus algorithm that controls an internal motor to execute the focusing operation.

The autofocus algorithm first filters the input image at the current motor position to reduce noise interference, and then enhances brightness through gamma correction. It then segments the image and calculates high-frequency information to characterize image clarity, adjusting the motor position based on the rate of clarity change. As the motor position changes, the mechanical distance matched by the optical lens group changes, thereby achieving the

focusing effect. This cycle continues until the clarity is maximized, at which point focusing is complete. An illustrative diagram of the autofocus algorithm is shown in Figure 1.

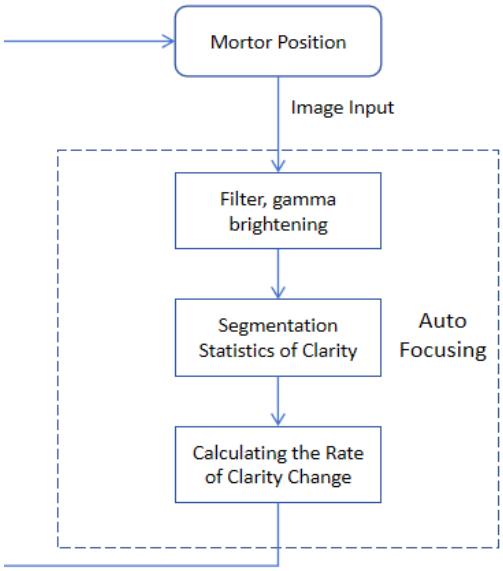

FIGURE 1. Schematic diagram of the autofocus algorithm start-up.

Zoom Technology: From Mechanical to Liquid Lens Solutions

Constraints of Fixed Focal Length

The difference between "fixed focus" and "zoom" lies in the variability of the focal length. Fixed focus means the focal length is fixed, and clear focus can only be achieved at a certain distance; zoom means the focal length is adjustable, and the magnification of the zoom lens can vary.[2] Initially, most endoscopic cameras adopted a "fixed focus" design.

Owing to the larger focal length resulting in a smaller field of view, different fixed-focus lenses typically have their respective usage scenarios. For example, ear, nose, and throat (ENT) and gynecology endoscopes commonly use a focal length of F14, as doctors prefer to observe smaller and more comprehensive images; urology often uses a focal length of F22; images from a focal length of F28 are more popular in thoracic surgery and some laparoscopic surgeries; while a focal length of F32 is the most common one in major abdominal surgeries. Therefore, although the advent of autofocus technology can provide doctors with a convenient and rapid focusing experience, fixed-focus cameras can only focus at a specific distance and cannot be adjusted. Clinically, it is still necessary to equip multiple fixed-focus mounts, such as F14, F22, F28, F32, etc., to meet the needs of different departments for different depths and field sizes, limiting the application of endoscopes in complex surgeries.

Zoom has always been a clinical challenge.[3] Endoscopic zoom lenses were developed to address this issue. Zoom lenses can change the focal length by moving the internal optical components, thus changing the field of view through "zooming". A single "zoom" lens equates to an integration of multiple "fixed-focus" lenses. When using a zoom lens, there's no need to switch between different fixed-focus lenses, as the clearest image is obtained at any position within a certain distance by operating the zoom. Now the zoom technology is divided into manual zoom and auto zoom.

Manual Zoom

Manual zoom is primarily achieved through detachable optical zoom adapters. By manually adjusting the optical adapter, the internal optical lens group is altered, achieving zoom.[4] While manual zoom cameras are more flexible than fixed-focus cameras, they still fall short in meeting the fast-paced and high-precision requirements of medical environments.

Auto Zoom

Owing to the precision required in surgical interventions, auto zoom systems must be miniaturized,[5] structurally simple, and compact, and must meet image quality requirements. With the continuous development of camera technology, particularly in liquid lenses, auto zoom endoscopic cameras have started to emerge. Liquid lenses use specific control methods to adjust the refractive index or shape of the lens, offering a novel approach to zooming. These lenses are characterized by fast zoom response times, low power consumption, and noise-free operation, which distinguish them from traditional lenses.[2] They offer the benefits of low manufacturing costs, simple structure, and easier miniaturization.[6]

The principle of auto zoom involves electrowetting, which manipulates the liquid's wetting properties via an electric field, thereby altering its shape and curvature. A liquid lens contains two immiscible liquids—nonconductive

oil and a water solution—separated by an interface. By applying voltage across the interface, the lens curvature can change in tens of milliseconds, altering the focal length. Increased voltage increases lens curvature and optical power.[7] Figures 2 and 3 show the liquid lens in de-energized and energized states, respectively. Liquid lenses, particularly those utilizing electrowetting, offer a tunable focal length by adjusting the curvature of a liquid surface.[8] These lenses have been successfully incorporated into zoom systems, such as the design by Park and Park,[9] which utilized liquid lenses to achieve variable focal lengths for compact mobile cameras. Moreover, recent developments have seen the combination of liquid lenses with other optical elements to enhance zoom capabilities without the need for moving parts, as demonstrated in the continuous zoom systems for telescopes by Jiang et al.[10] Additionally, stabilizing mechanisms for liquid lens-based zoom systems have been explored to improve precision and reliability, as discussed in the four-group zoom system proposed by Li et al.[11] Figure 4 shows the step-by-step workflow of FAF technology, from image capture to focus adjustment, and finally to image clarity feedback.

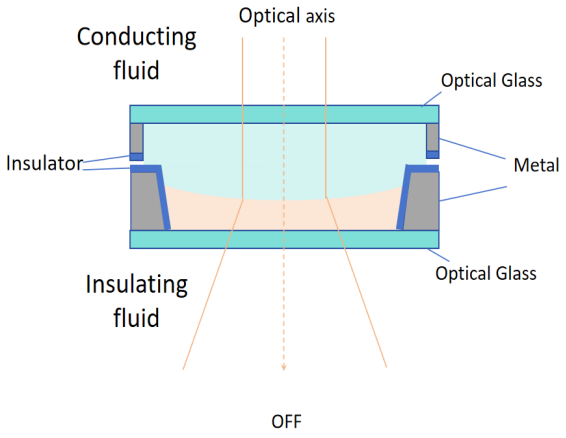

FIGURE 2. Schematic diagram of liquid lens in de-energized state.

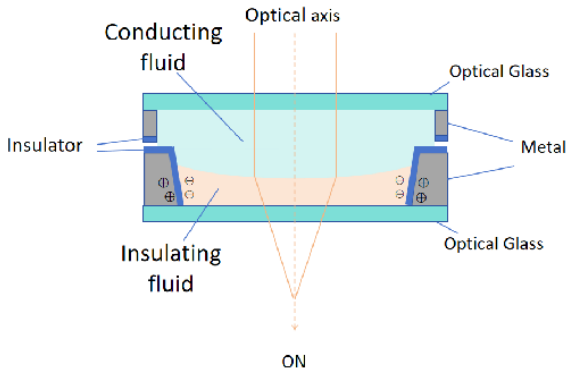

FIGURE 3. Schematic diagram of liquid lens in energized state.

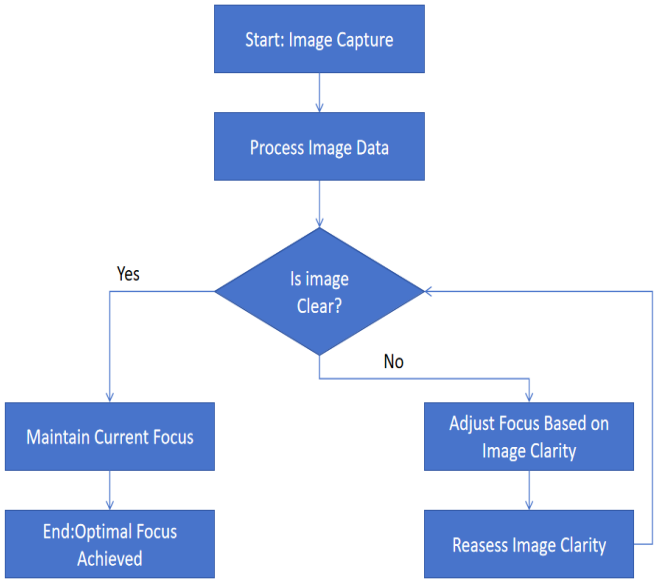

FIGURE 4. Schematic diagram of FAF workflow.

THE APPLICATION OF FULL-RANGE AUTOFOCUS TECHNOLOGY IN CLINICAL PRACTICE

The FAF technology, which integrates the advantages of both autofocus and zoom, has significantly enhanced the

field of medical endoscopy, particularly in clinical diagnosis and treatment. This technology enables continuous focusing from near to far distances, significantly improving the imaging quality and flexibility of endoscopes, providing doctors with clearer and more comprehensive views, and profoundly impacting disease diagnosis and treatment.

First, the technology enables continuous zoom across multiple focal lengths, from F14 to F32, facilitating one-click switching between distant, medium, and close-up views. The camera system can achieve intelligent scene linkage; by setting focal lengths for different surgical scenarios in the endoscope's control system, the camera automatically adjusts to the most appropriate and effective focal length for the scenario. A single FAF camera can seamlessly switch between focal lengths of F14 and F32, accommodating the usage habits of doctors across various departments.

Second, traditional endoscopy faced limitations in deep scene imaging, restricting doctors' ability to observe lesion areas. The FAF-equipped endoscopes achieve optical, lossless continuous zoom, allowing for undistorted magnification and direct observation of suspicious areas without losing detail. Compared to traditional digital magnification, this method offers superior magnification, lossless images, and reduced noise, effectively resolving issues with "extremely small" lesions, such as tiny blood vessels and outlines, improving visual precision. This is particularly crucial for early detection, such as during gastrointestinal examinations, where FAF can enhance the detection of minor abnormalities in the mucosa, increasing early cancer detection rates and the identification of other serious conditions.

Moreover, the FAF technology can be combined with auto zoom to achieve one-click autofocus. This ensures precise focusing with minimal margin for error, faster and more accurately than traditional manual focus methods. This enhances surgical efficiency and reduces the risks associated with inaccurate focusing, thus making surgeries more precise and improving the clinical experience.

Additionally, the application of FAF technology greatly improves patient comfort. In traditional procedures, frequent adjustments to the endoscope's position to achieve clarity can cause patient discomfort. However, FAF reduces the need for frequent positional adjustments, decreasing patient discomfort and enhancing patient satisfaction.

Finally, this technology offers greater opportunities for medical research and education. High-definition, full-range images allow researchers to closely observe and record disease progression, which is essential for studying mechanisms of medical diseases and developing new treatments. These high-quality images also serve as educational resources, assisting medical students and young doctors in understanding the characteristics of various diseases.

CONCLUSION

Considering the current research and development trends in endoscopic devices,[1] there is a growing preference for miniaturization to enhance the safety and comfort of endoscopic procedures.[8] Furthermore, with the future deep integration of artificial intelligence (AI)[12] and machine learning (ML) technologies, the autofocus and zoom systems of medical endoscopic cameras are expected to achieve greater levels of intelligence and automation. This could include real-time image analysis, predictive focusing, and automatic adjustment of parameters to meet the constantly changing requirements of the surgical field. These innovations will continue to improve image quality during procedures, providing doctors with more intuitive and effective tools for surgery.

AUTHOR CONTRIBUTIONS

Conceptualization, R.J.Z.; Methodology, R.J.Z.; Writing–Original Draft Preparation, R.J.Z.; Writing–Review & Editing, R.J.Z. and C.Y.; Project Administration, R.J.Z.

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The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Review

Artificial Intelligence-Driven Insights for Regulatory Intelligence in Medical Devices: Evaluating EMA, FDA, and CDSCO Frameworks

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ABSTRACT

The current review elaborates Artificial Intelligence (AI) in medical devices is changing the landscape of diagnostics allowing for more accurate and efficacious treatments leading to better patient care. An overview of AI technologies and their application in medical devices elaborates on AI technologies, such as neural networks and advanced data analytics being applied in diagnostic imaging and patient-monitoring preventative analytic models. Machine learning, a subset of AI, enables devices to learn from data and improve their performance over time, enhancing diagnostic accuracy and personalized treatment plans. An elaborated critical review is presented for the regulatory strategies implemented by relevant global leaders, such as the European Union (EU), the United States (US Food and Drug Administration, FDA), and India (Central Drugs Standard Control Organization of India, CDSCO). This is indicative of the EU regulatory approach as observed through reflection paper by the European Medicines Agency (EMA) on a methodology to assess AI technologies used in conjunction with medicinal products, and the Software as a Medical Device (SaMD) guideline by the FDA in the United States. The discussion is on adaptive regulatory strategies, an overview of some pre-certification programs, and detailed advice to manufacturers about compliance with the processes. Also, India aligning with the International Medical Device Regulators Forum (IMDRF) guidelines shows its appetite to help build an extensive regulatory framework for AI-powered medical devices. The current review concludes by highlighting the need for continued coordination between regulators, manufacturers, and healthcare players so that AI advances are safe and adherent to the regulations that improve overall patient care.

Keywords—*Regulatory framework, Patient monitoring, Diagnostics, Neural networks, Machine learning.*

INTRODUCTION

The medical device industry is being revolutionized by Artificial Intelligence (AI) through more efficient, data-driven, and adaptive regulatory practices. To improve processes, decision-making ability, and quality of healthcare provision, regulatory bodies around the world, such as the European Union (EU), US Food and Drug Administration (US FDA), and Central Drugs Standard Control Organization of India (CDSCO), are employing AI-based technologies. AI-driven medical devices extract valuable insights from medical data by using advanced methods of data analysis as well as machine learning (ML) algorithms. They then assist doctors in making better decisions, which have a positive impact on patients' health outcomes.[1] However, for medical devices guided by AI to be safe and efficient, they should adhere to Good Machine Learning Practices (GMLP), real-world performance tracking, compliance monitoring, and AI-ML software used as medical devices. Other essential components include regulatory frameworks, AI-powered regulatory documentation, AI-assisted regulatory expertise, and AI-driven regulatory insights.[2] The integration of these elements ensures that manufacturers of medical devices can safely and efficiently develop, test, and deploy AI-enabled devices.[3] This approach improves patient outcomes and enhances healthcare quality, as it affects all aspects of health services, including expenses, as we observe in the text. The FDA is at the forefront of developing guidelines for evaluating the safety and effectiveness of AI-enabled medical devices worldwide. The use of AI in healthcare raises a number of complex regulatory issues, some of which are unique to AI technology. A key challenge is the transparency of AI algorithms, which sets them apart from more traditional regulated technologies.[4] To address these challenges, regulatory bodies are developing training programs and guidelines to enhance regulatory expertise in AI and ML.

Overview of Artificial Intelligence in Medical Devices

Artificial Intelligence means a system that acts with the help of machines and predicts or suggests actions in real-world but potentially also in virtual environments according to the objectives set by humans. These systems require both ML and human-based input to identify, translate, and create the context around, and perceive real or fictive environments. It parses these perceptions automatically, and then abstracts them into models. The data are then leveraged to create models for mining information, or possible decisions are modeled by the process of model inference.[5] The applications of medical devices have been listed in Figure 1.

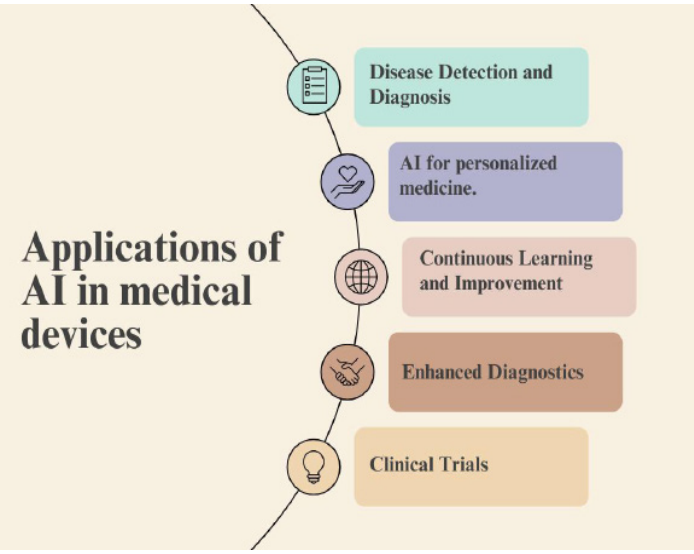

FIGURE 1. Application of AI in medical devices.

Disease detection and diagnosis: AI algorithms, including deep learning models such as convolutional neural networks, can help doctors make decisions in many areas of medicine, such as oncology, radiology, ophthalmology, and general medicine. These algorithms analyze medical images (e.g., MRI, CT scans, X-rays, etc.) and other patient information to assist in diagnosis. Studies have shown that these models can reduce waiting period, enhance medication compliance, and tailor insulin doses, among other benefits.

AI for personalized medicine: AI tools can recommend the most effective treatments based on genetic and medical history, as well as lifestyle factors, leading to more precise and effective treatments.

Continuous learning and improvement: AI devices can learn from real-world use to improve their performance over time, adapting to new clinical scenarios and

enhancing their detection capabilities, which in turn improve patient care.

Enhanced diagnostics: AI-powered diagnostics involve analyzing multiple medical data sources to improve early and accurate diagnosis of illnesses. This includes mining electronic health records (EHRs), automated laboratory report analysis, and medical image interpretation (e.g., radiology, pathology, etc.).

Performance evaluation: AI devices can be helpful in the performance evaluation process by increasing efficiency, improving patient outcomes, and simplifying data collection. This includes the use of AI in post-market surveillance and real-world performance monitoring to ensure the ongoing safety and efficacy of medical devices.[6]

Predictive analytics for monitoring: AI can be used in wearable devices to monitor patient vitals and provide predictive insights on conditions such as heart failure and glucose levels.

Regulatory compliance and clinical trials: AI can automate data generation, validation, and metadata analysis for regulatory submissions, enhancing clinical trials by predicting outcomes, optimizing patient recruitment, and ensuring compliance with global regulatory standards.

AI for diagnostics: ML models in diagnostic devices can aid in the automatic interpretation of test results, such as ECG and blood tests.

Natural Language Processing (NLP) for documentation: AI can automate and streamline clinical documentation, making it easier to comply with medical regulations and ensure accurate patient records.

Robotic surgery: ML algorithms can assist surgeons with precision during operations.

AI in Software as a Medical Device (SaMD): AI is being integrated increasingly into SaMD to enhance functionality and performance.

