



INTERNATIONAL JOURNAL OF ADVANCE RESEARCH, IDEAS AND INNOVATIONS IN TECHNOLOGY

ISSN: 2454-132X

Impact Factor: 6.078

(Volume 12, Issue 3 - V12I3-1146)

Available online at: <https://www.ijariit.com>

Can SaMD Enhance Diagnostic Consistency and Turnaround Time in Resource-Constrained Public Healthcare Settings without Hardware Modification?

Safal Mutha

mypublishedpaper@gmail.com

VIBGYOR High, Maharashtra

ABSTRACT

Long diagnostic turnaround times (TAT), equipment obsolescence, infrastructural inadequacies, and a lack of personnel are some of the ongoing issues facing resource-constrained healthcare systems. By integrating into current digital workflows, Software as a Medical Device (SaMD), especially AI-enabled systems, provides a scalable solution without necessitating changes to the underlying medical hardware. This study investigates whether SaMD may significantly increase turnaround time and diagnostic decision consistency in resource-constrained public healthcare settings. The results indicate that SaMD can greatly improve workflow efficiency and lower inter-operator variability. However, the main implementation obstacles continue to be algorithmic drift, regulatory fragmentation, cybersecurity concerns, and reimbursement constraints. The study concludes that SaMD is a workable, scalable solution for bolstering diagnostic systems in resource-poor areas when implemented through organised regulatory, financial, and cloud-based approaches.

Keywords: Software as a Medical Device (SaMD), Artificial Intelligence (AI), Diagnostic Decision Consistency, Digital Health Infrastructure, Public Health Technology Integration.

I. INTRODUCTION

The world is experiencing the growth of diagnostic pressures on the healthcare system, with low growth in both infrastructure and workforce. In some areas, especially the rural and poor areas, it is economically impractical to upgrade hardware like CT scanners, laboratory analysis equipment or radiology equipment. This raises a critical question: is it possible to improve the quality and speed of diagnostic processes without replacing physical medical devices?

Software as a Medical Device (SaMD) can be utilized as a means of improvement since it works without hardware while integrating with existing systems. With SaMD, implementation can be done via cloud infrastructure, hospital information systems, or mobile platforms, as opposed to the conventional hardware-based upgrades.

In addition to the constraints of financial resources, healthcare systems are restricted by procurement cycles, the regulation of new hardware, the logistics of the installation, and the necessity for long-term maintenance. This is because in most state hospitals, particularly in low-resource environments, the equipment donated or given at reduced costs will be rendered useless with a shortage of technicians, spares, and repair agreements. This is what is also known as the hardware graveyard, demonstrating how the purchase of new machines is not a guarantee of diagnostic improvement as long as it is not accompanied by a corresponding optimisation of existing infrastructure (1). This is the reason why solutions that contribute to optimisation of the infrastructure and not replacement of existing ones are more strategic and economically feasible.

At the same time, diagnostic workloads are growing as a result of demographic changes, the increasing number of non-communicable diseases, outbreaks of infectious diseases, and the increasing demands of patients to get fast results. Radiologists, pathologists, and lab technicians experience large volumes of report delays and inter-operator discrepancies. In this case, experienced clinicians will be likely to make inconsistent interpretations, especially when the picture is taken in high-volume imaging surroundings. The need to solve workflow inefficiencies and cognitive overload has therefore become just as significant as overall improvement in raw diagnostic capability.

SaMD offers a paradigm, as it is aimed at computational augmentation rather than physical expansion. SaMD may analyse current diagnostic output, e.g., imaging data, lab values, or electronic health records, and give standardised interpretations, risk stratification, and automated triage through artificial intelligence, machine learning algorithms, and clinical decision support systems, without modifications to scanners, analysers, or other specific equipment used by healthcare institutions (2).

Notably, such systems work on the existing digital platforms, so healthcare institutions do not need to modify any scanners, analysers, or other core equipment. Such a move toward software-centric optimisation is in line with the general trends in digital transformation of healthcare. Intelligent algorithms can be integrated into regular workflows, and through this, healthcare systems may potentially increase diagnostic variability, prioritise urgent cases better, and decrease turnaround times. The overall question, then, is not whether new machines are required, but whether clever implementation of software in existing systems can provide quantitative results in uniformity, proficiency, and general patient care outcomes.

The fusion of AI and human experience is referred to as “high-performance medicine” by Topol (Nature Medicine), who emphasises the augmentation of physicians over replacement. Another piece of evidence suggesting that deep learning systems are as good as, or even better than, humans in identifying diseases, based on an image, was found in a systematic investigation of radiology and diagnostic medicine (The Lancet Digital Health; Petrick et al., Medical Physics).

SaMD systems with AI capabilities can:

- i. Examine radiological images to find lesions.
- ii. Use lab values to perform predictive risk rating.
- iii. Analyze ECG waveforms
- iv. Use computerised CDSS to assist in clinical decision-making.
- v. Perform automatic triage in diagnostic environments with a high volume of cases.
- vi. This methodical integration sets deployable healthcare technologies apart from experimental AI models.