Importance of Regulatory Intelligence and Compliance Monitoring

Regulatory intelligence is essential for compliance monitoring, helping companies to keep updated about changing regulations. It ensures that the company remains in accordance with all laws and requirements. Regulatory intelligence empowers businesses in anticipating and dealing with global changes in regulations, without having to monitor manually different sources of regulatory data. A proactive approach ensures organizations respond faster to make the changes they need, mitigating risk and reducing costs. For example, regulatory intelligence platforms have tools for tracking changes in the rules and analyzing their impact to discover which obligations might stem from a change of laws that may apply specifically depending on what is being done by you.[7] These tools ensure the regulatory updates and reports generated on the platform itself, making it more efficient for operations at lower cost. For instance, the use of AI in regulatory intelligence is expected to automate monitoring and dissemination in the future, freeing up regulatory experts to concentrate on high-value tasks and decision-making.[8] Regulatory information tools for monitoring consist of regulatory agencies, website monitoring tools, news organizations, and subscription-based services regulatory intelligence for regulatory strategies and operations, product due diligence (pre- or post-deal), target products identification, and clinical development to regulatory submissions. This capability helps organizations stay current with applicable regulations, understand the implications, and create an intelligence report that can be used to remain compliant while reducing resource overhead.[9]

Need for Effective Regulatory Frameworks to Keep Pace with AI Innovations for Medical Devices

The current regulatory framework for AI-enabled medical devices is characterized by a wide void of strict laws and guidelines. The FDA (United States), the Medicines and Healthcare products Regulatory Agency (MHRA, UK), and the Health Canada have published preliminary thoughts; however, regulations by law are only enforceable when issued. Only Saudi Arabia has implemented proscriptive guidance so far. This ambiguity obliges manufacturers to employ regulations not modernized for the new and

revised short-cycle drugs, serving as roadblocks toward algorithmic adaptability along with dynamic data-driven updates by treating newly acquired information without constraints.[10]

REGULATORY APPROACHES TO AI IN MEDICAL DEVICES

Artificial intelligence in medical device regulations is now evolving quickly, as the EU, the United States, and India are adopting new pathways to ensure that these technologies are safe and effective. The EU is developing a comprehensive AI Act, which sets out strict rules on any use of the technology, while the United States continues to rely on its existing regulations and guidelines. India is aligning its regulatory framework with international standards, particularly those set by the International Medical Device Regulators Forum (IMDRF).[11] These regulatory mechanisms play an important role in preventing the operational and planning data management system from becoming points of failure, and thus protect patients as well as healthcare practitioners by determining that medical devices powered with AI underperform reliably.[11]

European Union

The EU wants to regulate AI in all areas, including healthcare, based on how dangerous it is. The proposed AI Act wants to make a legal definition of "AI system" and sets rules for how AI can be built into and used in medical devices. The EU AI Act makes sure that AI systems follow basic rights, safety rules, and morals by setting clear rules for how they can work.[12]

Overview of the European Medicines Agency's (EMA) Reflection Paper

The EMA has published a preliminary document discussing the use of AI and ML in the entire lifespan of medicinal products, including those for human and veterinary use.[13]

The use of AI/ML systems for the clinical management of individual patients may result in the Medical Device Regulation (MDR) classifying in vitro diagnostics (IVDs) used in performance evaluation as medical devices, as stated in the reflection paper. A document issued by the Medical Device Coordination Group (MDCG) offers detailed guidelines on the qualification and classification of software as medical devices in accordance with the MDR, the in vitro Diagnostic Devices Regulation (IVDR), or both.[14] Nonetheless EMA has no responsibility to classify software by the rules. Additional prerequisites are essential when utilizing CE-certified devices in a clinical trial to safeguard the rights, safety, and well-being of participants as well as the integrity, and applicability of evaluation data. It is clear from the reflection paper that EMA scrutinizes whether the characteristics of medical devices are suitable for generating evidence needed for marketing authorization application, or whether a device provides recommendations in the Summary of Product Characteristics (SmPC).[15]

EMA's Approach to Evaluating AI Technologies in Medical Device Development and Authorization

The EMA's strategy for assessing AI Technologies in the development of medical products is as follows:

The EMA has released a reflection paper that focuses on promoting the utilization of AI throughout the lifecycle of medicinal products. This covers medical devices that are used within clinical trials to provide evidence for a marketing authorization application or in case they are used with a medicinal product.[16] The EMA assesses such devices to decide whether they can provide adequate evidence for approval in EU countries. These recommendations include information about how to conduct AI research, which needs to be updated regularly, given the advances in the field and the new knowledge generated by research. If SmPC recommendations, such as posology or monitoring incorporate advice from an AI-enabled medical device, all relevant aspects of that combination are considered during assessment by the EMA.[17] According to this reflection paper, general guidelines and expectations applicable for medical devices would also apply to the clinical trial and marketing authorization contexts using AI/ML-based approaches.[18]

Overall, the EMA is adopting a risk-based strategy, instructing the sponsors to consider whether the AI system presents risks to patients, and if so, then to seek early regulatory advice from the EMA. The EMA is getting ready to examine applications that incorporate AI/ML systems into the lifecycle of medical products.[19]

Overview of the European Medicines Agency's (EMA) Reflection Paper

The EMA has released a preliminary document outlining its current stance on the use of AI and ML to enhance the safe and efficient development, regulation, and use of human and veterinary medicines throughout the lifespan of the product. The EMA acknowledges the potential of AI to improve different areas of the pharmaceutical industry, such as drug discovery, preclinical development, clinical trials, precision medicine, product information, manufacturing, and post-approval pharmacovigilance.[20] Nevertheless, the agency underscores the importance of adopting a human-centered approach in all aspects of AI and ML development and implementation. It is crucial to adhere to the existing legal obligations, prioritize ethical considerations, and uphold fundamental rights. The EMA promotes transparency and comprehensibility in the creation and verification of AI systems.[21] This entails providing explicit documentation of the utilized data, applied algorithms, and achieved performance, with the level of explanation aligning with the level of risk. Sponsors should utilize reliable and accurate data when creating and testing AI systems, carefully choose and validate algorithms for specific purposes, establish continuous monitoring and maintenance plans to identify and address any decline in performance over time, conduct thorough risk assessments, and take necessary measures to mitigate risks, and proactively collaborate with regulators to ensure compliance with AI-usage guidelines. The EMA's preliminary reflection paper was available for public consultation until December 31, 2023.[22]

US Food and Drug Administration

The US FDA regulates the utilization of AI in medical devices. The FDA evaluates AI/ML-enabled medical devices based on their use, using appropriate premarket pathways, such as 510(k) clearance and De Novo classification for noncontroversial new technologies, and traditional PMA for innovative devices.[23] The regulations governing medical devices are highly specific. The agency provides detailed recommendations and action plans for regulatory consideration in response to the challenges posed by the rapidly evolving field of AI technologies. These encompass the AI and Software as a Medical Device Action Plan, along with supplementary guidance on ML best practices, pre-specification change control plans, and transparency.[24]

FDA Guidelines for AI/ML-Based Software as a Medical Device

Software as a medical device is a term coined by the IMDRF to refer to software that is specifically created for medical usage and can function on its own, without incorporating into a physical medical device.[25]

Overview of the FDA guidelines for AI/ML-based SaMD: The FDA is in the process of developing regulatory pathways for SaMD driven by AI and ML. These pathways include traditional premarket pathways, such as 510(k) clearance, De Novo classification, and Premarket Approval (PMA). Recognizing that AI/ML technologies are adaptive by design, the FDA has acknowledged that traditional regulatory approaches may not be sufficient for these devices. This is particularly important because the FDA no longer believes that the old requirement of locking algorithms post-training is adequate. Instead, they are moving toward a more adaptive framework that allows algorithms to undergo modifications under predefined change control plans, ensuring safety and effectiveness. This approach addresses the specific challenges posed by AI/ML medical devices.[26]

Important FDA Guidance Documents

The document titled "Proposed Regulatory Framework for Modifications to AI/ML-Based Software as a Medical Device" published in April 2019 explores a potential

method for evaluating AI/ML modifications before they are released to the market.

In January 2021, the FDA issued the "AI/ML SaMD Action Plan", which offers a comprehensive framework for regulating AI and ML technologies in SaMD.[27]

The title of the event in October 2021 was "Good Machine Learning Practice for Medical Device Development: Guiding Principles".

In April 2023, draft guidance was released on "Marketing Submission Recommendations for a Predetermined Change Control Plan for AI/ML-Enabled Device Software Functions."[28]

The title of the publication in October 2023 was "Guiding Principles for Predetermined Change Control Plans in Machine Learning-Enabled Medical Devices."

The title of the publication released in June 2024 was "Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles." [29]

FDA Guidelines for AI/ML-Based Software as a Medical Device

The FDA's Total Product Lifecycle (TPLC) approach to regulation aims to expedite the enhancement process of SaMD utilizing AI and ML, while ensuring compliance with all essential safety protocols. Developers are anticipated to be transparent about the functionality of their products in real-world scenarios and adhere to both good ML practices (GMLP) and quality systems. The TPLC framework enables manufacturers to present change control plans that have been implemented prior to the initial premarket review process.[30] This allows for specific modifications to be implemented without necessitating a fresh evaluation process. The FDA granted approval up to 2024 to approximately 64 medical devices that utilize AI and ML, with the majority being approved through the 510(k) pathway. The agency is currently endeavoring to enhance its regulatory framework in order to match the rapid pace at which these technologies are evolving.[31]

The recommendations from the guidelines: The FDA's guidelines on AI/ML-based SaMD are classified into three broad categories, i.e., assuring the safety and effectiveness of these devices, promoting good ML practices in device development, and ensuring transparency about how algorithms reach their outputs.[32] Most important suggestions are as follows:

Thorough validation: AI and ML algorithms need to be thoroughly validated to show that they work as intended and give correct results. This would include clinical trials and tests against well-known ways of diagnosing.

Risk management: Companies that create AI/ML algorithms are to search for and mitigate any risks associated with it. Biases in the data used to train an algorithm, errors made by the algorithm itself, and security vulnerabilities are all potential problems.[24]

Real-world performance monitoring: AI and ML models can learn from experience to improve performance over time, so the FDA recommends using real-world clinical data to continually assess a device's safety and effectiveness.

India's Central Drugs Standard Control Organization

CDSCO's Alignment with IMDRF Guidelines

The CDSCO is aligning its medical device rules with IMDRF guidelines. The CDSCO issued a notification on August 1, 2019, revising the Medical Devices Rules of 2017 to make SaMD subject to its existing regulatory framework. Following the IMDRF guidelines provides a road map to manufacturers in India by which they can comply with their regulatory obligations for SaMD products. SaMDs are classified into risk-based classes (A–D), which are systematically defined as per the IMDRF risk framework.[38] It determines the required level of regulatory oversight and compliance. The CDSCO is working on creating a Digital Drugs Regulatory System (DDRS), which, however, is an AI-enabled open-source technology. The goal is to create a harmonious digital regulatory environment based on international standards and best practices. As long as AI medical devices safeguard patient data and offer safe access to it for unauthorized parties as defined by new legislation, they can continue to be relevant in accordance with the ethical and open principles outlined by the IMDRF. The CDSCO has leaned into the IMDRF guidance as a way of developing its medical device regulations, with an emphasis on technologies such as AI-powered SaMDs. The aim is to have a robust, risk-based, and globally harmonized regulatory system for medical devices in India.[39,40]

Overview of IMDRF guidelines for medical devices: The IMDRF has published a framework, which is adopted and applied by the CDSCO.

Main safety and performance IMDRF regulations are as follows:

IMDRF has released the document "Essential Principles of Safety and Performance for Medical Devices & IVDs" (IMDRF/GRRP WG/N47). This guidance provides high-altitude rules on designing and constructing medical devices to make them safe, by following which you can guarantee the safety characteristics that are in place when your device is used as intended.

IMDRF/GRRP WG/N71:2021 Medical device regulatory review reports guidance regarding information to be included (IMDRF/GRRP, 2020). The guidance is to provide common format requirements for the content and format of a regulatory submission dossier for a medical device.[41]

This report encompasses crucial sections, such as the following:

Regional administrative information
Submission context
Nonclinical evidence
Clinical evidence
Labeling and promotional material
Quality management system information

There are rules and principles for medical devices in India that were taken from the IMDRF and added by the CDSCO to the Medical Devices Rules, 2017. The CDSCO also publishes lists of medical devices that are categorized by risk. These lists match the IMDRF framework of classes A–D based on risk.[42]

Implications of CDSCO's alignment with IMDRF guidelines for AI-based medical devices in India: In India, the CDSCO has mostly made its rules about medical devices, such as SaMDs, the same as the rules and guidelines set by the IMDRF.

The CDSCO has implemented the IMDRF's risk-based system to categorize SaMDs into four groups based on their level of risk: low-risk (Class A), low–moderate risk (Class B), moderate risk (Class C), and high-risk (Class D).

Essential principles of safety and performance: The CDSCO makes sure that SaMDs follow the IMDRF's "Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices" when they design and make their products.

Labeling and advertising: In India, SaMDs must follow the IMDRF's "Principles of Labeling for Medical Devices and IVD Medical Devices" to make sure users get the right information.

Structure of regulatory submissions: The CDSCO has used the IMDRF's "Medical Device Regulatory Review Report" template to decide the information that should be included and how it should be organized in regulatory submissions for SaMDs.

TABLE 1. Comparative analysis for Regulatory framework for AI across various Regulatory agencies.

Feature	Sub-feature	European Union (EU)	United States (FDA)	India (CDSCO)
Focus	Regulatory framework for AI	Draft reflection paper on AI in medicinal products lifecycle defines "AI system" and proposes regulatory framework. EU AI Act focuses on general AI development and ethical considerations.	AI/ML action plan outlines focus on developing guidance for AI/ML in medical devices.[43]	Aligns with IMDRF principles for AI-based medical devices.[44]
	Traditional premarket pathways	Existing CE marking framework with risk-based assessment considering AI components.	Existing 510 (k) clearance, de novo classification, or premarket approval (PMA) pathways for SaMD.	Follows risk-based classification similar to the US FDA.
	Post-market surveillance	Requires manufacturers to have a post-market surveillance plan, potentially incorporating AI for anomaly detection and trend analysis.[45]	Requires manufacturers to monitor and report adverse events for SaMD, potential use of AI for real-world performance monitoring.	Requires manufacturers to submit periodic safety update reports (PSURs), potential for AI-assisted data analysis.
AI-specific requirements	Transparency and explainability	Emphasis on transparency in AI decision-making processes and explainability of results.	Focus on good ML practices (GMLP) for development and validation of AI models.	Aligning with IMDRF principles for data access, security, and responsible use.[45]
	Change management	The draft guidance highlights the necessity for predefined change control plans for AI systems to maintain continuous regulatory compliance.	Guidance on predefined change control plans (PCCP) for AI/ML outline processes for managing changes in AI models.	Aligns with IMDRF principles for managing changes in AI-based medical devices.
AI advantages for regulatory bodies	Efficiency and monitoring	Potential for AI to improve efficiency in monitoring medical device performance and identifying potential risks.	Potential for AI to streamline data analysis and automate risk assessment processes for SaMD.	Potential for AI-assisted automation in regulatory processes once frameworks are established.
Challenges	Regulatory uncertainty	Lack of clear and finalized regulations for AI in medical devices creates uncertainty for developers and regulators.[46]	Adapting existing frameworks to address the continuous learning nature of AI models presents challenges.[47]	Limited experience and resources for implementing AI-based regulatory processes.[48]

Standards that are the same everywhere: In India, SaMDs must follow international rules, such as IEC 62304 for software lifecycle, IEC 60601-1 for embedded software, and IEC 82304-1 for standalone SaMDs.42 Table 1 provides a comparative analysis of the regulatory frameworks for AI across various regulatory agencies, highlighting key similarities and differences in their approaches.

POSSIBLE INCLUSION AND ADVANCEMENT

Artificial intelligence and innovative regulatory intelligence integration with medical devices are to revolutionize efficiency, accuracy, and compliance. The changing landscape of the medical device regulatory framework is driven by the growth in AI solutions, which are now utilized by prominent regulators, such as the EMA, FDA, and CDSCO. This section discusses potential progress and distinct types of innovation that are tailored to each regulator's specific issues. Focus areas include better data integration and interoperability, regulator-specific AI applications via innovation, and an ethical and transparent framework for AI development. The purpose is to present AI's critical and ever-growing role in achieving better regulation, patient safety, and true international alignment.

Enhanced Data Integration and Interoperability

When it comes to regulating medical devices, it's very important to combine data from different sources, such as clinical trials, post-market surveillance, and EHRs. This is because these sources provide important information for making sure that all regulations are followed. In response to this need, AI algorithms are created that allow huge amounts of unstructured data from many systems to be collected, processed, and turned into useful information. These algorithms can extract and align large amounts of data in real time, while most other ways of integrating data are done manually.[49] One example of this trend is the use of ML models to connect patterns and changes in different databases. This allows regulators to see how the device works in a bigger picture for safety reasons. Also, it's faster to share data with regulatory bodies and other important parties, thanks to the progress in standardizing and connecting data. Health Level Seven International (HL7) standards or Fast Healthcare Interoperability Resources (FHIR) are examples of universal data standards and protocols that make sure that different systems talk to each other correctly so that data are used. Not only do these improvements speed up the regulatory process, but they also make it easier to spot and act on safety signals quickly. Data integration and interoperability made possible by AI help regulatory agencies make smarter rules to protect patients and keep up with MedTech innovation.[49]

Regulatory Body-Specific AI Innovations

Customization of AI solutions to tailor specific regulatory challenges encountered by EMA, FDA, and CDSCO is critical in streamlining regulatory operations and maintaining compliance acts. Every regulatory body works within different laws and healthcare contexts, calling for highly differentiated AI use cases that answer to individualized requirements. The EMA, for example, has been using AI to facilitate the review of clinical trial data processing validations with a view to speeding up the approval process swiftly and accurately while maintaining significant safety assessments.[49] Through real-time post-market surveillance, the FDA has led the way in its application of ML algorithms and other AI technologies to track adverse event data (and even device performance) continuously. In India, the CDSCO is turning to AI-powered ML tools that can help improve regulatory submission and approval time with so many medical devices entering a diverse market rapidly.[49]

These customized AI solutions have seen a level of advancements proven by successful implementation by regulatory bodies. The FDA's Sentinel Initiative alone is a case of how large-scale healthcare data are analyzed for post-market safety surveillance, bringing the process to detect potential safety signals by significantly reducing time with AI. This is the use of AI in implementing adaptive pathways by EMA, leading to quicker entry for innovative medicines into the hands (health) of patients while upholding high safety standards. For instance, in India, AI-driven platforms are developed to automate the CDSCO regulatory review process to save substantial time and effort on administrative tasks.[49]

Thus, these customized AI solutions are able to solve specific regulatory problems and also lay the foundation

for agility in regulation. Thus, this review article exhibits these progressions and contextual analyses which are used to understand the implementation of AI by regulatory bodies that augment their processes based on efficiency criteria for patient safety. This observation illustrates just how disruptive AI could be in regulatory intelligence, and why constant innovation is essential to adapt its capabilities to the evolving demands of their regulations.[49]

The FDA's Pre-Cert Program is designed to enhance regulatory efficiency and innovation. Pre-certified companies can release updates and new products more quickly, allowing for faster adoption of innovative technologies. This program also provides flexibility in evolving with technology, particularly for AI/ML, while maintaining a focus on safety through post-market monitoring and company excellence reviews.[49]

Ethical and Transparent AI

Progress in the evolution of responsible AI frameworks has become more urgent because medical devices are the area where advanced regulatory decisions are made, at least partially by an AI system. This is an additional measure important to ensure transparency and accountability, in turn ensuring the trustworthiness of AI-driven processes for public health maintenance. Ethical AI frameworks are created to enable the development of these systems, so that they are designed and implemented in line with ethical principles as well as regulatory standards.[49] This consists of having protocols for data privacy, bias mitigation, and ensuring equitable access to All-driven insights. These frameworks also underscore the need for accountability—that people must know who is responsible in cases where AI systems produce harm.

The use of explainable AI (XAI) models provides one of the most important advancements in this space. In cases where traditional AI systems are essentially "black boxes," withholding any information about their decision-making process, XAI models aim to better unpack the results of our AI systems. Regulators and stakeholders should be able to unpack the decision criteria upon which the AI has based its conclusions, so that decisions at any time can still accompany handling scrutiny. For example, subjecting an XAI model to a regulatory body looking at the integrity of any selected medical device should be able to understand how exactly it arrived at its decision based on concrete data and patterns.