A key objective of the research is to figure out whether SaMD, applied within the existing framework of the workings of current healthcare units and not necessitating any modifications to the underlying medical equipment, can meaningfully reduce the turnaround time, as well as enhance the uniformity of the diagnostic decision-making procedures in the resource-constrained clinical facilities. Specifically, the paper will seek to investigate the role of SaMD in inter-operator variability in diagnostic interpretation, quantify the qualitative turnaround time (TAT) improvements, and test the role of the implementation in financial, infrastructure, and regulatory constraints. It will also determine whether software-centric optimisation in place of hardware replacement is a feasible alternative in the context of the public health systems.

II. WHAT IS SOFTWARE AS A MEDICAL DEVICE?

Software as a Medical Device (SaMD) is defined by the International Medical Device Regulators Forum (IMDRF) as the software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device (IMDRF, 2013).

SaMD has a vast variety of clinical uses in the areas of diagnosis, treatment, and monitoring. Image interpretation tools based on AI are one excellent instance. These systems use machine learning algorithms to process radiological imaging or CT scans of the chest or mammograms to identify abnormalities and guide clinicians with their diagnosis. Recent extensive validation studies have shown that deep learning systems could deliver similar diagnostic accuracy to medical imaging interpretation of healthcare professionals (Liu et al., 2019; Petrick et al., 2013). Practical applications, including AI-based radiology processes in major municipal health networks are also evidence of how this type of software can work with the existing scanners without making any physical changes to them.

Digital therapeutics can also be included in SaMD. They are evidence-based therapeutic interventions that are provided by using software to prevent, manage, or treat medical disorders. As an example, there are prescription digital applications (e.g., diabetes management or mental health disorder cognitive behavioural therapy platforms) that offer therapeutic interventions (structured) using mobile or web-based platforms. In Europe and North America, the regulatory regimes now treat some digital therapeutics as reimbursable medical products, which shows they are formally treated as medical devices (Access and Reimbursement Pathways for Digital Health Solutions; PECAN DMD - Guide to DiGA in France).

The other significant type of SaMD is clinical decision support algorithms. Patient data (such as laboratory values, symptoms, vital signs, and clinical history) are analysed by these systems to produce a diagnostic or treatment recommendation. As an example, primary care electronic clinical decision support algorithms may be used to help frontline health workers to treat febrile illness or respiratory infection through the incorporation of point-of-care diagnostic outcomes into structured decision trees. Implementation studies conducted in low-resource settings demonstrate better decision quality and compliance with clinical standards in cases when such systems are included in the routine workflows (BMJ Global Health, Electronic Clinical Decision Support Algorithms Incorporating Point-of-Care Diagnostic Tests).

The scope of SaMD is also depicted in remote patient monitoring platforms. These programmes monitor, send, and process physiological information, including heart rate, glucose, or blood pressure continuously, not in a clinical setting. As an illustration, wearable sensors can also use cloud-based cardiac monitoring platforms to analyse electrocardiograms (ECGs) and notify clinicians about arrhythmias in real time. The combination of Internet of Things (IoT) devices with cloud computing tools has allowed scaling up the concept of remote monitoring, especially in the management of chronic diseases (A Survey on Internet of Things and Cloud Computing for Healthcare; Journal of Ambient Intelligence and Humanised Computing).

In order to clearly determine the difference between SaMD and the other two software types, one should compare it with Software in a Medical Device (SiMD). In contrast to SaMD, which does not require particular hardware to run, SiMD denotes software that is part of a physical medical device and embedded into it. As an example, the software program that operates the image reconstruction in a CT scanner, the software that controls the infusion rates in an insulin pump, or the software that manages the monitoring functions in a ventilator are examples of SiMD since their functionality cannot be considered separate from the actual physical device (IMDRF, 2013; FDA Guidance on Software as a Medical Device). When this happens, it is hardware and embedded software that performs the medical purpose, as opposed to pure computational analysis. This difference is regulatory and clinical. Where SiMD upgrades may involve hardware system change, replacement, or recertification, SaMD is capable of being deployed on a variety of devices and within a variety of healthcare environments without making changes to the underlying equipment, potentially being more scalable and flexible, especially in resource-limited environments.

How Artificial Intelligence Is Utilized Within SaMD

Software as a Medical Device (SaMD) can be supplemented with artificial intelligence (AI) and boosted with the help of advanced data interpretation, prediction, and workflow optimisation in the field of diagnostics and the clinical domain. In controlled SaMD systems, AI is the analytical engine that is fed with clinical data and generates medically actionable information.