The FDA is also showing initiatives in improving more ethically aligned and transparent AI through projects such as those exploring ways to bring XAI into its regulatory review pathways. By requiring that AI models used in regulatory submissions be interpretable, the FDA is ensuring that those tools can have both regulator and patient trust. On the other hand, some form of guidance and transparency in strategy, be it through routine audit processes for addition or on-account validation built-in algorithms, at EMA and CDSCO are likely to hold position.[49] The FDA is also showing initiatives in improving more ethically aligned and transparent AI through projects such as those exploring ways to bring XAI into its regulatory review pathways. By requiring that AI models used in regulatory submissions be interpretable, the FDA is ensuring that those tools can have both regulator and patient trust. On the other hand, some form of guidance and transparency in strategy, be it through routine audit processes for addition or on-account validation built-in algorithms, at EMA and CDSCO are likely to hold position.[49]

One World, One Regulation

In an era where AI technologies are rapidly advancing and transforming the landscape of medical devices, the need for a harmonized global regulatory framework has become increasingly evident. The vision of "One World, One Regulation" encapsulates the aspiration for a unified approach to ensure that AI-powered medical devices meet consistent standards of safety, effectiveness, and ethical use across all regions. This vision is not just about standardization but about fostering an environment where innovation can thrive without being hindered by disparate regulatory requirements. By aligning regulatory approaches, we can facilitate the rapid deployment of AI technologies, making advanced healthcare solutions more accessible globally. Moreover, a unified framework builds trust in these technologies by ensuring rigorous oversight and consistent performance standards. It also promotes collaboration among regulatory bodies, streamlining the approval process and reducing the burden on manufacturers. Ultimately, the "One World, One Regulation" approach is essential for realizing the full potential

of AI in healthcare, ensuring that these technologies can be safely and effectively utilized to improve patient outcomes globally.[49]

CONCLUSION

The regulatory framework for medical devices incorporating AI is currently experiencing substantial changes. The EMA, FDA, and CDSCO are actively formulating frameworks and guidelines to guarantee the secure and efficient utilization of AI. These initiatives seek to tackle problems stemming from unclear regulations and a lack of expertise in the field. The EMA's reflection paper emphasizes the importance of conducting a thorough risk analysis at the time of making decisions about the implementation of AI in medicines. This analysis should take into account factors such as the transparency and interpretability of the AI system as well as its ability to manage changes throughout its lifecycle.

Artificial intelligence has the capacity to completely transform the field of drug discovery and regulatory processes, encompassing everything from the initial development of pharmaceuticals to ongoing monitoring after approval. The EMA undertakes a comprehensive assessment of these assertions. Furthermore, the scientific validity and applicability of medical devices incorporating AI that are utilized in clinical trials within the EU are evaluated to ascertain their effectiveness and suitability in all member states. The EMA recommends that sponsors assess the potential hazards of implementing new AI systems on patients and promptly seek guidance from the regulatory body. Additional suggestions involve the creation and evaluation of AI systems using clear and well-documented approaches, offering strong justifications for AI implementation in particular situations, and comprehending the accompanying hazards and constraints. The FDA has released guidelines for SaMD that employ AI and ML. These guidelines provide recommendations for effectively utilizing ML, incorporating pre-established change control systems, and guaranteeing the openness of data and algorithms. The FDA acknowledges the revolutionary potential of AI and ML in medical devices while recognizing the distinct challenges posed by them. The adoption of the TPLC approach facilitates the ongoing enhancement and progression of AI/ML-based software as medical devices, ensuring the preservation of safety and efficacy throughout all premarket review activities. The CDSCO has implemented the regulations established by the IMDRF, encompassing the risk-based classification system and fundamental principles for guaranteeing safety and performance. The CDSCO follows IMDRF guidelines to ensure the performance and safety of medical devices and IVDs while designing and restructuring SaMD. Indian SaMD must adhere to global standards, including IEC 62304, for managing risks in the software life cycle, IEC 60601-1 for embedded software, and IEC 82304-1 for standalone SaMD.

Although regulatory ambiguity and limited expertise pose significant challenges, these regulatory bodies are making efforts to ensure the safe and effective utilization of AI in medical devices, ultimately improving patient outcomes. The main goal of the EU AI Act is to effectively govern scientific progress and the extensive implementation of AI in medical devices and other products and services. These organizations work diligently to ensure that AI systems comply with safety regulations and ethical considerations while also protecting fundamental rights.

AUTHOR CONTRIBUTIONS

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Original Research Article

Mongolian Medical Equipment Regulations: Challenges in Clinical Engineering Development

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ABSTRACT

To effectively deliver healthcare services, it is essential to strengthen and expand the education system for qualified clinical engineers and technicians. This should be combined with measures such as providing modern equipment to health facilities and making spare parts available. Internationally, one clinical engineer is typically responsible for approximately 100 pieces of equipment, while each large piece of equipment, such as magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography (PET scan), and angiography machines, is assigned to a dedicated engineer. However, in our country, no standard exists linking the number of engineers to the quantity of medical equipment. The Law on Drugs and Medical Devices, adopted in 2024, stipulates that general hospitals, specialized centers, and specialized hospitals must have a dedicated unit responsible for the use and safety of medical equipment, while other healthcare institutions must employ a full-time or subcontracted engineer. However, biomedical engineers and technicians are not classified as "medical specialists" under the Law on Health. Although four universities nationwide train biomedical engineers and technicians, the number of graduates still does not meet the growing market demand. There is also a need to diversify and develop biomedical engineers in line with international standards, including certification. These findings underscore the need for structural reforms in clinical engineering training, legal recognition, and workforce planning in Mongolia.

Objective: To assess the human resource needs and legal framework for medical equipment specialists and compare them with the WHO and regional country regulations.

Methods: We used analytical, cross-sectional, and descriptive study designs. A total of 272 engineers and technicians were interviewed using a pre-prepared questionnaire that included questions on work experience, postgraduate training, qualification level, and workload. We also reviewed WHO and regional regulations regarding the professional descriptions and certification of biomedical engineers. The data were analyzed using SPSS Statistics 26, and the results are presented in figures and tables.

Results: The study population comprised 72.4% males, 95.6% full-time employees, and 68.8% bachelor's degree holders. However, the majority (90.4%) did not have a specialty degree. Regarding on-the-job and other training, 73.5% had not received any training. The training status of professionals was not dependent on the organization they worked for. However, there was a statistically significant difference between foreign training and manufacturer-provided training. The professionals surveyed had received relatively little training since they started working. As their years of experience increased, the number of manufacturer-organized training sessions also increased. However, there was no relation between years of experience and the number of domestic, foreign, or postgraduate training sessions. Additionally, the number of medical devices managed per engineer varied, and the legal framework regulating social security, rights, and obligations remains insufficient. It also varied compared to WHO recommendations, medical engineering professional descriptions, and certifications across countries in the region.

Conclusion: Clinical engineers and technicians face a heavier workload. The lack of postgraduate training opportunities, an insufficient legal framework, and variations in medical engineering professional descriptions and certifications across countries in the region present significant challenges for the sector. Based on these findings, the study proposes strategic recommendations including legal recognition, certification systems, continuing professional development, and workforce planning policies to address these barriers and strengthen clinical engineering in Mongolia.

Keywords—*Human resources, Healthcare specialist, Legal framework.*

BACKGROUND

In Mongolia, health products and technologies, one of the six main components of the health sector systems developed by the World Health Organization,[1] are regulated by the Law on Health,[2] the revised version of the Law on Drugs and Medical Devices,[3] and the Law on Metrology.[4] To effectively deliver healthcare services, it is essential to strengthen and expand the education system for qualified engineers and technicians of medical equipment. This effort should be complemented by equipping healthcare institutions with modern medical devices and ensuring the availability of spare parts. In Mongolia, the state budget for medical equipment ranged from 9 to 41 billion tugriks between 2017 and 2021. Since 2018, maintenance costs for major technologies such as magnetic resonance imaging (MRI), computed tomography (CT), and angiography devices, previously covered by the organizations' operating expenses, have been separately allocated in the state budget. However, since 2020, healthcare institutions have been responsible for these costs.[5] Article 40.1 of the revised Law on Drugs and Medical Devices states that "Healthcare institutions specified in Articles 15.1.4, 15.1.5, 15.1.7, 15.1.11, 15.1.12, and 15.1.13 of the Law on Health shall have a unit responsible for the use and safety of medical equipment, and other healthcare institutions shall have a full-time or contracted clinical engineer who shall perform the corresponding functions."[3] However, the rights and obligations outlined in Articles 28.1 and 28.4 of the Law on Health, particularly Article 28.1.5, which states that professionals should have the opportunity to "improve their professional skills and participate in postgraduate training at the expense of the institution every five years,"[2] do not apply to clinical engineers. The WHO also published a report titled "Human Resources for Medical Devices: The Role of Biomedical Engineers as part of its Medical Device Technical Series", highlighting the global concern over the need for certification of professionals in the field of Biomedical Engineering (BME).[6]

The Mongolian standard sets the minimum staffing ratio of clinical engineers to technicians (4:2) for both specialized and general hospitals,[7,8] and 1 per 100 pieces of equipment for Family Health Centers,[9] soum (district) and village health centers,[10] and maternity houses.[11] Additionally, the National Center for Blood Transfusion and Research and the National Center for Zoonotic Diseases have a 2:1 ratio,[12,13] while the National Center for Pathology follows a ratio of 1:1.[14] Nevertheless, a report by the Ministry of Health of Mongolia indicated that, in practice, one engineer is responsible for 220 pieces of equipment in central hospitals and specialized centers, while one engineer manages 319 pieces of equipment in both the capital and local areas.[15]

According to the Order No. 439 issued in 2006 by the Minister of Health of Mongolia, one engineer is typically responsible for approximately 100 pieces of medical equipment, with one engineer dedicated to each major device, such as MRI, CT, PET scan, and angiography machines.[16]

The ME Uptime Project (2018), jointly conducted by the Ministry of Health of Zambia and the Tropical Health and Education Trust (THET) with the support of WHO, recommended that "1 BMET per 100 units of equipment is adequate," emphasizing the need for structured biomedical maintenance staffing.[17]

According to the US Bureau of Labor Statistics, the demand for biomedical engineers is projected to grow by 5% from 2022 to 2032, outpacing the growth of many other occupations.[18] This increase is driven by advancements in

healthcare technology and the rising demand for medical services due to an aging population.[18]

In Mongolia, two government and two private universities offer training programs for biomedical engineers and technicians. According to the 2023 statistics, approximately 900 engineers and technicians have been trained.[19] Although human resource requirements for medical equipment maintenance were established by the Minister of Health orders in 2006 and 2018, implementation remains limited.[16,20] Only 43% of the 16 healthcare institutions under the Ministry of Health have independent clinical engineering departments. Among the 25 healthcare institutions under the capital city health department, 24% have only 1 to 2 engineers. Moreover, 95% of the 21 provincial healthcare institutions operate with just 1 to 2 engineers and lack dedicated medical technical departments.[15]

Therefore, it is necessary to assess the adequacy of clinical engineers in the healthcare sector and compare the legal framework with that of other countries in the region.

OBJECTIVE

To assess the human resource needs and associated legal framework for medical equipment specialists and compare them with the WHO recommendations and regional country regulations.

METHODS

The study followed an analytic, cross-sectional, and descriptive study design. Human resource needs were assessed through indicators such as employment contract specifications, qualifications, training, years of experience, and workload. A structured questionnaire was used to collect data on the number of engineers and technicians currently working in the medical equipment field, their qualifications, and training from 76 healthcare institutions in the capital and local areas. Additionally, data was collected from 272 currently working specialists, covering job roles, contract types, main specialties, years of experience, and training. Mongolian laws, standards, rules, and regulations related to human resources for medical equipment, as well as WHO recommendations and regulations in regional countries, were also reviewed.

For the descriptive analysis, the mean, standard deviation, and 95% confidence interval of the mean were calculated for quantitative variables with normal distribution. For non-normal distributions, the median and interquartile range were calculated. Outliers in quantitative variables with non-normal distribution (defined as $x \leq Q1-1.5IQR$ or $x \geq Q3+1.5IQR$) were removed. After removing outliers, the mean, standard deviation, and 95% confidence interval of the mean were recalculated.

To assess differences in quantitative variables between groups, the Mann–Whitney U test was used for two independent groups, and the Kruskal–Wallis H test was used for three or more groups. Differences were considered statistically significant if the *P*-value was less than 0.05.

ETHICAL CONSIDERATIONS

The study methodology was discussed at the Institutional Review Board meeting of the Mongolian National University of Medical Sciences on January 21, 2022 (No. 2022/3-01), and permission to conduct the study was obtained.

RESULTS

We surveyed 272 professionals, comprising 83.9% of engineers and technicians working in the healthcare sector. Of the professionals surveyed, 72.4% were males, 95.6% were full-time employees, and 68.8% held a bachelor's degree. However, the majority (90.4%) of specialists did not have a professional degree (Table 1). This is attributed to the lack of a legal framework, professional career development roadmaps, job descriptions, and planning.

TABLE 1. General characteristics of medical equipment specialists in organizations, by percentage.

Indicators	Total, n = 272	MH*	PGH†	RDTC‡	DGH§	DHCII	SGH¶	SH††	ECMOHSC#	SO**
Gender										
Female	27.6	85.7	26.7	33.3	25.0	37.5	25.0	50.0	27.9	21.6
Male	72.4	14.3	73.3	66.7	75.0	62.5	75.0	50.0	72.1	78.4
Terms of the employment contract										
Contract	4.4	-	8.9	-	-	12.5	50.0	-	4.9	0.9
Full-time	95.6	100.0	91.1	100.0	100.0	87.5	50.0	100.0	95.1	99.1
Education level										
No education	0.7	-	4.4	-	-	-	-	-	-	-
High school	2.6	-	4.4	5.6	-	-	-	-	6.6	-
Bachelor	68.8	71.4	53.3	44.4	87.5	87.5	100.0	50.0	57.4	80.2
Licentiate	19.1	-	35.6	44.4	12.5	12.5	-	-	24.6	9.0
Master	8.8	28.6	2.2	5.6	-	-	-	50.0	11.5	10.8
Qualification										
None	90.4	100.0	77.8	94.4	100.0	87.5	100.0	100.0	90.2	93.7
Consultant	0.7	-	-	-	-	-	-	-	1.6	0.9
Qualified	8.8	-	22.2	5.6	-	12.5	-	-	8.2	5.4

Notes: *Maternal houses, †Provincial General Hospitals, ‡Regional Diagnostic and Treatment Centers, §District General Hospitals, IIDistrict Health Centers, ¶Soum General Hospitals, ††Specialized Hospitals, Capital Department of Health institutions, #Emergency Centers, Ministry of Health Specialized centers, **Supply Organizations.

TABLE 2. Training of biomedical engineers and technicians, by type of organizations.

Indicators	Total		UB Health Department		Local		Private		Ministry of Health		*P*
	n	%	n	%	n	%	n	%	n	%	
Internal training											0.371
Not attended at all	200	73.5	24	72.7	44	65.7	86	77.5	46	75.4	
Attended	72	26.5	9	27.3	23	34.3	25	22.5	15	24.6	
Foreign training											0.0001
Not attended at all	258	94.9	32	97.0	67	100.0	109	98.2	50	82.0	
Attended	14	5.1	1	3.0	0	0.0	2	1.8	11	18.0	
Postgraduate training											0.140
Not attended at all	187	68.8	23	69.7	44	65.7	84	75.7	36	59.0	
Attended	85	31.3	10	30.3	23	34.3	27	24.3	25	41.0	
Manufacturer training											0.0001
Not attended at all	176	64.7	33	100.0	58	86.6	36	32.4	49	80.3	
Attended	96	35.3	0	0.0	9	13.4	75	67.6	12	19.7	

Notes: Percentages may not add up to exactly 100% due to rounding, institutional differences in respondent numbers, and missing values for some variables.

As for the status of on-the-job and other training received by the surveyed professionals, 73.5% had not received any training. The training status did not depend on the organization they worked for. However, there was a statistically significant difference between the organizations in the availability of foreign and manufacturer training (Table 2).

Table 2 and Figures 1 and 2 show that the professionals surveyed receive relatively little training after starting their occupation. The average duration of postgraduate training is 32 days (95% CI, 22.8–41.2) in government organizations and 19.8 days (95% CI, 9.5–30.1) in private organizations (Figure 1).

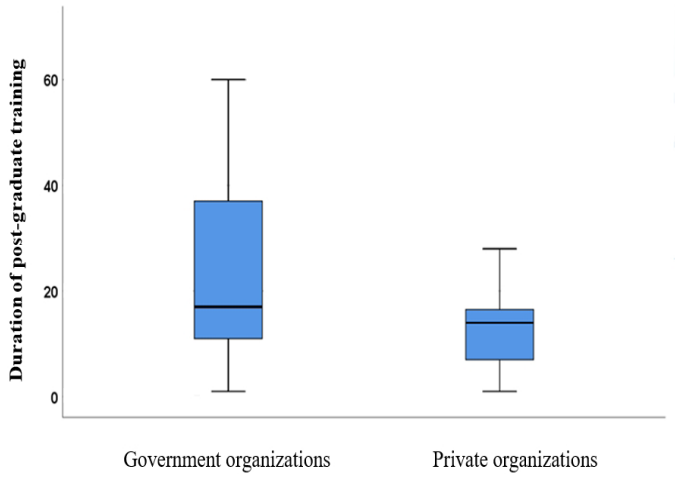

FIGURE 1. Internal training participation by organizations.

Manufacturers are equally represented in government and private organizations, with 17.2 (± 16.3) days of training. The maximum duration of postgraduate training was 93 days in government organizations, while it was 70 days in private organizations, indicating that training was more concentrated in government organizations (Figure 2).

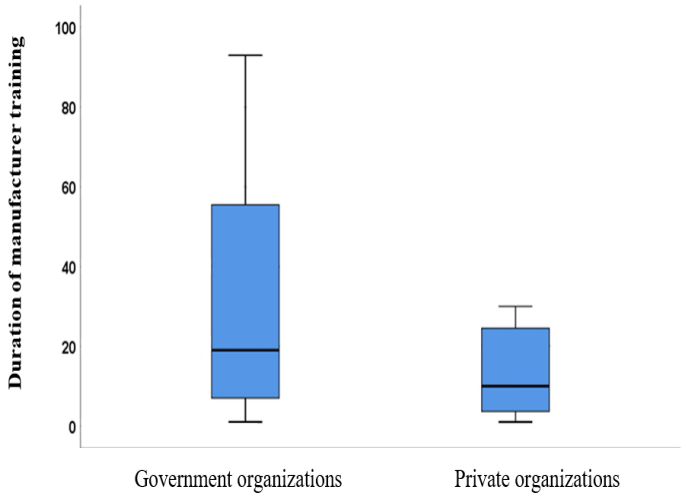

FIGURE 2. Manufacturer training participation by organizations.

As the number of years of experience in the field increases among the surveyed professionals, participation in training organized by the manufacturer increases. However, participation in domestic, foreign, and postgraduate training was not associated with the years of experience (Table 3).

As the number of years of experience in the field increased among the surveyed professionals, participation in training organized by the manufacturer also increased. On the other hand, participation in domestic, foreign, and postgraduate training was not significantly associated with years of experience (Table 3).

TABLE 3. Training of biomedical engineers and technicians, by years of experience.

Indicators	1–3 years		4–6 years		7–9 years		10+ years		*P*
	Number	%	Number	%	Number	%	Number	%	
Internal training									0.437
Not attended at all	72	78.3	39	73.6	32	71.1	51	67.1	
Attended	20	21.7	14	26.4	13	28.9	25	32.9	
Foreign training									0.197
Not attended at all	90	97.8	51	96.2	43	95.6	69	90.8	
Attended	2	2.2	2	3.8	2	4.4	7	9.2	
Postgraduate training									0.064
Not attended at all	71	77.2	37	69.8	30	66.7	44	57.9	
Attended	21	22.8	16	30.2	15	33.3	32	42.1	
Manufacturer training									0.001
Not attended at all	74	80.4	28	52.8	25	55.6	44	57.9	
Attended	18	19.6	25	47.2	20	44.4	32	42.1	

DISCUSSION

In the ISCO-08 system of International Standard Classification of Occupations published by the International Labor Organization-ILO, biomedical engineers are classified under the Group 2149 category, "Engineering professionals not elsewhere classified."[21] In Mongolia, Order No. 16, "National Lists, Classifications and Definitions of Occupations and Jobs", issued by the Minister of Labor and Social Protection on February 10, 2010, Biomedical engineers are classified under the Group 2149 category, "Engineering professionals not elsewhere classified."[22]

The World Health Organization's Medical Devices Technical Series report, Human Resource Development and the Role of Biomedical Engineers, highlights that BME is not officially classified within the health category in international and national occupational classifications.[23] This lack of recognition impacts the assessment and development of the profession, hinders acknowledgment of its critical role, and negatively affects the sustainability of human resources in the health sector.[6] Over the past decade, the rapid advancement of medical science and technology has led to continuous investments in new healthcare technologies, significantly increasing the workload of engineers and technicians.

According to our findings, there are 324 (± 234) pieces of equipment per engineer, which exceeds international standards. This highlights the need for additional professional human resources in the healthcare sector. Additionally, there is a need for continuous training of existing specialists, improvement of the legal framework, and the development and implementation of job descriptions and career development plans. The Law on Drugs and Medical Devices (revised version) mandates that large hospitals establish medical equipment units and requires other healthcare organizations to employ full-time or contracted clinical engineers. However, clinical engineers and technicians are not classified as "medical specialists" under the Law on Health, which regulates social security, rights, and obligations for human resources in the sector. This results in a regulatory gap, violating provisions such as the requirement for professionals to improve their skills and attend postgraduate training at the organization's expense every 5 years.

A study on the prevalence of biomedical engineers per 10,000 population in the WHO Western Pacific Region found that Japan had 1.58, Malaysia 0.82, Mongolia 0.81, and Kiribati 0.27, while China had 0.03 and the Republic of Korea had < 0.01.[24] A study by the WHO (2015) found that the proportion of male engineers (77%) was three times higher than that of female engineers (23%). However, five countries, namely Argentina, Ukraine, Macedonia, Malaysia, and Sudan, reported that the number of female engineers exceeded that of males. In contrast, Laos, Micronesia, Rwanda, Sierra Leone, Tanzania, and Vanuatu did not register any female engineers at all.[24] According to the WHO research, Mongolia has 240 Biomedical or Clinical Engineering specialists.[24]

Regarding the structural organization and human resource supply for the maintenance and reliable operation of medical equipment, as of 2023, 43% of the 16 healthcare institutions under the Ministry of Health had an independent clinical department staffed with 10 to 20 engineers and technicians. In contrast, 24% of the 25 healthcare institutions under the Ulaanbaatar City Health Department (UBHD) had only 1 to 2 engineers, while 95% of the 21 provincial healthcare institutions had just 1 to 2 engineers, without an independent medical technical department.

The WHO emphasizes the need for long-term, sustainable efforts to train highly skilled engineers and technicians to ensure the normal and reliable operation and maintenance of medical equipment. This approach will help reduce maintenance costs and improve the quality of medical care and services.[25]

In Mongolia, medical equipment engineers are referred to as "Biomedical Engineers", regardless of the field they work in (hospitals, supply organizations, factories, etc.). They are also typically certified as consulting healthcare engineers or certified healthcare engineers.[26]

A series of technical documents issued by the WHO has defined BME as follows: "Biomedical engineering" includes equivalent or similar disciplines, whose names might be different, such as medical engineering, electromedicine, bioengineering, medical and biological engineering, and clinical engineering.[27]

However, in some countries, the term "Biomedical engineer" is used interchangeably with "Clinical engineer" in hospitals.

The American College of Clinical Engineering defines a clinical engineer as "a professional who supports and advances patient care by applying engineering and managerial skills to health care technology".[28]

The Association for the Advancement of Medical Instrumentation describes a clinical engineer as, "a professional who brings to health-care facilities a level of education, experience, and accomplishment which will enable him to responsibly, effectively, and safely manage and interface with medical devices, instruments, and systems and the user thereof during patient care".[29]

Japan has a government-certified Clinical Engineering Technologist (CET) designation. To become a CET, one must graduate from a university, college, or vocational school with a degree in clinical engineering and pass a national examination. CETs specialize in the operation and maintenance of medical equipment. In 1987, the Clinical Engineering Law was enacted, regulating CETs as medical professionals who specialize in the operation and maintenance of life-saving equipment.[30]

In Taiwan, the Taiwan Society for Biomedical Engineering certifies clinical engineers, medical device technicians, and biomedical engineers. It has been administering formal certification exams since 2007.[30]

In 2005, international clinical engineer certification was introduced in China. The Medical Engineering Division of the Chinese Medical Association organizes the examination. In 2012, the Chinese Registered Clinical Engineer Certification program was launched, with the examination including both theoretical and practical tests.[30]

In Mongolia, medical equipment engineers are awarded consulting and specialized engineering degrees following Order No. 213 of the Minister of Health, dated September 2, 2005, titled "On Organizing Training for Granting Specialist and Consulting Engineering Degrees to Healthcare Engineers."[26]

These findings demonstrate that despite the establishment of basic legal provisions, significant gaps remain in human resource development and regulation for clinical engineering. The data show limited access to training, a high equipment-to-engineer ratio, and the lack of professional recognition. Compared to WHO, IMDRF, and the regulations of countries like Australia, Japan, Korea, China, and the Philippines, Mongolia's medical device regulation shows gaps in terminology, classification, post-market surveillance, packaging, labeling, advertising, and disposal. However, import regulations align with international standards.[31]

As highlighted by Ayala (2022), the role of clinical engineering has progressed alongside the increasing complexity of medical technologies—extending beyond equipment maintenance to encompass integrated management, innovation, and participation in policy-making processes.[32]

As Mijares (2023) emphasizes in his study of clinical engineering in Venezuela, the interaction between health technologies and national political systems plays a critical role in determining the quality and accessibility of medical care. The research underscores that sustainable clinical engineering development requires not only technical expertise, but also alignment with coherent public health policies and transparency in procurement and evaluation processes.[33]

Based on the findings and challenges discussed above, the following policy strategies are recommended to strengthen the clinical engineering profession in Mongolia.

Recommendations:

Establish a national certification and accreditation system for clinical engineers, aligned with WHO and IMDRF standards.

Revise the Law on Health to recognize clinical engineers as health professionals, ensuring their inclusion in workforce development and social protection policies.

Develop structured career pathways and continuing professional development (CPD) requirements, including the implementation of a system for mandatory training every 3 to 5 years.

Define institutional staffing norms based on the level of healthcare facilities and the quantity and complexity of medical equipment. Large hospitals should establish dedicated clinical engineering units or departments.

Implement a nationwide technical training program in collaboration with foreign universities and medical equipment manufacturers.

CONCLUSION

Clinical engineers and technicians in Mongolia face significantly higher workloads. The lack of structured postgraduate training, legal recognition in the health sector, and insufficient support for professional development present critical challenges to the field. Internationally, countries such as Japan, Taiwan, and China have adopted national certification systems and legal frameworks that formally recognize clinical engineering as a healthcare profession. Aligning with WHO recommendations and regional best practices, this study recommends establishing a national certification and accreditation system, revising health laws to include biomedical engineers as health professionals, and implementing structured career pathways with mandatory continuing education. These measures will help ensure safe and effective medical device management, improve healthcare service delivery, and foster long-term sustainability of the BME workforce in Mongolia.

AUTHOR CONTRIBUTIONS

Conceptualization, A.D., M.-E.L., and G.-O.N.; Methodology, M.-E.L.; Formal Analysis, M.-E.L. and G.-O.N.; Writing–Original Draft Preparation, M.-E.L. and G.-O.N.; Writing–Review & Editing, M.-E.L.; Supervision, A.D.; Project Administration, M.-E.L.; Funding Acquisition, G.-O.N.

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DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study methodology was discussed at the Institutional Review Board meeting of the Mongolian National University of Medical Sciences on January 21, 2022 (No. 2022/3-01), and permission to conduct the study was obtained.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Review

Newer Diagnostic Methods to Detect Oral Cancer and Their Applications in Prevention and Treatment Strategies: A Systematic Review

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ABSTRACT

Background: Oral cancer, which includes cancers of the lips, tongue, mouth, throat, and other oral tissues, is a serious health concern globally. It is one of the major causes of cancer-related mortality because of several factors, including the severity of certain oral malignancies and their late-stage detection. **Objective:** To comprehensively investigate recently developed technologies for detecting oral cancer and evaluate their accuracy, reliability, and potential application in both therapeutic and preventive contexts. **Methods:** A thorough literature search was performed using the PubMed, Scopus, and Web of Science databases, focusing on works published between 2014 and 2024. This review evaluates various methods for diagnosing oral cancer, including advanced imaging techniques (MRI and CT scans), biomarker testing, molecular diagnostics, noninvasive salivary diagnostics, optical coherence tomography (OCT), and the application of artificial intelligence (AI) and machine learning (ML) to enhance diagnostic accuracy. **Results:** All relevant studies meeting the inclusion criteria were analyzed. Several important findings regarding confocal laser scanning microscopy (CLSM) and OCT demonstrated high sensitivity and specificity in identifying oral cancer. This systematic review also highlights the promise of fluorescence spectroscopy, salivary biomarkers, genetic markers, and AI/ML technologies in early disease detection and monitoring. **Conclusion:** New diagnostic procedures outperform traditional ones in accuracy and reliability in the detection of oral cancer. These innovations enable earlier diagnosis, facilitate targeted therapies, and support personalized treatment strategies. As preventive and monitoring strategies evolve, treatment efficacy improves, and patient trust and engagement increase, ultimately leading to better outcomes and enhanced quality of life for patients.

Keywords—*Clinical applications, Diagnostic methods, Early detection, Noninvasive techniques, Oral cancer, Systematic review.*

BACKGROUND

Oral cancer accounts for approximately 3% of the total cases of cancer globally, establishing it as an important public health issue. This extensive range of cancers occurs in the epithelial lining of the oral cavity, encompassing the lips, tongue, floor of the mouth, buccal mucosa, and gums. Oral cancer is the most prevalent cancer in Indian men, exhibiting variation by region, with the highest incidence rates observed in South Asia.[1–4]

Early detection of oral cancer is crucial for improving treatment efficacy and survival rates. Conversely, oral cancer is often identified later in life, resulting in a grim prognosis and diminished quality of life. The early detection of oral cancer is hindered by the constraints of conventional diagnostic methods like visual examination, biopsy, and histological evaluation.[5–9]

Recent technological advancements have led to the development of innovative diagnostic techniques that significantly enhance the early detection and monitoring of oral cancer. Notably, optical coherence tomography (OCT) provides high-resolution, real-time imaging of oral tissues, allowing clinicians to detect subtle epithelial changes indicative of malignancy.[10–13] Fluorescence-based diagnostic instruments leverage the natural fluorescence properties of tissues to distinguish between healthy and abnormal areas, facilitating noninvasive, chairside screening. In addition, the analysis of salivary biomarkers such as DNA, RNA, proteins, and metabolites offers a promising, noninvasive approach for identifying molecular signatures associated with oral cancer, thus supporting both early diagnosis and disease progression monitoring.[14–17]

Early diagnosis of oral cancer can improve treatment outcomes and survival rates, and these new diagnostic tools show promise in this regard. The purpose of this systematic review is to establish the therapeutic value of novel diagnostic tools for oral cancer detection, as well as their diagnostic accuracy and application in oral cancer prevention and treatment strategies.[18–21]

This systematic review offers a thorough overview of the latest methods for detecting oral cancer, highlighting their clinical applications and diagnostic accuracy. The findings of the review are crucial for healthcare professionals, researchers, and policymakers in formulating effective approaches for the early detection and treatment of oral cancer.

METHODS

Study Design and Setting

During the months of October through December 2024, this systematic review was conducted to examine and assess recently developed methods for diagnosing oral cancer, assessing their accuracy, reliability, and applications in preventative and therapeutic approaches at Vishnu Dental College in Bhimavaram, Andhra Pradesh.

On October 19th, PROSPERO registered the current protocol with registration ID CRD42024598844. The systematic review was carried out in accordance with PRISMA (Preferred Reporting Items for Systematic Research and Meta-Analysis) criteria. A strong agreement is suggested by a Kappa value of 0.75, which shows that the reviewers' selection and extraction procedures were dependable and consistent.

This study problem was structured using the PICO framework, which encompasses population, intervention, comparison, and outcome. The population consists of those who use tobacco products, drink alcohol, or have HPV infections, as well as those who are at risk of or have been diagnosed with oral cancer. Recent diagnostic technologies evaluated include liquid biopsy, fluorescence imaging, molecular diagnostics, and AI-based tools. Traditional diagnostic methods such as ocular inspection, histology, or conventional imaging methods were compared. Better

early detection rates, better prevention and treatment planning techniques, and a decrease in the death and morbidity rates from oral cancer were the intended results.

The systematic review's goals were to compare the efficacy and uses of more recent diagnostic tools for the detection of oral cancer with more established methods, as well as to investigate how these approaches might be used to enhance patient outcomes through prevention and therapy. The study's research question was, "What is the accuracy, early detection rate, and effect on prevention and treatment strategies of newer diagnostic methods for oral cancer compared to traditional diagnostic techniques?"

Study Eligibility Requirements

A variety of trial designs were included in the systematic review for a thorough evaluation of the more recent techniques for diagnosing oral cancer. Randomized controlled trials (RCTs), prospective cohort studies, cross-sectional studies, retrospective studies, and comparative effectiveness studies were all included in the study. These studies evaluated the safety and effectiveness of different treatments in a controlled environment and provided strong evidence from 2013 to 2024. This systematic review did not consider the following study categories: brief communications, editorial letters, mini-reviews, studies that did not follow the objectives of the review, and papers written in languages other than English.

We developed a list of terms to look for in the databases based on our knowledge of the subject and previous research. Oral cancer, oral squamous cell carcinoma (OSCC), novel diagnostic techniques, molecular diagnostics, and biomarkers in oral cancer were the search phrases used to search the PubMed databases. Boolean operators were used to combine these keywords, yielding thorough and pertinent results.

("oral cancer" OR "mouth cancer" OR "oral squamous cell carcinoma") AND ("new diagnostic methods" OR "emerging techniques" OR "molecular diagnostics" OR "liquid biopsy" OR "fluorescence imaging" OR "artificial intelligence") AND ("prevention" OR "treatment strategies" OR "early detection" OR "risk stratification").

(Newer[All Fields] AND ("diagnosis"[MeSH Terms] OR "diagnosis"[All Fields] OR "diagnostic"[All Fields]) AND ("methods"[Subheading] OR "methods"[All Fields] OR "methods"[MeSH Terms]) AND Detect[All Fields] AND ("mouth neoplasms"[MeSH Terms] OR ("mouth"[All Fields] AND "neoplasms"[All Fields]) OR "mouth neoplasms"[All Fields] OR ("oral"[All Fields] AND "cancer"[All Fields]) OR "oral cancer"[All Fields]) AND Applications[All Fields] AND ("prevention and control"[Subheading] OR ("prevention"[All Fields] AND "control"[All Fields]) OR "prevention and control"[All Fields] OR "prevention"[All Fields]) AND (("treatment"[All Fields] AND "strategies"[All Fields]) OR "treatment strategies"[All Fields])) AND ("systematic review"[All Fields] OR "systematic reviews as topic"[MeSH Terms] OR "systematic review"[All Fields])

Literature Search Protocol

Two reviewers independently searched for the publications. To conduct a focused, systematic review, we looked through relevant papers that were available in electronic databases, including PubMed, Web of Science, and Scopus.

Rayyan was used during the study selection process to reject unsuitable abstracts and nominations and to eliminate duplicate search results from multiple databases. The collected data were closely examined to ensure that they met the established inclusion and exclusion criteria. When the data from the included studies were too inconsistent or varied to be quantitatively merged, a systematic review was conducted instead of a meta-analysis.

Selection of Included Research Articles

For more knowledge of the state of research on this subject, the discovered papers were filtered to include clinical studies and RCTs. Their study goals and importance were then added to this review. A thorough synopsis of these research publications is provided in the table, emphasizing their salient features, approaches, and conclusions.

Quality Assessment of Studies

AMSTAR 2 (A MeaSurement Tool to Assess systematic Reviews) is a previously published and validated tool for assessing the methodological quality of systematic reviews (with and without meta-analyses). Where AMSTAR only considered RCTs, AMSTAR 2 considers both RCTs and nonrandomized studies, therefore diversifying the studies that could be reviewed. The tool comprises 16

items, with each item touching upon important aspects of review methodology. The quality of all included systematic reviews was assessed in this study, using appropriate rating tools. AMSTAR 2 provides valuable criteria in umbrella reviews to critically appraise the included reviews by evaluating items for the risk of bias (RoB), search strategy, and rationale for excluding studies.

RESULTS

Data Extraction and Synthesis Process

On October 19th, 2024, a preliminary keyword search was conducted in numerous electronic databases, including PubMed, Web of Science, and Scopus, yielding 729 results. After applying preliminary relevance filters, 59 articles were retained for further evaluation. Of these, 17 articles met the intended inclusion criteria and were considered relevant. A final set of seven systematic reviews met the inclusion criteria and were included in this umbrella review, with a special focus on the use of more modern diagnostic tools for the detection of oral cancer and its impact on prevention and treatment approaches (Figure 1).[5,7,9,10,12,13,22]

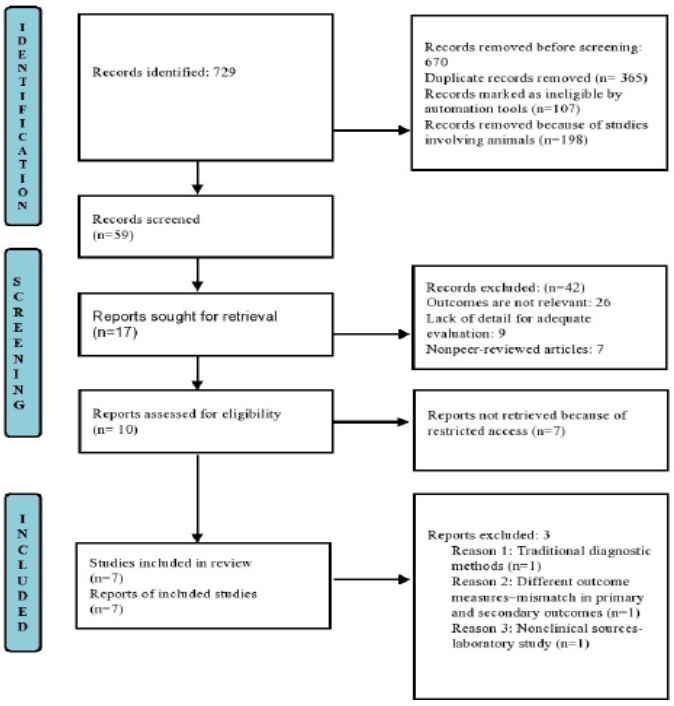

FIGURE 1. PRISMA 2020 flow diagram for new systematic reviews, which included searches of databases and registers only.