In radiology, deep learning algorithms are widely used for image recognition tasks such as the detection of pulmonary nodules, intracranial haemorrhage, breast cancer, and other abnormalities on CT, MRI, and mammography. In a systematic review and meta-analysis published in *The Lancet Digital Health*, it was established that deep learning systems could identify diseases during medical imaging just like healthcare professionals (Liu et al., 2019). Also, extensive real-world validation from the Moscow Radiology Experiment proved that AI-based computer vision technologies could analyse 1.3 million imaging studies and enhance reporting consistency without supplanting imaging hardware (Diagnostic Accuracy of Artificial Intelligence for Analysis of 1.3 Million Medical Imaging Studies: The Moscow Experiment).

AI-based predictive analytics has been used in laboratory medicine to identify early clinical deterioration by analysing sets of combinations of biochemical and hematological parameters. As an example, workflow automation and digital integration have been demonstrated to decrease the turnaround time in laboratories and maximise their efficiency (Reducing Laboratory Total Turnaround Time Using System Dynamics Simulation; Optimising Clinical Laboratory Efficiency Through Digital Shadow and Lean Six Sigma Integration). Such systems allow predictive risk scoring on conditions like sepsis or acute dysfunction in the organs on the basis of routine laboratory data.

Convolutional neural networks have been used in the field of pathology to scan digitised histopathology slides that identify malignancy, tumour burden, and microscopic patterns. Similar diagnostic sensitivity has been seen in imaging and endoscopic settings in comparative studies comparing AI-based computer-aided detection systems and clinicians (Petrick et al., 2013; Comparison of the Ability of Artificial-Intelligence-Based Computer-Aided Detection Systems and Endoscopists). The applications enhance reproducibility and lessen inter-observer variability.

Another important area that uses AI-enabled SaMD is risk stratification and automated triage. Urgent radiology cases can be prioritised automatically using AI algorithms by flagging critical findings (e.g., intracranial haemorrhage or pulmonary embolism cases). Evidence published in the *Journal of the American College of Radiology* shows that AI triage systems are able to significantly decrease radiologist report turnaround time in real-world practice (Impact of Artificial Intelligence Triage on Radiologist Report Turnaround Time). In response to the COVID-19 pandemic, AI-assisted interpretation of CT reduced reading time significantly in high-traffic facilities, enabling a faster triage and clinical decision-making process (Integrating Digital Technologies and Public Health to Fight COVID-19 Pandemic).

Automated image segmentation and lesion quantification also provide additional examples of the use of AI in SaMD. Algorithms have the potential to outline tumour borders, determine the volume of the lesion, and normalise the reporting of measurements through serial examination with imaging. This type of quantitative automation improves the consistency of reporting and reduces variability in measurements that are performed by a person (Petrick et al., 2013).

Natural language processing (NLP) helps AI extend its capabilities to unstructured clinical data. NLP algorithms are used to extract meaningful medical data in clinical notes, discharge summaries, and radiology reports in order to facilitate structured documentation and risk modelling. Such systems improve clinical decision support and analytics at a population level by converting narrative data into variables that can be calculated (Reducing the Workload of Medical Diagnosis Through Artificial Intelligence: A Narrative Review).

ECG and physiological waveform interpretation is also performed with the help of AI. Deep learning algorithms have been created to identify arrhythmias and conduction abnormalities based on ECG data with high diagnostic accuracy, facilitating telecardiology and remote monitoring (Reducing the Workload of Medical Diagnosis Through Artificial Intelligence: A Narrative Review).

Machine learning-based early warning systems of patient deterioration examine vital sign, laboratory, and demographic variables in order to produce predictive risk scores of adverse events. These predictive models can be used to proactively intervene, and it is in line with value-based healthcare.

At the population level, AI-based SaMD assists in surveillance and outbreak analytics. In COVID-19, there was the integration of AI-based imaging analytics and epidemiological information into digital health infrastructures to aid in making public health decisions and distributing resources (Integrating Digital Technologies and Public Health to Fight the COVID-19 Pandemic).

Lastly, AI aids in treatment recommendation through personalisation, incorporating multimodal patient data such as laboratory results, imaging results, and clinical history to help clinicians customise treatment plans. Such a strategy is an indication of the greater trend of precision medicine with AI-enhanced decision systems (Topol, 2019).

III. THE CONSTRAINT: HEALTHCARE DELIVERY IN RESOURCE-POOR SETTINGS

Resource-poor healthcare delivery is not only influenced by financial constraints but also influenced by structural and systemic constraints that ultimately impact the quality and timeliness of the diagnostics. As the technological advancement of the world progresses, most of the public healthcare systems, especially in the low-income regions, are left to work in an infrastructural setting not designed to handle high-volume digital integration. Consequently, evidence-based digital interventions should be considered in the context of local capacity and sustainability and the distribution of the workforce.

One of the major limitations is the gaps in infrastructure. Poor and unreliable internet access constrains online implementation of the modern digital systems, especially in rural and marginal health centres. Old IT architecture and outdated hospital information systems might not be interoperable with the required standards, which decreases the possibility of smooth integration with new digital tools. Unstable power also worsens such complications, and it affects imaging equipment, laboratory blood testing equipment, and online platforms, making the process of obtaining a diagnosis more difficult and making the work process more ineffective.