Newer Diagnostic Methods to Detect Oral Cancer

Enhanced tools for diagnosing oral cancer now include narrow band imaging (NBI), confocal laser scanning microscopy (CLSM), saliva-based biomarkers, fluorescence diagnostic techniques, and OCT. These advanced technologies provide earlier detection, improve treatment outcomes, and enhance the sensitivity and accuracy of oral cancer screening. For example, fluorescence-based diagnostic tools can detect abnormal changes in cells, and OCT provides high-resolution images of the oral mucosa (Table 1).

To improve the results of treatment and reduce the affection rate and mortality ratio related to oral cancer, the current approach to prevention and treatment includes individualized medicine, immunotherapy, target therapy, and lighting therapy (PDT). Robot surgery is included. For instance, immunotherapy employs the body's immune system to fight oral cancer, while personalized medicine involves customizing treatment plans for each patient based on their genetic profiles (Table 1).

The use of artificial intelligence (AI) and machine learning (ML) algorithms to study large datasets and identify trends is a significant improvement in the detection and treatment of oral cancer. Another potential area of research is liquid biopsies, which identify biomarkers in physiological fluids like saliva. Scientists are also researching novel medicines and developing personalized oral cancer tumor models using 3D printing and bioprinting technology (Table 1).

Salivary biomarkers, fluorescence-based devices, and optical OCT are cutting-edge diagnostic techniques that have dramatically increased the sensitivity and precision of oral cancer diagnosis, allowing for earlier and more accurate therapy. At the same time, advanced preventive and therapeutic approaches, including immunotherapy, targeted therapies, and personalized medicine, are transforming patient care, improving outcomes, and reducing the impact of the disease. Recent results, such as liquid biopsy, 3D biological suppression, and diagnostic

TABLE 1. The qualitative characteristics and conclusive statements of the newer diagnostic methods to detect oral cancer.

Author, Year, & Reference No.	Aim of Study	Search Strategy	No. of Studies Included	Screening Method Used	Outcome Measures	Summary
Brocklehurst, et al.[5]	To evaluate how well the existing screening techniques reduce the death rate from oral cancer.	Cochrane Central Register of Controlled Trials MEDLINE via OVID EMBASE via OVID CANCERLIT via PubMed	1	Visual examination, toluidine blue, fluorescence imaging, or brush biopsy.	Individuals diagnosed with stage III or worse oral cancer. Survival rates across the population.	In high-risk individuals, there is evidence that a visual examination as part of a population-based screening program lowers the death rate from oral cancer.
Jerjes, et al. 2024[7]	To evaluate optical coherence tomography's (OCT) diagnostic precision in identifying oral malignancies.	PubMed, Embase, Scopus, Google Scholar, Cochrane Central Register, and Web of Science	9	OCT Artificial intelligence (AI)	Diagnostic outcomes, such as sensitivity and specificity.	OCT has very high sensitivity and specificity, making it a promising new diagnostic technique for oral cancer.
Bastías, et al. 2024[9]	To conduct a scoping review of salivary molecules examined as potential indicators for oral squamous cell cancer (OSCC) diagnosis.	EBSCO, PubMed (MEDLINE), Scopus, and Web of Science	62 studies were included. 100 molecules were assessed.	TNF-α, IL-1β, IL-6, IL-8, LDH, MMP-9, TNF-α, IL-1β, IL-6 IL-8, LDH, and MMP-9 are the most promising salivary biomarkers for cancer detection.	Ability for detecting OSCC and oral potentially malignant disorders (OPMDs), OSCC outcome prediction, and the prediction of the malignant transformation of OPMDs.	It may be possible to use salivary biomarkers to help detect, manage, and forecast the malignant transformation and spread of OSCC and OPMDs.

Author, Year, & Reference No.	Aim of Study	Search Strategy	No. of	Screening Method Used	Outcome Measures	Summary
Kim, et al.[10]	To examine the effectiveness of OCT in identifying malignant lesions in the mouth.	PubMed, Cochrane Central Register of Controlled Trials Embase, Web of Science Scopus, Google Scholar.	12	OCT	The diagnostic odds ratio (DOR), along with summary receiver operating characteristic curve (SROC), area under SROC, sensitivity, specificity, and negative predictive values, were the outcomes.	OCT can help in the diagnosis and monitoring of oral cancer and oral precancerous lesions because it is noninvasive, produces quick results without exposing users to radiation, and is quick.
González-Moles, et al. 2022[12]	To find evidence gaps and suggest future research directions that ought to be pursued and formulate improvement plans.	MEDLINE Embase, Cochrane Central Register of Controlled Trials DARE	12	Light-based detection or oral spectroscopy.	New cases per year, deaths annually, and mortality rate.	Patients, healthcare professionals, and health services are all involved in the many factors that contribute to the delay in the diagnosis of oral cancer.
Li, et al. 2024[13]	To assess the differences in accuracy between the various imaging techniques used in these diagnostic procedures.	Embase, Web of Science, PubMed, and Scopus.	17	AI	Overall diagnostic odds ratio (DOR), sensitivity, specificity, negative predictive values, and summary receiver operating characteristic (SROC) curves.	With billions of phone users worldwide, AI-based identification employing clinical photography has a high DOR and is readily available now.
Almangush, et al.[22]	To provide a summary of the data currently available on immunohistochemistry prognostic biomarkers for oral tongue squamous cell carcinoma (OTSCC).	Scopus, Ovid Medline, Web of Science, and Cochrane Library.	11	Immunohistochemical prognostic biomarkers.	Identifying informative prognostic biomarkers for oral tongue squamous cell carcinoma.	Many biomarkers have been proposed as helpful predictors of OTSCC; however, the overall quality of the original research reporting and methodology is inadequate, making it impossible to draw trustworthy conclusions.

diagnosis controlled by AI, indicate the possibility of improving oral cancer detection and treatment (Table 1).

Quality Assessment Results

The AMSTAR 2 assessment of seven systematic reviews found that, while all reviews included well-defined PICO components, performed study selection and data extraction in duplicate, and reported potential conflicts of interest, they were overall rated as "critically low" because of several key methodological flaws. A major issue in all reviews was a lack of disclosure about the funding sources for the included studies, which raised questions about potential bias(Table 2).

Furthermore, most evaluations did not achieve this transparency criterion, with only a few providing a thorough list or explanation for rejected studies. Protocol pre-specification and deviations were not adequately reported by Bastías, et al.,[9] González-Moles, et al.,[12] and Almangush,[22] further weakening their credibility. Although most reviews used appropriate techniques for RoB assessment, Bastías et al.,[9] did not perform this adequately, and González-Moles et al.,[12] provided partial information (Table 2).

Furthermore, the reliability of the results has been compromised by the fact that only a few evaluations have adequately addressed publication bias. Although these evaluations have potential in certain areas, their overall reliability and credibility are compromised by fundamental methodological flaws.

Despite meeting important quality standards (e.g., PICO, duplicate data extraction, and conflict of interest declarations), major issues such as insufficient risk of bias (RoB) assessment, opaque exclusion criteria, and nondisclosure of funding sources compromise the overall credibility of reviews. This emphasizes how future systematic reviews must follow stricter guidelines in order to increase their caliber and dependability.

DISCUSSION

This systematic review sought to provide an overview of more modern techniques for diagnosing oral cancer, as well as their use in preventative and treatment approaches. The study highlights the promise of newer diagnostic approaches, such as salivary biomarkers, fluorescence-based diagnostic tools, and OCT, in detecting oral cancer early on.

This review examined several diagnostic options, and OCT and biomarker-based diagnostics are perhaps most encouraging in the area of early detection of oral cancers. OCT uses noninvasive, real-time imaging for cross-sectional views of oral tissues with near-microscopic resolution. Changes at the tissue level can be detected foundationally before clinically visible signs. Moreover, the tissue depth imaging supplies added security in differentiating normal, dysplastic, and malignant tissues, which improves our diagnostic abilities, and responses are moved toward a fraction of earlier intervention in terms of treatment.

Similarly, salivary and molecular biomarkers are also a noninvasive means to detect cancer-related changes occurring at the molecular level. Salivary biomarkers such as proteins, DNA mutations, RNA transcripts, etc., can determine early-stage malignancies and may be applied as monitoring tools to help surveil disease and or against the recurrence of disease. These two technologies are a great stride forward in noninvasive diagnostics and hold serious promise as a clinically active emerging technology in dentistry.

Newer Diagnostic Tools

According to the review's conclusions, modern diagnostic tools are more sensitive and specific than traditional methods. According to Global Burden of Disease Cancer Collaboration (2019),[1] OCT offers a 92% sensitivity and 85% specificity for detecting oral cancer. Likewise, Bray F et al. (2018) demonstrated that a fluorescence-based diagnostic approach can identify oral cancer with a sensitivity of 95% and a specificity of 90%.[2]

New Prevention and Treatment Strategies

Innovative techniques to prevent and cure oral cancer are also being investigated.[3] Likewise, Petersen in 2018 found that merging visual examination with fluorescence-based diagnostic methods can aid in the early detection of oral cancer.[3]

The most recent diagnostic techniques for identifying oral cancer are assessed in these systematic reviews, which also investigate their potential uses in therapy and

TABLE 2. AMSTER 2 Checklist.

Sl. No	AMSTER 2 Checklist	Brocklehurst, et al.[5]	Jerjes, et al.[7]	Kim, et al.[10]	Bastías, et al.[9]	González-Moles, et al.[12]	Li, et al.[13]	Almangush, et al.[22] (2017)
1.	Did the research questions and inclusion criteria for the review include the components of PICO?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2.	Did the review report contain an explicit statement that the review methods were established prior to the review and did the report justify any significant deviations from the protocol?	Yes	Yes	Yes	No	No	Yes	No
3.	Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4.	Did the review authors use a comprehensive literature search strategy?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5.	Did the review authors perform study selection in duplicate?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6.	Did the review authors perform data extraction in duplicate?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7.	Did the review authors provide a list of excluded studies and justify the exclusions?	Partial	Partial	Partial	No	No	No	No
8.	Did the review authors describe the included studies in adequate detail?	Yes	Yes	Yes	YES	Partial	Yes	Yes
9.	Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	Yes	Yes	Yes	NO	Partial	Yes	Partial
10.	Did the review authors report on the funding sources for the studies included in the review?	No	No	No	No	No	No	No
11.	If meta-analysis was performed, did the review authors use appropriate methods for the statistical combination of results?	N/A	N/A	Yes	No	N/A	Yes	Yes
12.	If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	N/A	N/A	Yes	N/A	N/A	Yes	Partial
13.	Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes	Yes	Yes	No	Yes	Yes	Yes
14.	Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
15.	If they performed quantitative synthesis, did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	N/A	N/A	Yes	Yes	No	No	No
16.	Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Review Quality	Critically low	Critically low	Critically low	Critically low	Critically low	Critically low	Critically low

prevention.[11–13] The research focuses on cutting-edge diagnostic methods that have the potential to improve early detection and clinical outcomes, such as liquid biopsy, optical imaging, molecular biomarkers, and AI-based diagnostic tools.[14–17]

By identifying specific tumor markers, these cutting-edge diagnostic approaches can guide individualized treatment strategies and significantly improve screening programs, particularly in high-risk populations. Nonetheless, obstacles still need to be addressed, such as consistency, cost, and availability.[18–21]

Comparison with Existing Literature

Brocklehurst, et al.[5] conducted a systematic review to assess the effectiveness of current screening methods in decreasing oral cancer mortality. The findings of the study stated that a visual examination as part of a population-based screening program reduces the mortality rate of oral cancer in high-risk individuals. In addition, there is a stage shift and improvement in survival rates across the population as a whole.

Jerjes, et al.[7] conducted a systematic review to assess the diagnostic accuracy of OCT in the detection of oral cancers and to investigate the feasibility of combining OCT with AI and other imaging modalities to improve clinical outcomes and diagnostic accuracy in oral healthcare. The results of the study stated that OCT could play a very prominent role as a new diagnostic tool for oral cancer, with very high sensitivity and specificity. Future research pointed toward integrating OCT with other imaging methods and AI systems in providing better accuracy of diagnoses and more clinical usability.

Bastias, et al.[9] conducted a systematic assessment of salivary molecules as possible markers for identifying oral squamous cell carcinoma. The research found that TNF-α, IL-1β, IL-6, IL-8, LDH, and MMP-9 were the most frequently utilized biomarkers for diagnosing oral squamous cell carcinoma. The findings of this systematic review align with the present review.

Kim, et al.[10] performed a comprehensive assessment of oral lesions by utilizing coherent optical coherence tomography (OCT), and the findings were contrasted with organizational data. According to the study's findings, OCT can help with the diagnosis and monitoring of oral cancer and oral precancerous lesions, is noninvasive, and yields quick results without exposing patients to radiation.

González-Moles, et al.[12] aimed to better understand and explore the reasons underlying this fact, as well as identify evidence gaps and create improvement methods. Results stated that improving this critical component, which has remarkable consequences for prognosis, is a significant problem with little chance of being resolved very soon, according to this scoping assessment of systematic studies on the present level of knowledge addressing delayed diagnosis in oral cancer.

Li, et al.[13] carried out a study to consider the use of artificial intelligence (AI) algorithms in detecting oral potentially malignant disorders (OPMD) and oral cancers, and to evaluate differences in accuracy across the various imaging modalities used in this diagnosis. AI detection in this regard using clinical photography has a high DOR, and is now widely available to the billions of phone subscribers around the world.

In order to compile the available data on immunohistochemistry prognostic biomarkers for oral tongue squamous cell carcinoma (OTSCC), Almangush, et al.[22] carried out a comprehensive review. Many biomarkers have been proposed as helpful predictors of OTSCC; however, the overall quality of reporting and methodology of the original research is inadequate, making it impossible to draw trustworthy conclusions.[22]

In conclusion, despite substantial progress in diagnostic techniques for oral cancer, additional investigation and standardization of these methods are necessary to enhance the therapeutic benefits in early detection, prevention, and tailored treatment plans.[23–25]

Limitations

There are a few limitations to this review. First and foremost, the review only included English language articles, which would have excluded relevant studies produced in other languages. Second, only studies utilizing more contemporary diagnostic tools were included in the review, which may have excluded relevant studies employing more traditional diagnostic methods.

Clinical Implications

The findings of the review have major clinical implications. Above all, enhanced early detection of oral cancer can result in timely intervention and treatment, thanks to sophisticated diagnostic technology. Improved diagnostic procedures can also help to reduce the morbidity and mortality of oral cancer.[26]

Future Perspectives

Future research should primarily focus on developing and validating more advanced diagnostic equipment for the detection of oral cancer. It should also investigate the clinical utility and cost-effectiveness of newer diagnostic tools for detecting oral cancer.[27,28]

CONCLUSION

Finally, this systematic review emphasizes the importance of improved diagnostic technologies in detecting oral cancer at an early stage. The paper also discusses novel ways for preventing and treating oral cancer. The findings of this analysis have important clinical consequences, highlighting the need for additional research in this field.

SUPPLEMENTARY MATERIALS

Not applicable.

AUTHOR CONTRIBUTIONS

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Not applicable.

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Case Study

Case Study: Augmented Reality Enabled Mental Health Chatbot

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ABSTRACT

Background and Objective: In recent years, there has been a growing demand for mental health support. This has led to a focus on providing personalized and continuous care. However, traditional mental health systems often have long wait times and limited support for engagements beyond clinical hours. The goal of this project is to create ARden, a digital companion using augmented reality, to help improve mental health for those in need.

Material and Method: This study aims to fine-tune a Large Language Model with domain-specific knowledge, ensuring a personalized and intelligent companion—ARden. The chatbot is integrated with the AR companion using an Application Program Interface (API). The mixed reality companion is accessible via a mobile application, making care available without the additional hardware costs associated with head-mounted displays.

Results: The development of ARden has introduced new possibilities for personalized and interactive mental health support. Early feedback suggests that the chatbot may help improve user engagement and satisfaction, supported by encouraging retention metrics. By combining augmented reality, large language models, and a character-based interface, ARden offers an approach that could contribute positively to mental health support.

Conclusion: ARden aims to help users with emotional regulation during long wait times between mental health interventions, overcome communication barriers, and provide exercises and suggestions to improve mental health wellbeing. This approach offers a promising solution to existing mental health challenges and holds potential for further improvement and scalability.

Keywords—*Augmented reality, Large language model, Mood score.*

INTRODUCTION

Mental health problems pose a critical public health burden, yet traditional solutions remain insufficient to address the growing demand. The advent of social media and increased isolation among the younger population have exacerbated mental health challenges for these individuals. According to NextStep Solutions, a leading provider of behavioral health software, 29% of the U.S. population experiences at least one form of mental illness.[1]

Along with the factors that have led to an increase in mental health issues, there is also a severe shortage of psychiatrists, with only nine per 100,000 people. This deficit contributes to negative mental health outcomes, including an increased risk of suicide.[1]

At present, individuals seek help from their family, social circles, the internet, and mental health professionals to overcome these issues. However, several barriers limit the effectiveness of current mental health systems, including social stigma and a shortage of mental health professionals.

Currently, most of the mental health help that individuals receive is in the form of cognitive behavioral therapy and medication. Cognitive behavioral therapy (CBT) is based on the idea that professionals are trained to help individuals overcome the issues they are facing and enable them to tackle problems on their own by using structured systems. However, due to understaffing, the current system struggles with increased costs, long wait times, and other challenges. Despite its shortcomings, seeking professional help remains the best option for those facing mental health challenges.

Recent studies have explored the potential of chatbots to improve mental health outcomes. Denecke et al.[1] examined two prominent AI-driven mental health chatbots, WYSA and SERMO. Wysa Inc., headquartered in the USA, is an everyday mental health application, and Sermo, also headquartered in the USA, is a social platform for physicians to collaborate and stay informed. WYSA detects negative moods and integrates features like depression assessments and meditation exercises, while SERMO addresses psychological impairments using Cognitive Behavioral Therapy (CBT) techniques. Quantitative analysis revealed that frequent users of WYSA experienced greater mood improvements than occasional users. Experts acknowledged that SERMO is well-suited for patients struggling with face-to-face communication, although challenges remain, including issues with data retention, dataset generation, and the inability of AI systems to handle emergencies effectively.

Potts et al.[2] addressed the lack of accessible mental health services in rural areas by introducing a multilingual chatbot, ChatPal. It was developed by the academic consortium led by Ulster University (UK), which collaborated with partners in Ireland, Scotland, Sweden and Finland. Funded by the Northern Periphery and Arctic (NPA) Programme, ChatPal aimed to provide support in English, Scottish Gaelic, Swedish, and Finnish. The study employed a single-arm pre-post intervention design, enrolling participants from rural areas to use ChatPal over 12 weeks, with well-being measured via scales like SWEMWBS. ChatPal, developed with Rasa (backend) and PhoneGap (frontend), features mood logging and mindfulness exercises. While ChatPal is seen as a complementary tool for mental health services, the study calls for further research to confirm its effectiveness. The chatbot's multilingual capabilities improve accessibility, but technical issues remain, particularly with integration and functionality.