Human resource shortages are also of importance. Numerous resource-constrained environments are plagued by the acute shortage of trained experts, such as radiologists, pathologists, laboratory physicians, and biomedical engineers. There is also usually no balance in the distribution of the workforce, as the specialists can be seen in tertiary centres in the urban areas, leaving rural and district hospitals understaffed.

This disequilibrium is a contributing factor to extended turnaround time, sluggish reporting, and more intraoperative differences in diagnostic interpretation. In that case, medical practitioners often work with extreme workloads, which predisposes them to fatigue-associated errors and inconsistency in decision-making.

These structural and labour constraints provide a structural blockage to the provision of diagnostic services. In turn, the implementation of interventions to enhance the healthcare performance under the conditions of resource limitation should be preoccupied with scalability, low reliance on hardware growth, and limited dependence on highly professional staff. Any technological remedy, such as AI-based SaMD, should then be considered based not just on clinical precision but also on its versatility in limited operation ecosystems.

In addition to labour and infrastructural constraints, the other longstanding problem in the resource-deficient healthcare systems is the sustainability of medical equipment investments. Massive quantities of diagnostic equipment, including imaging equipment, laboratory analyzers, and monitoring equipment, have been donated or subsidised over the past decades as part of global health initiatives. Though they are well intended, such contributions are not always able to have a long-term impact in the absence of maintained ecosystems.

This has been informally referred to as the phenomenon of the hardware graveyard, which is considered to be hospital storerooms or unused wards, where equipment that is not functioning gathers. Commonly, devices have ended up being unusable due to the ineptitude of the biomedical engineer, non-existence of servicing contracts, inaccessibility of the spare parts, non-compatibility with the local infrastructure, or lack of training for the end users. There are cases where highly complex machines may need reliable power supplies, controlled environments, or specialised consumables that may be unavailable in the low-resource context. Due to this, hard-to-recycle capital hardware investments could decay quickly, providing minimal long-term diagnostic utility.

The results are not limited to the wastage of equipment. In case of failure of equipment to provide services, the channels of referrals will be broken, reporting time will be postponed, and patients will have to relocate to far tertiary centres to receive diagnostic services. Accessibility to specialist consultation is also a major problem that adds to these inefficiencies, especially in rural regions where radiologists and pathologists are minimal. These systemic bottlenecks have the effect of accelerating the turnaround time, slowing the initiation of treatment, and expanding gaps in healthcare access for the population.

In this respect, the solutions based mainly on the purchase of new equipment may run a risk of following the same pattern of unsustainable growth. Software as a Medical Device (SaMD) is a strategically different model by contrast. SaMD uses the current diagnostic equipment and digital processes to increase interpretation, prioritisation, and decision support, instead of either substituting or introducing new physical infrastructure. Although the disproportionately large clinical benefits in limited settings can be achieved with even small gains in workflow coordination, triage automatization, and reporting standardisation.

Thus, the smoothing of the current systems by means of intelligent software integration might be a more sustainable and economically feasible avenue toward the intensification of healthcare delivery in resource-starved environments as an alternative to the further development of the hardware-based one.

IV. MEASURING DIAGNOSTIC DECISION CONSISTENCY

Diagnostic decision consistency is the extent to which the various clinicians make similar decisions in the interpretation of identical clinical data. Variability in interpretation may occur in diagnostic fields due to differences in training, experience, fatigue, work pressure and subjectivity as in radiology and pathology. This inter-operator variability can result in inconsistent reporting, slow decision-making and, in some instances, differences in patient management.

Minimising inter-operator variability has thus become a key goal in integrating artificial intelligence in the diagnostic process. Deep learning systems are created to process images and clinical data based on universal computational standards and thus reduce differences in subjective interpretation. Systematic reviews and comparative studies suggest that AI-based imaging systems are capable of similar or superior diagnostic results to healthcare professionals when identifying disease in medical imaging (Liu et al., 2019). With the use of standard pattern-recognition algorithms across cases, AI-enabled SaMD can be used as a decision-support tool or second reader, which enhances consistency during interpretation and increases the overall diagnostic reliability.

Another role of AI-related tools incorporated into the SaMD systems is quality control and standardisation of reporting, which can enhance the consistency of diagnostics. In imaging processes, the deep learning algorithms may identify incomplete or low-quality scans through detecting missing anatomies, low-contrast stages, or poor acquisition settings. They are also able to identify motion artefacts and technical acquisition defects that can impair interpretability, triggering repeat imaging as needed. These automated quality controls minimise the chances of diagnostic potential and minimise variability due to technical reasons.

Moreover, AI systems are capable of producing instant notifications when vital clinical metadata are not present, including the lack of patient history, incomplete laboratory data or the absence of previous imaging comparisons. Robotic measuring instruments also increase consistency by normalising lesion segmentation, volumetric quantification, and longitudinal change analysis. This minimises inter-observer differences in the sizes and disease progression measurements of tumours, which in the past have been a cause of reporting discrepancy (Petrick et al., 2013).

Advanced systems also conduct automated consistency checks between existing and previous reports, determining any difference in measurements or diagnostic impressions over time points. Integrating the structured reporting templates and the use of algorithm-driven validation layers, AI-based platforms foster consistent terminologies and interpretive consistency. Comparative analyses of computer-aided detection and diagnostic systems have shown that these automated assistance systems have the potential to enhance consistency and decrease subjectivity in the interpretation of imaging (Liu et al., 2019; Petrick et al., 2013).

All these features can be viewed as an example of how AI-based SaMD can be used to go beyond disease detection to include systematic quality control, structured reporting, and longitudinal consistency monitoring in the context of diagnostic processes.

V. AI AS AN AUXILIARY TOOL AND SECOND OPINION

Artificial intelligence does not replace a clinician's role in SaMD; AI is employed to support decision-making and not perform it autonomously, and in most regulatory settings, AI is not yet a replacement but a supplement to clinicians. The second-opinion model is especially applicable in diagnostic imaging, in which the inter-observer variability can affect clinical management. The introduction of algorithm-based results and human interpretation by the AI systems adds one more standardised analysis to the clinician, which may either prove the correctness or wrongness of the assessment.

One massive real-life application of this auxiliary model is the Moscow Radiology Experiment. Under this project, computer vision AI technologies were incorporated into the daily workflow of public hospitals, and about 1.3 million radiology studies were analysed. Instead of making independent final diagnoses, the AI systems identified possible abnormalities, prioritised critical cases, and gave organised recommendations to radiologists. The research study revealed that AI-assisted review enhanced consistency in reporting and minimised variability across radiologists, especially in high-volume settings. Notably, the system has served as a decision-support mechanism in the already existing infrastructure and did not eliminate human interpretation but served to reinforce it (Diagnostic Accuracy of Artificial Intelligence for Analysis of 1.3 Million Medical Imaging Studies: The Moscow Experiment). This second-reader role is in line with more general systematic reviews. In the meta-analysis published in *The Lancet Digital Health*, deep learning systems demonstrated a similar diagnostic performance to that of healthcare professionals in image-based disease detection but noted that the best performance occurred when AI was used to complement but not to replace clinician judgement (Liu et al., 2019). This type of hybrid model can minimise the error of oversight, enhance sensitivity to fine discoveries, and encourage uniformity of reporting formats.

The relevance of the method is particularly high in resource-limited environments, where the lack of specialists and excessive workloads raise the chances of developing fatigue-related diagnostic variability. In this case, AI-enhanced SaMD can be used as a consistency enhancer, providing analysing support in the form of structure and lessening the cognitive load. As a secondary layer, AI offers to enhance the reliability of the diagnostic process without removing the supervision of clinicians, which, in turn, conforms to the requirements of human-in-the-loop implementation in the regulations.

VI. MEASURING TURNAROUND TIME (TAT) IMPROVEMENTS

To enhance diagnostic efficiency in resource-limited healthcare systems, one must not only focus on the accuracy and consistency of the diagnostic result but also pay attention to time-sensitive performance indicators. Turnaround Time (TAT) is one of the most vital operation measurements in this regard and can be defined as the period between the acquisition of a test and the eventual provision of the completed clinical report. In diagnostic settings with high volume (especially radiology and laboratory medicine), long TAT can slow the treatment decision-making process, cause an overload of patients, and overuse already limited healthcare resources.

Under this framework, SaMD with artificial intelligence can be used to reduce the TAT mainly by using intelligent triage and workflow automation. The AI-based triage algorithms are developed to process the incoming diagnostic data on the fly and to automatically assign priorities to the cases showing high-risk or red-flag results. Indicatively, the neural imaging processes can identify characteristics that may indicate intra-brain haemorrhage on CT images through the AI systems and promote them to the head of the reporting list. This prioritisation is automatically achieved; hence, time-sensitive conditions are reviewed in time. In practice such AI-assisted triage systems have demonstrated a capability to reduce report turnaround time in clinical practice by significant factors (Impact of Artificial Intelligence Triage on Radiologist Report Turnaround Time: Real-World Time Savings and Insights From Model Predictions).

Besides prioritisation, AI-based SaMD minimises the reporting delays through automation of routine analysis activities. Lesion segmentation, volumetric quantification, and measurement calculations, as well as structured reporting templates, can be automatically generated, and this decreases cognitive and administrative load on radiologists. These systems reduce the amount of time that an individual case must be read by manual procedures and enhance departmental throughput. Other investigations looking at AI-assisted image interpretation have found statistically significant improvements in reading time with no harm to the diagnostic accuracy (Liu et al., 2019; The Impact of Artificial Intelligence on the Reading Times of Radiologists for Chest Radiographs).

In comparison to the overall research goal, i.e., the enhancement of diagnostic performance without changing the underlying hardware, AI-based triage and workflow automation have shown how operational improvements can be achieved by mere software integration. When faced with resource-poor environments, where the capacity to increase workforce in specialist roles is sometimes impossible, achieving TA reduction by means of intelligent prioritisation and task automation can be a scalable and sustainable alternative to infrastructure growth.