Social desirability and social support are factors that contribute to positive mental health outcomes. Similarly, a need to belong, which is heightened among young adults, is associated with negative outcomes. Thus, looking at the current landscape of mental health issues, it is clear that providing emotional support through interventions can help people, but is no replacement for a true emotional connection with others. It can serve to help people deal with issues in a healthier way, leading to better outcomes.

Another study aimed to evaluate the effectiveness of ChatGPT in providing mental health support, with a particular focus on anxiety and depression. The primary objective was to assess the quality of responses generated by ChatGPT to user queries related to these mental health conditions. The study specifically analyzed the model's responses to three queries: two relating to anxiety management and medication, and a third regarding alternative treatment options. Moreover, the study examined the

consistency and reliability of ChatGPT's responses across successive interactions.

It was found that ChatGPT did not provide information about medication.[3] Some advantages include its ability to offer personalized advice based on a person's history, improved accessibility in remote locations, and lower costs compared to traditional therapy. However, the information must be cross-checked with professionals due to some inconsistencies, and it cannot substitute for mental health care. The model also cannot provide prescriptions. ChatGPT's responses to prompts can be inappropriate, possibly due to the type of questions being asked. Thus, while ChatGPT is useful, the model developed for the user must address its shortcomings in some way.

Yang et al.[4] investigated the capabilities of large language models (LLMs) within the healthcare domain, focusing on both their potential applications and inherent limitations. The primary goal was to assess the effectiveness of general LLMs in healthcare settings and to identify areas where domain-specific models could offer improved performance. General-purpose LLMs often lack the specialized knowledge required for healthcare applications due to the disparity between the general text used in their training and the professional, domain-specific content needed for clinical use. The study highlighted the promise of domain-specific LLMs. For instance, BioBERT was developed by Korea University and trained on PubMed data. Another example, SCIBERT, was created by the Allen Institute for AI and was trained on broad scientific texts from Semantic Scholar. Similarly, PubMedBERT, by Microsoft Research, was specifically trained on PubMed abstracts. These models are all based on the BERT architecture and require significant computational resources for operation. Despite their promise, the study acknowledged the challenges that remain in their clinical implementation.

The performance of domain-specific LLMs was found to be superior compared to general models, particularly in patient interactions. A tailored model called ChatDoctor, which is a fine-tuned large language model based on Llama and trained on 100,000 real-world patient-doctor dialogues from an online consultation platform, and supported by an NIH grant. It demonstrated enhanced efficacy in clinical settings. However, the study also identified significant challenges in deploying LLMs in healthcare, particularly concerning data integrity, interpretability, and the high costs associated with developing these models. The integration of LLMs into clinical practice as supplementary tools was explored, emphasizing the need for improvements in task optimization and conversational assistance.

The challenges related to interpretability, data limitations, and ethical considerations must be addressed to fully realize the potential of LLMs in clinical practice. The research suggests that future efforts should focus on optimizing these models for specific tasks, improving data diversity, and ensuring the accuracy and reliability of the content generated by LLMs, particularly when cross-referenced with professional expertise.

User retention is also reported to be a critical factor, emphasizing the importance of highly engaging interactions with chatbots. It was demonstrated that inadequate retention rates often stem from a lack of personalization, which impedes the effectiveness of mental health apps. To address these challenges, the paper proposed several solutions, including the personalization of chatbots by utilizing the user's previous conversations. Additionally, incorporating peer communication methods was found to enhance both engagement and effectiveness. The developed app should adapt based on user feedback, with the overall goal of creating a more user-centric, adaptable, and effective platform.

In another study, data from the chatbot interactions, including session details and mood logs, were analyzed to extract features such as tenure, mood logging frequency, and conversation interactions. K-means clustering was employed to categorize users into three groups: abandoning, frequent transient, and sporadic users. This analysis compared user behaviors, engagement, and retention metrics with those of other mental health apps. The study emphasizes the importance of high engagement and retention metrics and the need for personalized user experiences.[5]

The effectiveness of the chatbot heavily depends on the underlying language model that powers it. Llama 2, an advanced open-source language model from Meta AI, can generate text similar to that of a human and is useful

for chatbots, translation, content production, and other applications. Llama 2 offers notable advantages in versatility and adaptability when fine-tuned for specific domains, addressing limitations observed in previous models.[6]

Roumeliotis et al.[6] investigated the challenges and opportunities faced by developers when deploying and fine-tuning Llama 2, with the hypothesis that the open-source nature of Llama 2 facilitates faster development compared to closed-source models. Early adopters' experiences in deploying and fine-tuning Llama 2 were observed over a 10-day period, with particular attention given to the medical domain, a primary area of interest for fine-tuning efforts.

Data on model deployment, fine-tuning, and other relevant factors were gathered during this period. Textual data was then processed through keyword identification, K-means clustering, and word cloud visualization. The resulting analysis reveals that Llama 2 can be seamlessly deployed and fine-tuned to the domain-specific requirements of various industries, thereby addressing challenges encountered with earlier models.

Yang et al.[7] compared four Large Language Models (LLMs) for mental health analysis, focusing on the effectiveness of prompting strategies such as Chain of Thought prompting, emotion-enhanced prompts, and few-shot learning. The findings emphasized the importance of domain-specific fine-tuning for improved results in building mental health solutions.

Regular large language models often fall short in specialized areas like medicine, where domain-specific knowledge is crucial.[8] The authors proposed PMC-Llama, an open-source language model specifically tailored for medical applications.8 They systematically analyzed the process of adapting a general-purpose LLM to the medical domain by integrating 4.8 million biomedical academic papers and 30,000 medical instructional materials, and extensively fine-tuned it for compliance with the domain-specific knowledge base.

Mental health professionals use screening questionnaires (SQs) to identify symptom areas that require further exploration. Regular screening can enable the early identification of individuals in high-stress professions who may require mental health support. Data indicate that a significant percentage of public safety personnel screen positive for at least one mental health disorder, highlighting the advantages of frequent screening.[9]

Integrating LLMs into chatbots could enhance their ability to provide tailored support, especially when fine-tuned for specific screening tasks within high-stress populations.

Incorporating Virtual Reality (VR) and Augmented Reality (AR) into mental health interventions offers a transformative approach to enhancing user engagement and interaction. They can improve access to and availability of therapy due to their personalized nature. Proper training for mental health professionals, rigorous scientific research, and strict adherence to data privacy and ethical guidelines are essential for the responsible use of mental health apps, making them more engaging, targeted, and therapeutically effective.

Integrating Augmented Reality (AR) into chatbot platforms represents a promising advancement in mental health care. Current mental health chatbots, while offering useful features, have limitations. One major bottleneck is the need to ensure data privacy, especially since chatbots that provide personalized suggestions must store previous user interactions.[2] Ensuring that user data is protected from unauthorized use is crucial for trust and widespread adoption.

Another challenge is the need for relevant content and fine-tuning large language models to provide helpful and contextually appropriate responses. It must converse with the user in a manner that is genuinely helpful to them. Fine-tuning the model requires resources, and the model needs continuous updates to stay relevant.[3] A drawback is that the way the model arrives at decisions is not explained clearly.

User retention is another significant challenge for chatbot applications. Generalizations about user behavior have led to the development of different user archetypes.4 This information about how users interact with the chatbot can be used to improve the retention metrics of the application we build.

For chatbots to be effective for emotional support, they must understand how users feel and react empathetically. This is possible by using libraries with words and the emotions associated with those words. However, chatbots are only as good as their prompts, and the sentiment and emotion lexicons used for emotion-enhanced prompts suffer from annotation bias and limited vocabulary, which may not reflect the evolving language used in recent datasets.[4]

Recent advancements in training large language models across multiple languages have increased accessibility and improved the generalizability of studies.[5] Although this is important, the focus of this paper is on developing a robust mental health chatbot primarily for English-speaking users, as they represent the majority of current users.

Given the limitations of existing mental health chatbots and the recent advancements in technology, this paper proposes the development of a chatbot using the Llama 2 model integrated with Augmented Reality technology. The proposed chatbot will prioritize high user retention, accuracy, privacy, and address current chatbot limitations while incorporating the additional functionalities discussed.

This study proposes an Augmented Reality-enabled Mental Health Chatbot that can provide supplementary support between visits to mental health professionals. Although chatbots cannot replace traditional therapy, they can offer continuous mental health support, helping individuals declutter their thoughts and providing accessible care at any time.

The aim was to analyze user engagement with a mental health chatbot, focusing on its potential to improve user retention through interactive and personalized experiences. User retention was examined to identify challenges and optimize engagement by understanding different user archetypes. The impact of the chatbot on users' mental health needs to be monitored over time when used alongside professional medical guidance.

The chatbot was developed as an app, making it accessible to a broader audience with user-friendliness. This study used LLM models that enable personalization, which is critical for effective content delivery. Various personalization techniques, such as retaining the memory of previous conversations, were implemented to create a more tailored and continuous user experience.

Retaining the memory of previous conversations helped continue interactions from the last episode, rather than starting from the beginning each time.

METHODOLOGY

Workflow

The large language model (LLM) is customized with extensive medical literature and fine-tuned for optimal effectiveness. The application processes auditory input to provide information to the LLM. Additionally, the application features a character that users interact with, designed to appear friendly and empathetic. This companion, integrated with the LLM, facilitates user interaction and contributes to mental health improvement through the application's functionalities.

Data

A mental health chatbot requires vast amounts of data to provide accurate and reliable solutions to individuals' mental health challenges. Developing a comprehensive database that integrates both local knowledge and online resources is essential.[7] This database also contains research articles tailored to the individual's specific needs, such as those addressing emotional support, depression, anxiety disorders, and eating disorders. General information regarding interventions can also be obtained from reputable

Profiling

Mental health professionals initially assess and profile individuals based on their diagnosis, which is then fed as input to the model (Figure 1). This profiling enhances the personalization of the chatbot. Users are prompted to select a broad category that aligns with their experiences, and the application provides relevant information based on both the user's selection and the therapist's assessment online sources, complementing the personalized data.

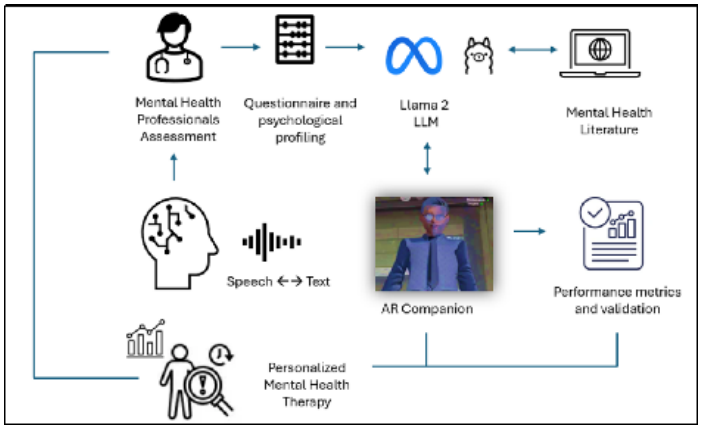


FIGURE 1. Workflow of AR Companion (ARden) assisted personalized therapy.

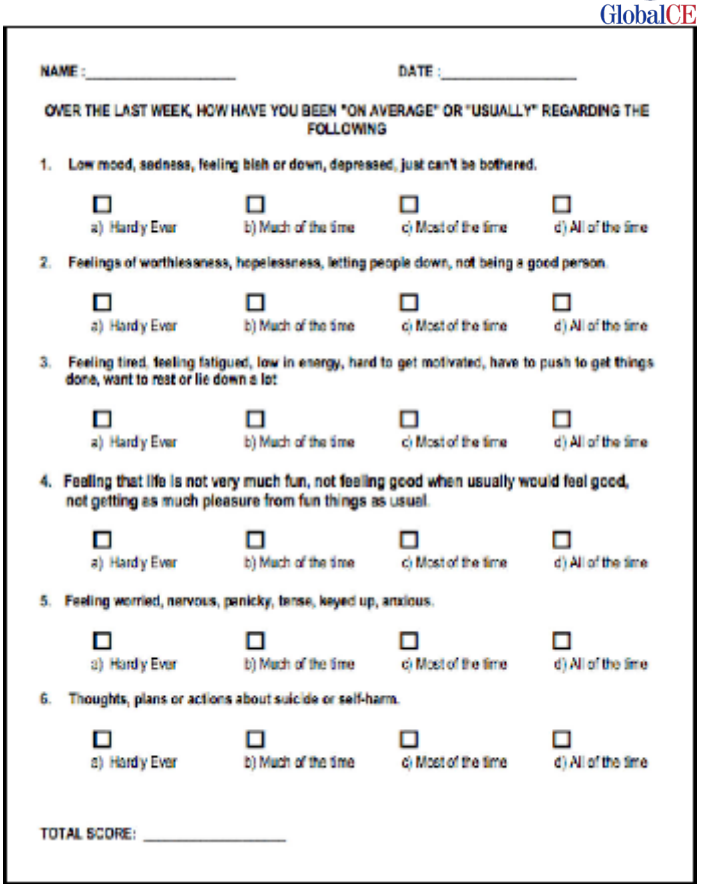
This work aims to understand individual perspectives and provide relief from mental health conditions, such as stress, anxiety, and depression, through personalized solutions. To effectively address the needs of users experiencing mental health issues, collaboration with professionals is essential. Through multiple sessions with a counseling psychologist, they assess a person's characteristics, drawing upon their experience and intuition developed through years of study and practice. The chatbot can then create a tailored solution or personalized interaction method for each individual, taking professional input into account. For instance, if a person tends to respond only to non-confrontational communication, the chatbot will recognize this and deliver information in a compassionate, non-threatening manner to ensure the individual is receptive.

A questionnaire is developed, as shown in Figure 2, based on input from the psychologist, with its design undergoing thorough consultation and multiple levels of review by the therapists. This personalized profiling ensures that users receive appropriate, targeted support, rather than generic interventions.

Mental Health Chatbot

Large Language Model

The process begins by uploading appropriate resources as PDF files, followed by the application of a text extraction algorithm to retrieve the content while removing



NAME :_____ DATE :_____

OVER THE LAST WEEK, HOW HAVE YOU BEEN "ON AVERAGE" OR "USUALLY" REGARDING THE FOLLOWING

1. Low mood, sadness, feeling blah or down, depressed, just can't be bothered.

☐ a) Hardly Ever ☐ b) Much of the time ☐ c) Most of the time ☐ d) All of the time

2. Feelings of worthlessness, hopelessness, letting people down, not being a good person.

☐ a) Hardly Ever ☐ b) Much of the time ☐ c) Most of the time ☐ d) All of the time

3. Feeling tired, feeling fatigued, low in energy, hard to get motivated, have to push to get things done, want to rest or lie down a lot.

☐ a) Hardly Ever ☐ b) Much of the time ☐ c) Most of the time ☐ d) All of the time

4. Feeling that life is not very much fun, not feeling good when usually would feel good, not getting as much pleasure from fun things as usual.

☐ a) Hardly Ever ☐ b) Much of the time ☐ c) Most of the time ☐ d) All of the time

5. Feeling worried, nervous, panicky, tense, keyed up, anxious.

☐ a) Hardly Ever ☐ b) Much of the time ☐ c) Most of the time ☐ d) All of the time

6. Thoughts, plans or actions about suicide or self-harm.

☐ a) Hardly Ever ☐ b) Much of the time ☐ c) Most of the time ☐ d) All of the time

TOTAL SCORE: _____

FIGURE 2. Questionnaire.

any non-text elements (Figure 3).[8] The extracted text is then segmented into manageable pieces to facilitate meaningful embeddings. Llama 2, implemented via the Langchain framework, is employed to generate embeddings that capture the semantic essence of each text fragment. These embeddings are stored and managed in Pinecone, a cloud-based vector store. This fully managed service handles hardware infrastructure required for efficiently storing and searching vector data. Once the embeddings are uploaded to Pinecone's cloud storage, natural language queries can be processed. Pinecone performs a similarity search by converting queries into text representations and generating embeddings via Langchain Llama 2. This search identifies the most similar embeddings, retrieving the corresponding text fragments. These fragments are then combined to form a cohesive natural language response, enabling smooth and effective user interaction in question-and-answer scenarios.

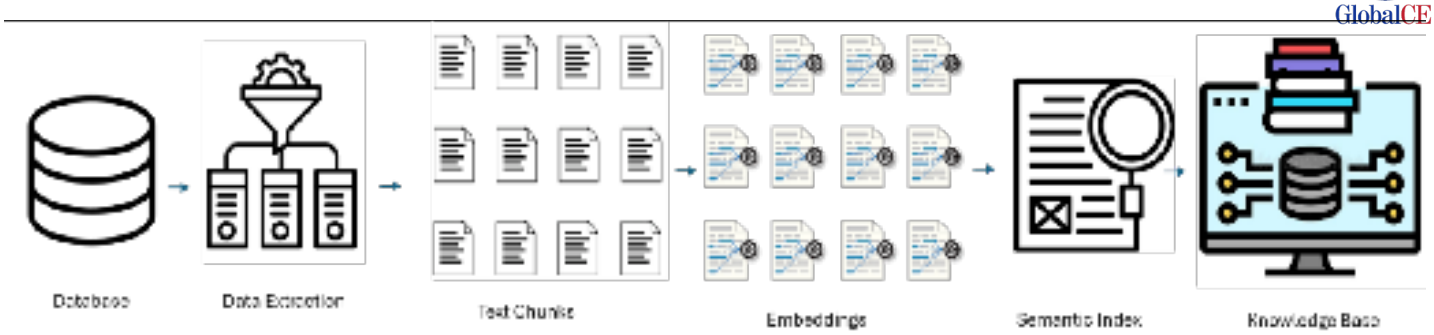


FIGURE 3. Knowledge base construction.

Model Selection

Llama 2 was selected for this preliminary study due to several compelling factors. Its open-source framework supports accessibility and collaborative development, offering a parameter range from 7 billion to 70 billion. Additionally, Llama 2 distinguishes itself through its speed, which outperforms earlier models. This is particularly advantageous for time-sensitive tasks and applications requiring rapid processing, like mental health chatbots. Moreover, Llama 2 offers comprehensive documentation and a supportive open-source community, facilitating its integration. As large language models evolve rapidly, future iterations of this work will consider adopting more advanced models.[9]

Integration with Chatbot

Firstly, a Unity project was set up with the necessary dependencies installed to enable the companion to be deployed into a mobile application. Inworld AI is an engine that was used to create a character prefab to import into Unity. To begin with, the Inworld AI software had to be downloaded and interfaced with the Unity platform. Then, after the avatar was generated using Ready Player Me, a cross-game avatar platform that enables avatar creation and seamless integration into other platforms, its characteristics were customized using the Inworld AI portal. The API keys were then configured within the Unity project to import the character into the environment. The built-in speech of the character was replaced with the mental health chatbot. Visual customizations from Ready Player Me were refined, and Inworld AI's tools were used to adjust baseline emotional expressions and idle animations to suit a mental health companion.

The imported character in the project had to be positioned, rotated, and scaled to the correct proportions relative to the room. This process required trial and error, and it had to be made such that it aligned with the real-world surfaces and surroundings based on the camera position. The avatar was also fitted with a script to make it move wherever the user desired by just clicking on the spot. This was done to ensure the companion was placed in the position where the user was most comfortable. This level of personalization was aimed at giving the user the best experience possible.