VII. DEPLOYMENT STRATEGIES FOR RESOURCE-CONSTRAINED SETTINGS

The central part of facilitating scalable implementation of AI-enabled Software as a Medical Device (AI-SaMD) is cloud-based infrastructure, especially in healthcare systems with limited resources. Cloud architecture permits standardised models to be implemented in multiple facilities at the same time since algorithms are hosted on centralised servers instead of on-site hospital hardware. This allows centralised algorithm updates whereby betterments, bug fixes and proven performance improvements can be made at a consistent rate without the need to physically make physical changes to the local systems. Where biomedical engineering capacity is constrained as in, such centralised maintenance helps eliminate the need to rely on on-site IT teams and minimises downtime caused by manual software maintenance.

Access to diagnostic tools and decision-support systems is also made available remotely through cloud infrastructure. Peripheral clinicians or clinicians in rural centres can be able to share superior analytical resources on centralised systems, thus bringing specialist-level care to locations experiencing workforce deficits. This teleaccessibility is especially relevant when the health systems are spread over a wide area whereby the physical access to referral pathways can slow down the interpretation of diagnostic results.

The Electronic Clinical Decision Support Algorithms (eCDSA) also demonstrate how computerized systems can enhance frontline healthcare provision also, through the integration of structured clinical logic and patient clinical data, eCDSA steer healthcare professionals through evidence-based clinical diagnosis and treatment processes. The algorithms assist in standardized end-of-care decision-making in low-resource settings, where specialist communication might not be easily accessible. Research on primary healthcare systems revealed that eCDAs that include point-of-care diagnostic outcomes enhance clinical guideline compliance and diagnostic accuracy in the non-specialist provider (BMJ Global Health, Electronic Clinical Decision Support Algorithms Incorporating Point-of-Care Diagnostic Tests).

Collectively, the cloud-based implementation and decision-support algorithm can illustrate how the digital infrastructure can be used to expand clinical knowledge, limit reliance on local technical assets, and enhance uniformity in the healthcare delivery process without the need to increase the hardware infrastructure.

Causing AI-enabled SaMD to run in the cloud, it is possible to update algorithms and make them run in a variety of facilities to achieve performance similarity and regulatory adherence. Remote access functions enable clinicians in remote or rural facilities to access sophisticated diagnostic models without moving patients to specialised facilities, which helps to solve shortages in specialists and geographic inequalities.

Another viable digital strategy is Electronic Clinical Decision Support Algorithms (eCDAs). eCDAs are programmed rule-based or AI-enhanced logic-based systems installed on software platforms to direct healthcare professionals in a standardised approach to diagnosis and treatment. These systems combine patient symptoms, vital signs and lab results with situational risk factors into algorithm-based decision trees. eCDAs can support non-specialist providers to make guideline-adherent choices in the conditions of respiratory infections, malaria, or maternal health complications in low-resource primary care settings. They enhance the quality of the diagnostic results when specialists are unavailable, and the level of diagnostic accuracy and consistency is continually lower in the case of using only individual clinical judgement.

Mobile health (mHealth) extends these functions to encompass SaMD and eCDA capability using smartphones and tablets, and community health workers can gather patient information, use cloud-based algorithms, and get real-time decision support even in the far-flung settings. MHealth solutions are also a low-cost way of making diagnostic assistance and surveillance services available outside hospital facilities in environments where physical infrastructure is poor but where the presence of mobile devices is high. Combining cloud infrastructure, eCDAs and mHealth forms a combined digital ecosystem that can empower diagnostic processes without necessitating physical medical hardware expansion.

VIII. RISKS: CYBERSECURITY AND PERFORMANCE DRIFT

As conditions in the real world of application do not match the environment of AI training, the capabilities of AI-enabled SaMD might be negatively affected, a process known as dataset shift. One can use the following example: when training a model based on the imaging data of a single demographic group, the quality of its diagnosis can be reduced when used on the population with a different age distribution, ethnicity, or comorbidities (Liu et al., 2019). On the same note, the predictive reliability may be influenced by variations in the prevalence of a disease or the alterations in the patterns of clinical presentation, such as those noted in the COVID-19 pandemic, to necessitate model recalibration (Integrating Digital Technologies and Public Health to Fight COVID-19 Pandemic).

It is also significantly contributed to by technical variability. The variations in the characteristics of the input data can be changed by differences in imaging protocols, scanner calibration, or acquisition parameters, and this might decrease model accuracy (Petrick et al., 2013). Artificial data quality variations, missing electronic health records, or modifications in programmes could also have an additional impact on algorithmic outputs.

Due to such risks, it is necessary to monitor continuously, implement change management and perform the evaluation of the real performance. Both the FDA and IMDRF regulatory frameworks focus on lifecycle, pre-established update structures, and post-market monitoring to address the clinical validity of adaptive AI systems in the long term (FDA AI/ML-Based SaMD Action Plan; IMDRF, 2013).