Inworld AI, a character engine developed by TheGist, Inc. (dba Inworld AI, New York, NY, USA, with its platform publicly launched c.2022 and continuously updated), is used to create non-playable characters in games using AI, natural language processing, emotional simulation, and behavior modeling. It generates expressions and facial features based on the character's behavior using AI models that mimic human gestures.[10] The avatars were also modified in this study. This behavior is determined by the information we feed it. Characteristics such as anger, confidence, and aggressiveness, for example, can be changed using the user interaction tools.

These characteristics influence how the avatars communicate and interact with the user. This can be brought to the user by our custom mental health chatbot, which bypasses the default conversational settings.

The first step was to create the chatbot, which has already been described. Post-chatbot creation, it is to be interfaced with the character instead of the in-built GPT-3 model. Emotion detection is another important aspect of

this application that needs to be improved upon in the next iterations of it.[11]

User Interface (UI)

The initial version of the UI had a canvas with buttons to allow the user to navigate between different functionalities of the application. However, this was removed to truly make the application even more user-friendly and non-frustrating. The idea of the avatar companion fulfilling all of the user's commands and the avatar acting as the interface was more appropriate. Thus, the UI was changed to make the companion-user relationship the most important aspect of the project. This also enables future iterations of the application to have more interesting use cases and functionalities.[12]

Natural Interactions

Talking with the character mimics human conversation. This is an intuitive approach that lowers the cognitive load for the user. This lower barrier to entry can be the difference between the app being used or not.

Convenience

As the interface is completely voice-based, people with disabilities, such as motor or vision impairments, can use the application. Going forward, it can use the information from the user to guide them to take medication on time.

Efficiency

The commands are much faster when voice-based compared to navigating through menus and typing the queries, as with conventional chatbots.

Personalization

As the chatbot learns from previous interactions with the user, this brings a level of personalization to the user interface that is just not possible through hard-coded menus. The chatbot has the ability to give personalized information in less time. It is hypothesized that, as the relationship between the user and ARden grows, the application will achieve higher retention and usage rates. This is much more than what a traditional interface can do.

RESULTS

Recommendation From Professionals

The AI companion was developed in consultation with mental health professionals to ensure the ethical integrity of the application while validating the responsible AI training, clinical relevance, and accuracy of their responses. The application developed primarily complements the therapeutic practices, addressing the gap in mental health delivery systems.[13] In alignment with this approach, the proposed idea of this AR-enabled chatbot application was taken to a mental health professional at the National Institute for Empowerment of Persons with Multiple Disabilities (NIEPMD) in India for initial validation. The key suggestions that were implemented include: ease of use, efficient interaction without too many menus, and personalization.

The other recommendation was to target general mental health needs, thereby broadening the scope of the application. This further enhanced the efficacy of the large language model by allowing it to specialize in high-demand and specific areas of mental health. Subsequent steps focused on niche areas such as stress management, anxiety, and depression, to name a few.

Once a basic prototype was developed, it underwent further evaluation for feedback on clinical efficacy. The user base was defined in the review process of the prototype. The prototype was intended to be prescribed to selected users based on their psychological profiles, following consultation with a certified mental health professional. Consequently, the chatbot should be deployed as part of a hybrid healthcare model, ensuring that the mental health professional remains actively involved in the patient care loop.

Patient confidentiality was a major concern. Based on these inputs and further research, it was evident that any solution in this domain must strictly adhere to data privacy regulations.[14] While our study has not yet encountered situations that raise privacy concerns, future research and similar product developments will need to ensure robust measures that protect patient data.

Parameter Tuning

As outlined in Figure 4, the mental health chatbot offers a range of features that are designed to be beneficial

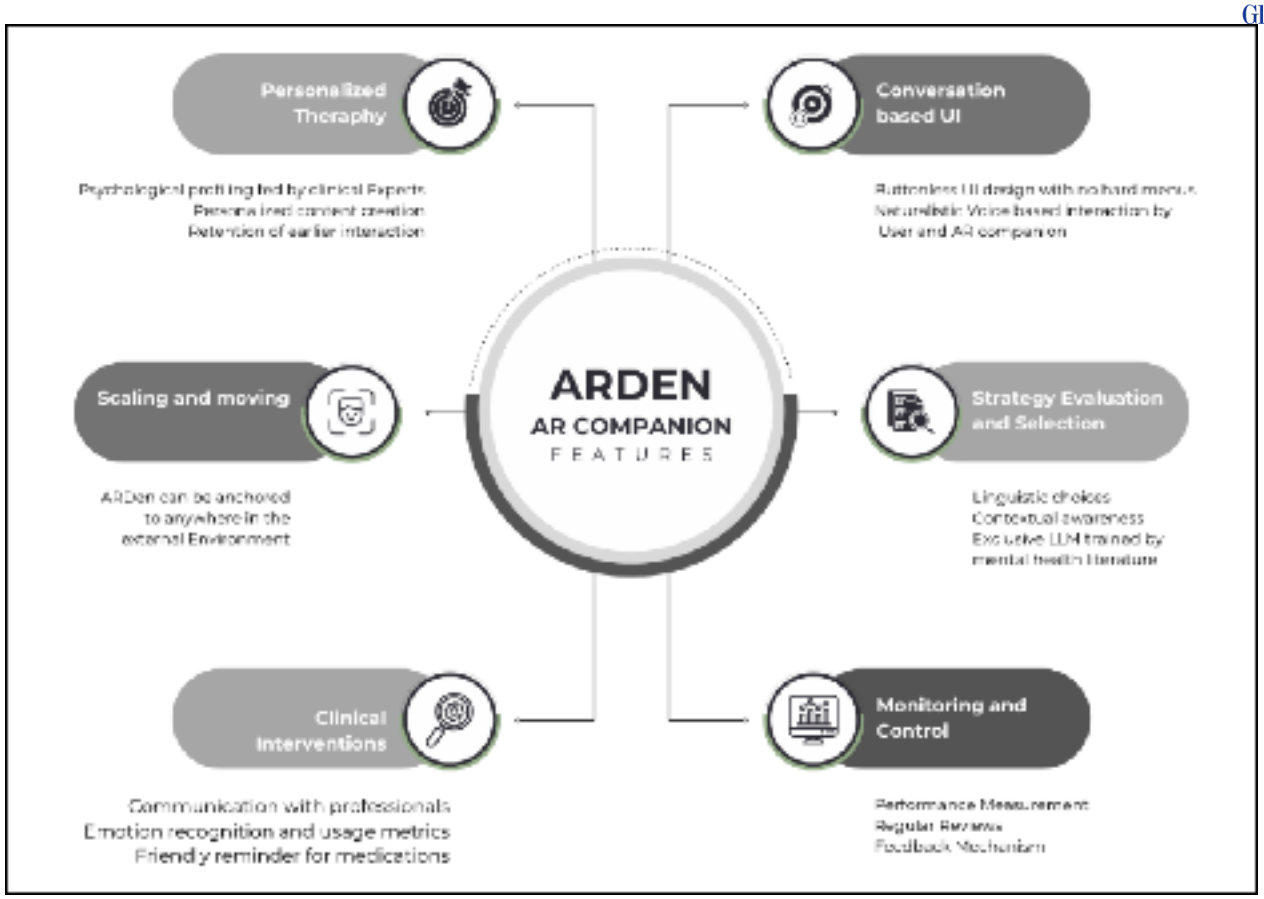


FIGURE 4. Features of AR companion.

to patients. To achieve this, various parameters are optimized to define the state-of-the-art large language model-based chatbot. Fine-tuning is accomplished by adjusting parameters such as temperature, maximum generation length, and sampling, among others.[15] Rigorous evaluations of the developed model are performed to mitigate risks and streamline responses to align with the user's needs and expectations.

The paradigm of the response is facilitated by the availability of these parameters. Temperature is a variable that tells us how incidental the output or the response generated is.[16] The values can be interpreted as follows: if the temperature values are low, the model is more deterministic. This is ideal for maintaining consistent and reassuring conversations in mental health settings. Higher values may introduce more variability, which may not be required for this purpose. Due to this, the temperature was originally set to 0.5.[17]

Tokens with a combined likelihood exceeding a threshold (p) are examined in top-p sampling, which is sometimes referred to as nucleus sampling. This restricts the token selection process by regularly modifying the queries according to their probabilities. This approach preserves focus on the majority of tokens while ensuring diversity.

As shown in Table 1, the maximum length of the response generated is set to be 512 words. Seeing as shorter responses can keep the conversations focused but might lead to leaving out details, this is an area with tradeoffs. Other parameters, such as learning rate and beam search width, also play a crucial role in making the model dynamic and user-friendly. The existing learning rate of the large language model is 0.0002.[18]

TABLE 1. Hyperparameters of Llama 2.

Parameters	Value
Learning Rate	0.0002
Response Speed	120–250 s
Chunk Size	512
Temperature	0.5
Sampling	Top P or nucleus sampling
Software Development Kit	Boto3(AWS SDK for Python)

A model that is fine-tuned with relevant mental health data and uses emotion tracking tools to adjust the model's tone and word choice would be ideal for this purpose. Setting parameters that encourage the chatbot to ask questions and take pauses would ensure user engagement, thereby enhancing interaction.

The recent Llama 3 model launched by Meta represents a more advanced and efficient iteration of large language models, offering significant potential for future applications in the development of mental health chatbots. The following comparisons (Table 2) outline the key improvements in the model, as indicated by Meta's advancements.

TABLE 2. Comparison of Llama 2 and Llama 3.

Feature	Llama 2	Llama 3
Training Data	Trained on around 2.2 trillion tokens	Trained on approximately 15 trillion tokens
Model Sizes	Released in 7B, 13B, and 70B parameter sizes	Available in 8B and 70B parameter versions
Context Window	Supports up to 4,096 tokens	Supports up to 8,192 tokens
Performance	Better performance over Llama 2	Outperforms Llama 3 across all benchmarks

Response of the chatbot

The chatbot shows compassion towards the user by first validating what the user feels and gently suggesting what the user could do to improve their situation. Throughout the entire conversation, the companion constantly exhibits friendly body language.

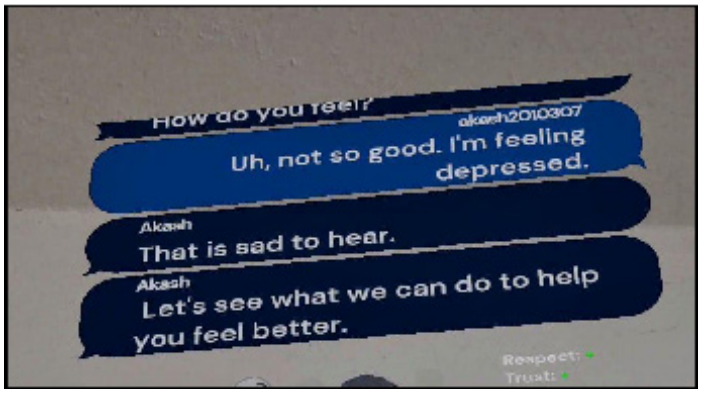


FIGURE 5. Sample response for depression.

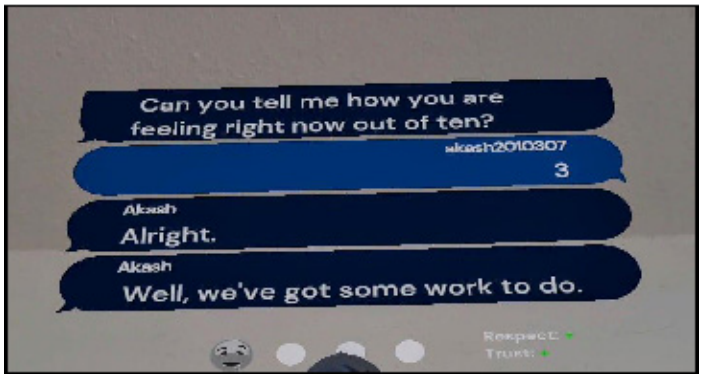


FIGURE 6. Sample response for anxiety.

As seen in Figure 5, the character interacts with the user with compassion and empathy, which is crucial when dealing with sensitive topics. In Figure 6, the chatbot asks the user to rate their feelings on a scale of 1 to 10, which lets the chatbot deal with the situation differently based on the user's response. When the situation is particularly difficult, the user is directed to consult with the therapist.

In Figure 7, the user is being suggested exercises to follow in order to feel better. In general, the exercises that therapists suggest to their patients can be reinforced in this app in order to ensure proper completion. Also, the app's interactive nature immerses the user in the exercise, leading to improved outcomes. In summary, the application interacts with the user in a compassionate way to provide insights and aims to improve mental health outcomes. An integrated mechanism for analyzing and

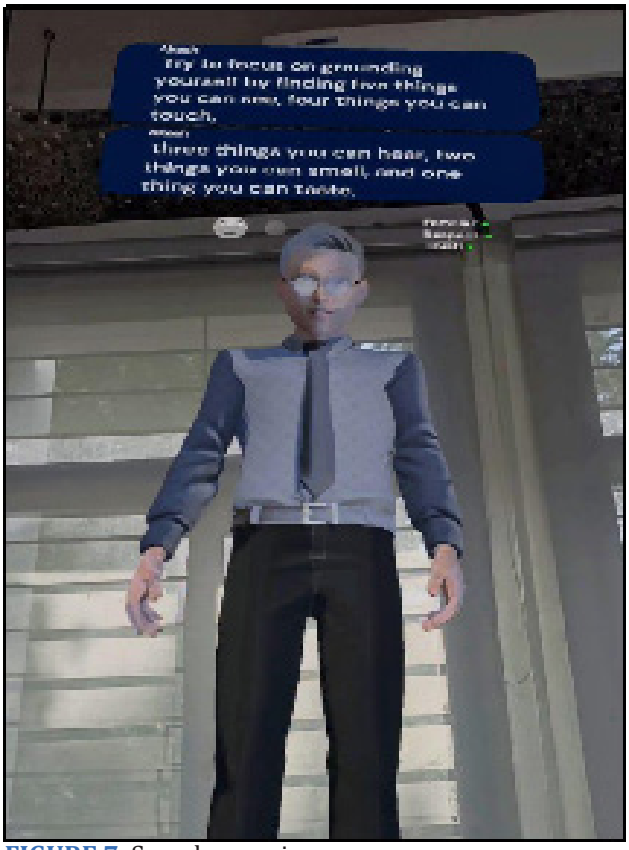


FIGURE 7. Sample exercise.

presenting emotions detected from the users' interactions with the chatbot proved to be useful. Throughout these interactions, prominent emotional states such as happiness, sadness, and anger could be identified to help understand the mental state of the user. It was evident that this analysis would help the user track their mood.

A formal study is planned to evaluate the therapeutic potential of the app. Participants' moods will be assessed over a 30-day period using daily self-report scales, with additional objective measures, such as physiological indicators or behavioral assessments, potentially incorporated. Data analysis will compare pre- and post-study mood scores, along with any improvements reported by participants. To further validate these findings, future research could focus on longitudinal studies and randomized controlled trials involving individuals diagnosed with mental health conditions, aiming to rigorously quantify the chatbot's impact on mental health outcomes.

Testing Feedback

The application was tested for user interaction (UI) experiences, and some bugs were observed within the app, such as the character moving on its own at times, the app crashing during longer interactions, and the character not always being anchored in the environment correctly. In terms of functionality, it was suggested to add more exercises and activities, like guided meditations.

Clinician Feedback

The designed application was evaluated by two different psychiatrists. They suggested further work on adding more evidence-based exercises and ensuring the clinical accuracy of the information provided. They also wanted more features in the app so that clinicians can, with patient consent, access summaries of patients' interactions or mood trends to better inform therapy sessions. Apart from this, they had questions regarding crisis management protocols within the app and the specifications of data privacy and security for sensitive user information. Along with these important considerations, the overall feedback was encouraging, with psychiatrists recognizing the potential of Arden to support individuals between interventions and overcome communication barriers.[19]

CONCLUSION AND FUTURE WORK

As discussed, the application was developed after analyzing the capabilities and limitations of existing solutions. It was determined that increased user engagement is essential for the application to be truly beneficial. With the advancement of AR technology and its capabilities, the study focused on designing a system that integrates both large language models (LLMs) and augmented reality (AR).

The companion application was successfully implemented using Unity and deployed on mobile platforms. The constructed avatar was equipped with an API interfacing with the LLM, which functions as a chatbot. This chatbot was fine-tuned with relevant medical literature to provide accurate and useful information to the user. Thus, the study produced an initial design of an AR-enabled avatar, equipped with an LLM, for emotional regulation purposes.

The design developed in this study serves as a reference for future advancements in the field. Designing an effective mental health chatbot involves several critical aspects, including, but not limited to, tracking the mood scores of users,[20] enhancing the LLM's capabilities,[21] maintaining data privacy, and ensuring the chatbot retains context from previous interactions with the user.

Mood scores are an effective method for monitoring the mood and mental health of a person over a period of time. This approach can be validated with the assistance of mental health professionals.[22] The system can offer more personalized support based on mood scores.

Collaboration with mental health professionals has offered important insights into the everyday challenges patients encounter. It is essential that products in this field are developed and tested alongside these professionals to ensure they effectively address real-world needs, particularly by improving the mental health of young adults.[23]

This study was conducted prior to the release of Llama 3, GPT-4, and other newer models. With further advancements in large language models and emotional recognition, future chatbots are expected to exhibit more human-like qualities and be capable of taking in multimodal inputs from users more effectively.

Throughout the development of this application, a few key findings emerged regarding emotion detection. It became apparent that an application of this sort must take into account the following for the emotion detection capabilities: the user's speech and voice tone patterns, facial expression changes, linguistic cues, contextual awareness of the model, and multimodal data integration capabilities. These are all areas where humans naturally excel and are currently superior compared to models.

Real-time emotion detection remains a challenging task, which requires further research. Taking emotion recognition capabilities alongside the other functional abilities of the application previously discussed, it is clear that further research is required for applications of this kind before they can be effectively deployed. We anticipate that, with further technological advancements, this design of an AR-enabled mental health chatbot will contribute to improved mental health support.

AUTHOR CONTRIBUTIONS

All authors contributed equally to this work.

FUNDING

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DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Not applicable.

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Letter

A Hybrid Model of In-house and Outsourcing Maintenance for Medical Devices in Africa

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Dear Editor,

The recent discussion on adopting a hybrid model that combines in-house and outsourced maintenance for medical devices in Africa presents a promising strategy to improve healthcare infrastructure sustainability.

BACKGROUND

Many low- and middle-income countries (LMIC) in Africa cannot afford to procure medical devices every year or every time a device breaks or malfunctions. It is essential for all health care facilities, regardless of their size, to implement a maintenance program for medical equipment. The complexity of the program depends on the size and type of facility, its location, and the resources required.[1]

Basic diagnostic, therapeutic, and rehabilitation devices are maintained within the in-house facility. However, maintaining capital and high-tech medical devices is a headache in many African countries. In Africa, maintenance problems as well as many recommended solutions are also complex. Entrusting a new graduate biomedical engineer/clinical engineer with the responsibility of maintaining high-tech devices without providing proper training, spare parts, toolkits, etc., is a major concern for clinical/biomedical engineers.

Medical device repair and maintenance are extremely important, and the healthcare center has to manage the periodic schedules and updates of the devices. Most maintenance and repair activities are done in response to the operator's request for support. The maintenance and repair service should include a planned preventive maintenance design.[2]

METHODS

Sampling techniques are used to compare the results of in-house maintenance and outsourcing methods of maintenance. A mathematical tool/model will be developed to identify the method of maintenance that is best suited for a specific device. Currently, there are generally two approaches for managing medical device maintenance: In-house and outsourcing. But there is also a third approach, which is a "hybrid of in-house and outsourcing maintenance".

Capital medical devices and high-tech gadgets require expert maintenance, which is often unaffordable for in-house workshops in many African countries. It is usually recommended to outsource the maintenance of such high-end equipment to suppliers/manufacturers. Sticking to a single approach is not advisable for resource-constrained countries in Africa. Thus, the hybrid approach incorporating both in-house maintenance and outsourcing is found to be very effective.

The key factors of cost, work quality, obtaining expertise, tools, equipment, and technology, risk reduction, response time, and management focus on core health service activity should be considered when deciding on the best approach for a health facility.

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The key factors of cost, work quality, obtaining expertise, tools, equipment, and technology, risk reduction, response time, and management focus on core health service activity should be considered when deciding on the best approach for a health facility.

CONCLUSIONS

In general, the health facility can choose which approach is apt depending on the frequency of maintenance, skill, training, and budget availability. Performance evaluation and calibration are the missing links occurring during the in-house maintenance activity. Thus, it is important to outsource high-tech and capital medical devices that offer features of cost-effectiveness, control, and flexibility.

Different medical devices, from simple to complex, different brands, availability/lack of spare parts, availability/lack of training, and workshops will make it very difficult for in-house technicians and engineers to take care of everything in the health facility. Basic medical devices can be maintained by in-house service personnel, but complex devices can be maintained only by outsourcing maintenance to suppliers/companies. Thus, a hybrid in-house outsource maintenance approach is highly recommended in resource-limited countries in Africa. It will avoid debate and confusion as to which approach is better for LMIC, because one approach cannot replace the other.

AUTHOR CONTRIBUTIONS

A.H.A. is the sole author of this work and is responsible for all aspects of the research and writing.

CONFLICTS OF INTEREST

The author declares he has no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

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Original Research Article

Quantitative Evaluation of Venipuncture Training Models: A Study Using a Puncture Force Testing Device

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ABSTRACT

Background/Objectives: This study introduces a quantitative assessment of venipuncture training models using a customized puncture force testing device. The device, engineered to quantify the force and torque exerted during a puncture under regulated speed and angle conditions, aims to augment the authenticity and efficiency of medical training models. In Japan, a diverse group of medical professionals receive training in venipuncture, utilizing models in a variety of educational environments. However, the existing models often fall short of replicating the physiological realism of human tissue, which limits the effectiveness of the training.

Methods: To address this issue, the study employed a puncture force testing device that includes a needle, syringe, load test stand, and digital force gauge, among other components. This arrangement facilitated the precise control and recording of puncture force at varying speeds and angles. Three distinct venipuncture models (Models A, B, and C), filled with water to mimic venous blood, were tested under these regulated conditions.

Results: The findings revealed notable differences in puncture force among the models, with Model C closely resembling human tissue because of its lower maximum puncture force.

Conclusion: The study also observed a variation in the force required at different puncture speeds, thereby enhancing our understanding of model behavior under diverse conditions. Moreover, the use of a mechanically controlled puncture device eliminated the variability associated with individual technique, allowing for a more quantitative and reproducible evaluation. In conclusion, the study proposes a more quantitative and objective approach for evaluating venipuncture models. This progress is vital for refining these models to more accurately simulate human tissue, consequently improving the quality of medical training in venipuncture procedures.

Keywords—*Clinical skills, Intravenous injection, Nursing students, Public health nurses, Venipuncture.*

INTRODUCTION

Mental health problems pose a critical public health burdIn Japan, a broad spectrum of medical professionals, including physicians, dentists, public health nurses, midwives, nurses, licensed practical nurses, clinical laboratory technicians, radiology technicians, and clinical engineers, are trained in intravenous injection and blood sampling. These professionals acquire venipuncture skills through various training schools and clinical practice. Simulation education, exemplified by skills laboratories, is actively conducted primarily in medical schools. Ishikawa et al. reported that at least 74 out of 80 faculties in Japan had a skills laboratory at the time of their survey.[1] Suzuki et al. reported that an intravenous blood collection and injection model was used in 53 faculties, with more than 300 sets available.[2]

These models are utilized not only in training schools but also in postgraduate education to enhance clinical skills across various professions. Training facilities for medical professionals in Japan comprise 81 medical schools,[3] 1 medical doctor training programs at a ministerial university, 828 three- or four-year training schools for nurses, and 180 training schools for licensed practical nurses.[4] In addition, there are 103 clinical technologist training schools,[5] 55 training schools for radiology technologists,[6] and 88 training schools for clinical engineers who are members of educational associations nationwide.[7]

A comparative study of cannulation training for veins in nursing students observed no statistically significant differences in performance between groups of students trained with each other and with a rubber mannequin.[8] Jones et al. suggested that student-to-student and mannequin training are equally effective. They also noted that the use of mannequins can reduce risk.[8] Despite the widespread use of these models, it has been noted that the skills acquired from training on a mannequin are limited because of their unique characteristics that differ from those of the human body.[9–11] To address this issue, we attempted to measure the force and torque applied when puncturing a model to establish a quantitative evaluation method to improve the quality of these models.[12,13] However, the methods used in previous studies are dependent on the human technique, which remains a challenge.

In this study, we developed a puncture force testing device capable of testing puncture speed and angle under specific conditions. We conducted tests on a product similar to the model used in the previous study to compare it with conventional methods.

METHODS

Puncture Force Testing Device

We constructed a puncture force testing device, which incorporates a force gauge and a load test stand, to assess the venous blood collection and injection model. This device allows for the evaluation of the model under consistent puncture speed and angle (Figure 1).

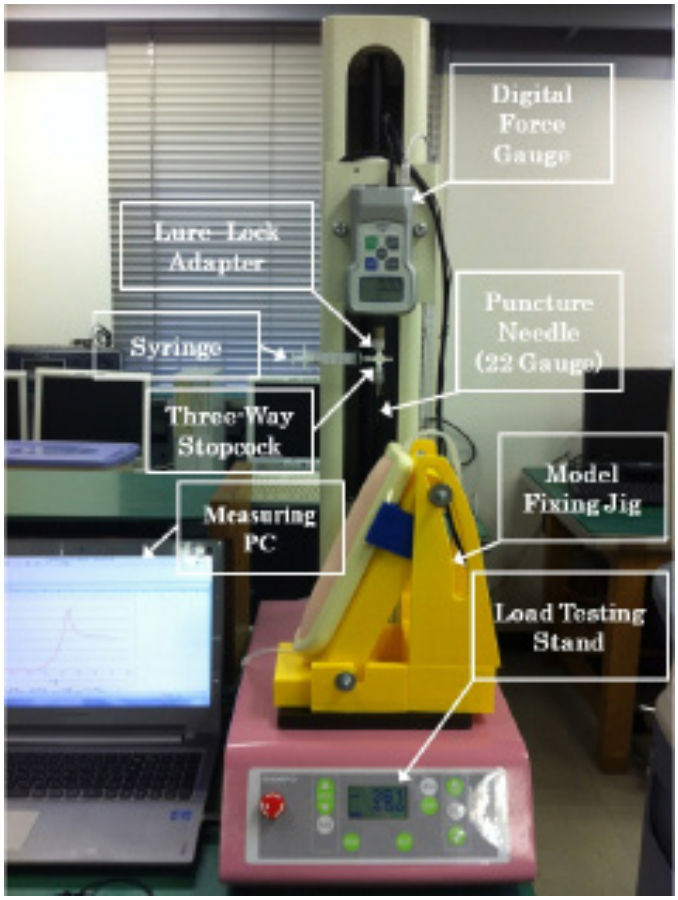

FIGURE 1. Puncture force testing apparatus utilizing a load test stand.

In contrast to our previous study,[12] which employed a syringe-type force sensor operated manually by participants—potentially introducing variability associated with individual technique—the device developed in the present study enables puncture under controlled conditions with a fixed speed and angle.

This system offers improved reproducibility and eliminates inter-operator variability, thereby enhancing the reliability and objectivity of the puncture force measurements.

The apparatus comprises a needle (NN-2232S: Terumo), a Luer–Lock adapter (PS6608: ISIS), a three-way stopcock (394900: BD), a syringe (SS-05SZ: Terumo), a force test stand (FGS-100VC: Nidec-Sympo), a digital force gauge (FGP-1: Nidec-Sympo), a personal computer (ideapad Z500: Lenovo), and a jig made of acrylonitrile-butadiene-styrene (ABS) resin produced by a 3D printer for securing the model.

The puncture force tester can move a digital force gauge up and down at a variable speed (10–400 mm/min) by either automatic or manual operation. When a puncture is performed with the load test stand, the puncture force is transmitted to the measurement axis of the digital force gauge via the needle. The measured data can be continuously recorded by a personal computer connected to the digital force gauge. The force waveform obtained by the digital force gauge is smoothed by an integrated measurement filter. In the experiments, the 90% response time to step input was set to 3 ms, and the sampling frequency was 100 times per second.

A three-way stopcock was attached to verify whether the needle tip was inserted into the model's blood vessel after puncture with the load test stand. If the puncture was successful, water filled in the model's blood vessel could be aspirated from the port of the three-way stopcock by a syringe. The puncture needle is a sterile disposable needle commonly used for blood collection in adults (22G, short bevel type). The Luer–Lock adapter, made of polyetheretherketone (PEEK) resin, is used to screw the puncture needle into the device. The tool adheres to the same standard as the method used to secure needles in actual clinical practice, allowing the puncture needle to be changed according to the application. The jig for securing the model, made of ABS resin, is used to puncture the model at an angle suitable for blood collection and puncture. The jig was fabricated using a 3D printer (Replicator2X: Makerbot).[12]

Figure 2 provides an example of a puncture force waveform measurement and the items measured. In Figure 2, "F_{max}" represents the maximum puncture force.

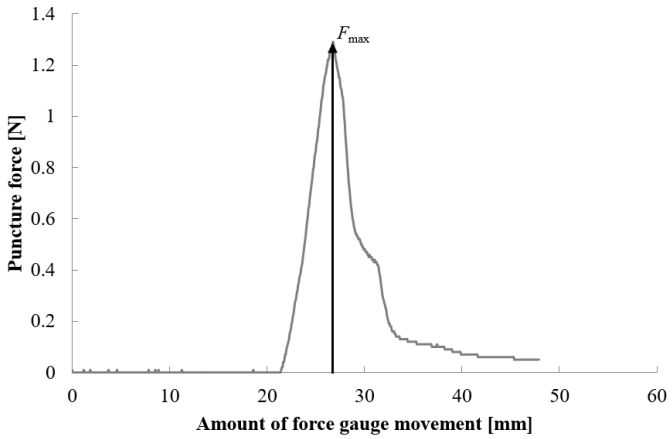

FIGURE 2. Puncture force waveform measurement and the corresponding measured item (The puncture force waveform was smoothed using a low-pass filter built into the force gauge. The filter parameters were set such that the 90% response time to a step input was 3 ms).

Subjects and Methods of Experiments

We prepared three models, designated as Model A, Model B, and Model C, similar to those used in the previous study (Figure 3).[9,10] Models A and B are designed to be worn on the arm of the training collaborator, while Model C is shaped like an arm. The simulated vessels of the models were filled with tap water to mimic blood, and a drop pressure was applied to simulate venous blood pressure, as per the models' instruction manual.

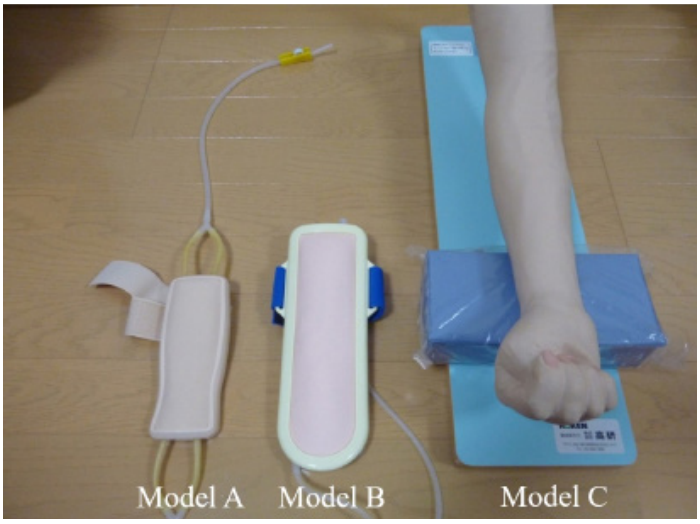

FIGURE 3. Intravenous blood sampling practice model.[12,13]

During the puncture test, the puncture angle was mechanically fixed at 25° using a jig, in accordance with the standards specified in the blood collection method guidelines.[14] We also set the puncture speed at 200 mm/min and 400 mm/min. We used two different puncture speeds to examine the model's dependence on speed, as it has been reported that the puncture reaction force decreases as the speed increases when puncturing the biological tissue.[15]

We conducted 12 tests for each model at a sampling frequency of 100 Hz. The needle was manually advanced into the model's simulated blood vessel using the stand, and the stand was stopped when the needle reached the vessel. We replaced the needle used for the puncture after each test. A puncture was deemed successful when water could be aspirated from the three-way stopcock by a syringe. The number of tests was set to 12 to allow for comparison with our previous study,[12,13] in which the same model was used and experiments were conducted with 12 participants.

RESULTS AND DISCUSSION

The average of the maximum puncture force is presented in Figure 4. An analysis of variance revealed a significant difference ($p < 0.05$) between the groups with a puncture speed of 200 mm/min and those with a puncture speed of 400 mm/min. Furthermore, multiple comparisons using Fisher's protected least significant difference (PLSD) indicated significant differences in all combinations, except between Model A and Model B in the group with a puncture speed of 200 mm/min ($p < 0.05$). Notably, Model C exhibited a significantly lower maximum puncture force than the other models at all puncture speeds ($p < 0.05$). The puncture speed dependence test results showed that only Model B exhibited a dependence on puncture speed ($p < 0.05$).

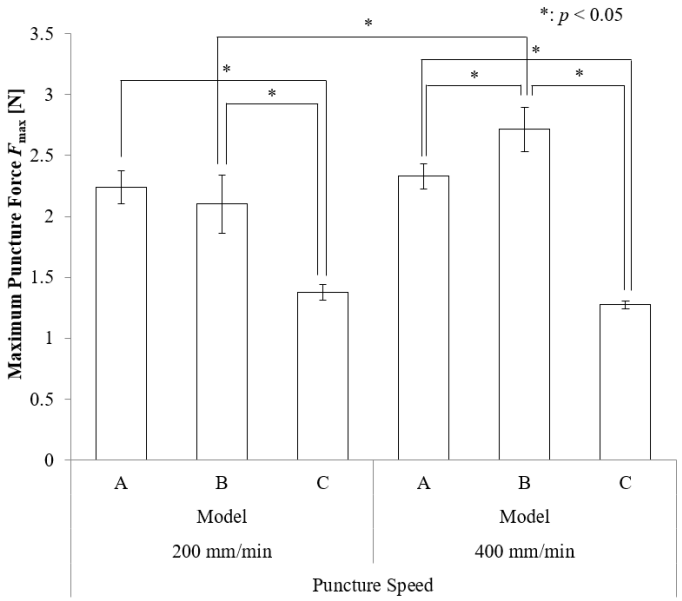

FIGURE 4. Average maximum puncture force (mean ± standard error, $n = 12$)

Compared to the results of multiple comparisons in a previous study by the authors, the current study demonstrated significant differences in all pairs at a puncture speed of 400 mm/min. This suggests that the differences in model characteristics are equally or more detectable.[12]

In the previous study, 12 using the same models, puncture experiments were conducted by 12 participants with a syringe-type force sensor. While that study found statistically significant differences between most model pairs, no significant difference was observed between Model A and Model C. In contrast, the present study, which employed mechanically controlled puncture conditions and the same number of trials ($n = 12$), revealed significant differences among all models at a puncture speed of 400 mm/min.

These findings suggest that the method developed in this study enables more sensitive and consistent detection of differences in model characteristics.

Okuno et al. reported that the puncture force for the median cubital vein on a volunteer was 0.64 ± 0.23 N (21 G, regular bevel).[16] Consequently, all models were deemed stiffer compared to the human body, aligning with the observations in the authors' previous studies.[12,13] In a subjective evaluation, Model C was assessed to be the most similar to the human body, although there were opinions that the skin and blood vessels were slightly stiff.[12] In the experimental results of this study, Model C was the closest to the human body among the three models. Therefore, the subjective evaluations of the models by previous studies[12] and the quantitative evaluation by the current method are in agreement, and the results are considered to be reasonable.

Several factors could account for the variation in results, even when punctures are performed under specific conditions. Given that blood vessels have a cylindrical shape, their thickness can vary depending on the position of the puncture. Moreover, the blood vessels themselves are not uniformly manufactured. Consequently, the large standard error in Model B might be because of the nonuniform thickness of the blood vessel compared to other models or the blood vessel being stiffer than in other models. These tendencies are more pronounced.

However, when compared to the experimental results using the syringe-type puncture force waveform measuring device, the smaller standard error and the independence of this experimental system from human techniques suggest the possibility of a more quantitative evaluation.[12,13]

Since the number of trials in both the previous study[12] and the present study was the same (n = 12), the comparison based on standard error is considered appropriate. Therefore, the smaller standard error observed in this study reflects reduced variability and supports the potential for more consistent and quantitative evaluation.

In addition, an investigation of puncture speed dependence by Naemura et al. reported that the higher the puncture speed, the higher the peak value, up to a region of 600 mm/min or less. The trend became more pronounced with increasing needle diameter, and differences in the needle tip shape were considered to contribute to variations in its magnitude.[17] Lorenzo et al. demonstrated that during needle insertion, the cutting force at the needle tip changes markedly when penetrating tissue, while the shaft friction force increases proportionally with insertion depth but does not change abruptly at penetration.[18] These reports suggest that the maximum puncture force increases when the incision force of the needle is insufficient relative to the puncture velocity. Since Model B was considered the stiffest model in previous studies, it is possible that this tendency was significantly observed.[12,13]

CONCLUSION

In this study, we sought to evaluate the model using a puncture force test device that allows for puncture under specific conditions. Multiple comparisons of the average maximum puncture force indicated that the model was capable of detecting differences in model characteristics to an equal or greater extent than the method using a syringe-type puncture force waveform measuring device. Furthermore, the results, which had a small standard error, and the device that enabled puncture force measurement under certain conditions eliminated the need to consider the effects of individual differences among experiment participants. This facilitated a more quantitative evaluation of the model. However, the maximum puncture force of the model was higher than the results of puncture experiments on the human body reported in previous studies, including a study by the authors.[12,13] Therefore, it is necessary to innovate materials for the skin and blood vessels by developing synthetic materials with lower elasticity in order to enhance the model's resemblance to the human body.

AUTHOR CONTRIBUTIONS

Conceptualization, N.N., K.H. and K.A.; Methodology, N.N.; Validation, N.N.; Formal Analysis, N.N.; Data Curation, N.N.; Writing–Original Draft Preparation, N.N.; Writing–Review & Editing, N.N., K.H. and K.A.

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DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors on request.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

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