CASE STUDIES

Success: The Moscow Experiment

The Moscow Experiment is one of the most widespread real-life applications of AI to radiological systems in the world. AI-guided computer vision systems were directly fitted into the current radiologic processes of municipal healthcare establishments and used on about 1.3 million imaging studies. Instead of substituting radiologists or scanners, the system acted as a decision-support layer, highlighting the suspicious changes and standardising reporting frameworks. Published reviews were of better rad diag consistency among radiologists and quantifiable workflow efficiency improvement without hardware upgrades (Diagnostic Accuracy of Artificial Intelligence to Analyse 1.3 Million Medical Imaging Studies: The Moscow Experiment). This case shows that software integration by itself is sufficient to improve performance in the existing infrastructure.

Success: AI Deployment during COVID-19 in China and Europe.

The CT analysis systems monitor case data in real-time and provide diagnostics through AI capabilities to ensure faster case triage during the peak of COVID-19 surges (Pitcock et al., 2020). These tools automatically recognised radiographic patterns that are suggestive of COVID-19 pneumonia and prioritised the acute cases. It is reported that AI support ensured a great decrease in the time of CT interpretation and facilitated quick decision-making in case radiology departments were overwhelmed (Integrating Digital Technologies and Public Health to Fight the COVID-19 Pandemic). The relevance is in the fact that it shows how to be used with scaling during crisis situations, without increasing the physical imaging capacity.

Success: Digital C215 Mental Health Infrastructure.

There are a number of health policy models that have included prescription digital therapeutics within a public health care system, usually in Europe. These are controlled software-based interventions which provide orderly psychological treatment and behavioural assistance through mobile or Internet systems. By incorporating digital therapeutics into insurance systems, these systems will solve specialist shortages and make care more accessible without building more facilities. This is a representation of how SaMD can address the problem of workforce limitations by integrating its policy-backed instead of increasing hardware.

Lessons Learned

Lack of Reimbursement Codes: Most AI-based SaMD tools have not been adopted sustainably due to the lack of reimbursement systems. Hospitals are also unlikely to implement otherwise clinically effective tools in the absence of specific billing codes or digital health certification pathways to understand the financial return.

Poor Regulatory Clarity: Different or changing regulatory directions in jurisdictions have slowed down deployment. Because developers might be uncertain about classification, validation needs, or the approval of updates, this raises the cost and slows down the innovation, and this is especially an issue with adaptive AI systems.

The Usability Problems of Low-Resource Conditions: The failure of some solutions of AI was due to the lack of adjustment to local workflows, language conditions, or infrastructure constraints. Devices that needed a high-bandwidth internet connection, sophisticated quality imaging, or complicated data entry interfaces were hard to maintain in the peripheral hospitals.

Excessive use of AI applications that have not been proven yet: In some instances, the fast use of unproven AI implementation, particularly in cases of an emergency, posed the question of accuracy and safety. The absence of strict clinical validation and post-market follow-ups may erode confidence and even ruin patient care.

All these points, taken together, point to the fact that though AI-based SaMD can significantly enhance diagnostic efficiency and consistency, its successful implementation is conditioned by regulatory alignment, financial sustainability, adaptability across contexts, and the ability to keep it valid.

DISCUSSION

The results of this paper demonstrate that Software as a Medical Device (SaMD) has a high potential to resolve the systemic inefficiencies in the resource-constrained medical care setting. Large-scale applications, including the Moscow Radiology Experiment and AI-assisted COVID-19 imaging implementations, have proven improvements in the consistency of diagnostic decisions and turnaround time and do not necessitate replacement of existing hardware infrastructure. These results are indicative that it might not only be required that healthcare systems be upgraded to performance levels that are capital intensive, but rather that it may be achieved by the intelligent addition of software.

The major contribution of SaMD is that it helps lower inter-operator variability. SaMD reduces discrepancies caused by training differences, fatigue, or workload pressures between clinicians by standardising interpretation on algorithmic analysis and reporting. This is especially important in community healthcare systems in which the lack of uniformity in specialist distribution is common in some cases with respect to the uniformity of diagnostics. In addition, AI-driven workflow automation and triage allow alleviating cognitive load and allow healthcare providers to concentrate on more sophisticated clinical judgements, instead of spending time on repetitive analytical procedures.

Though, the debate should also note that technological capability is not the sole factor that can ensure successful implementation. The continuous challenges include algorithmic drift, cybersecurity threats, regulatory fragmentation and reimbursement impediments. Infrastructure instability in resource-poor environments (e.g., unreliable internet connection and outdated IT infrastructure) can also make deployment harder. Thus, a systematic model of implementation that includes regulatory compliance, protection of cybersecurity, employee education, and validation of a specific context is needed to achieve a lasting effect.

Economically, SaMD is a transition where the hardware-based capital spending way of thinking is substituted with software-based operational optimisation. When correlated with the value-based healthcare concepts, the turnaround time enhancements and diagnostic consistency could be reflected in the decreased hospitalisation, interventions sooner, and patient outcomes. However, the success in the long term will be determined by creating the reimbursement channels and providing the fair access to the validated and clinically effective software solutions.

In general, the discussion supports the idea that SaMD cannot be considered as a technological innovation only but as a systems-level intervention that can be used to enhance diagnostic capacity under limited conditions. The research progress to be undertaken in the future ought to be based upon the longitudinal outcome research, the cost-effectiveness analysis, and the implementation science frameworks in order to have a deeper insight into the ways in which SaMD can be integrated into the various public healthcare ecosystems in a sustainable manner.

CONCLUSION

The real-world deployments, systematic reviews and studies of the infrastructure of public health indicate that SaMD has the potential to enhance consistency of diagnostic decisions and turnaround time in a measurable way and does not alter the underlying hardware. AI-based SaMD can decrease inter-operator variability, automate workflow, prioritise urgent cases and increase healthcare access in resource-constrained environments.

SaMD is not only a technological innovation; it is a structural change in the nature of diagnostic healthcare provision within the limited contexts.

Moreover, the sustainability of SaMD implementation in the long run will be based on the ongoing performance assessment, adaptive regulatory frameworks, and the equitable access plan. Since healthcare systems are currently moving toward digital transformation, integrating validated, secure, and context-sensitive software solutions into normal clinical workflow may act as an agent of change within the system. With proper governance, workforce education and financial modelling, SaMD can not only result in more efficient and consistent diagnosis but also transform how healthcare systems constrained by resource limitations can provide quality and timely care.

REFERENCES

- [1] Reddy, M. (2022). *Medical equipment donation: An end in itself or a means to an end?* PMC.
- [2] Ebad, S. A. (2025). *Artificial intelligence-based software as a medical device (AI-SaMD): A systematic review of clinical, regulatory, and technological insights.*
- [3] International Medical Device Regulators Forum. (2013). *Software as a medical device (SaMD): Key definitions (IMDRF/SaMD WG/N10 Final)*. International Medical Device Regulators Forum.
- [4] International Medical Device Regulators Forum. (2014). *Software as a medical device (SaMD): Possible framework for risk categorization and corresponding considerations*. IMDRF.
- [5] U.S. Food and Drug Administration. (2019). *Policy for device software functions and mobile medical applications: Guidance for industry and Food and Drug Administration staff*. U.S. Department of Health and Human Services.
- [6] U.S. Food and Drug Administration. (2021). *Artificial intelligence/machine learning (AI/ML)-based software as a medical device action plan*. FDA.
- [7] Health Canada. (2019). *Software as a medical device (SaMD): Definition and classification guidance document*. Government of Canada.
- [8] European Parliament and Council of the European Union. (2017). *Regulation (EU) 2017/745 on medical devices*. Official Journal of the European Union.
- [9] Access and reimbursement pathways for digital health solutions and in vitro diagnostic devices: Current scenario and challenges.
- [10] Creating a national infrastructure for digital mental health services.

- [11] Co-design open-source medical devices: How to minimize human error using UBORA e-infrastructure.
- [12] Automatic COVID-19 lung infected region segmentation and measurement using CT-scan images. *ScienceDirect*.
- [13] Petrick, N., et al. (2013). Evaluation of computer-aided detection and diagnosis systems. *Medical Physics*.
- [14] Comparison of the ability of artificial-intelligence-based computer-aided detection (CAD) systems and endoscopists.
- [15] Reducing the workload of medical diagnosis through artificial intelligence: A narrative review. *PMC*.
- [16] Liu, X., Faes, L., Kale, A. U., Wagner, S. K., Fu, D. J., Bruynseels, A., ... Denniston, A. K. (2019). A comparison of deep learning performance against health-care professionals in detecting diseases from medical imaging: A systematic review and meta-analysis. *The Lancet Digital Health*, 1(6), e271–e297.
- [17] Turnaround time: An efficacy measure for medical laboratories.
- [18] Optimizing clinical laboratory efficiency through digital shadow and Lean Six Sigma integration.
- [19] The impact of artificial intelligence on the reading times of radiologists for chest radiographs. *npj Digital Medicine*.
- [20] Reducing laboratory total turnaround time (TAT) using system dynamics simulation: Chemistry analyzer application.
- [21] Impact of artificial intelligence triage on radiologist report turnaround time: Real-world time savings and insights from model predictions. *Journal of the American College of Radiology*.
- [22] A survey on the Internet of Things and cloud computing for healthcare.
- [23] The impact of the hybrid platform of Internet of Things and cloud computing on healthcare systems: Opportunities, challenges, and open problems. *Journal of Ambient Intelligence and Humanized Computing*.
- [24] Electronic clinical decision support algorithms incorporating point-of-care diagnostic tests in low-resource settings: A target product profile. *BMJ Global Health*.
- [25] SaMD: Software as a medical device – The ultimate guide.