

AI-Powered Healthcare Information Systems Securing Diabetes Management Through Integrated Technology Solutions and Enhanced Patient Care Delivery

Khadeza Yesmin Lucky¹, Shariful Haque², Khaled Al-Samad³,
Roksana Akter⁴, Omar Faruq^{5*}, Kazi Sanwarul Azim⁶, Md Shakirul Islam Joy⁷

¹College of Business, Westcliff University, 17877 Von Karman Ave, 4th Floor, Irvine, CA 92614, USA.

Email: k.lucky.446@westcliff.edu, ORCID ID: 0009-0002-6186-485X

²Department of Business Administration, International American University, 3440 Wilshire Blvd, Los Angeles, CA 90010, USA. Email: research@sharifulhaque.org, ORCID ID: 0009-0003-0832-5539

³Doctor of Business Administration, International American University, 3440 Wilshire Blvd, Los Angeles, CA 90010, USA. Email: khaledsmd@gmail.com, ORCID ID: 0009-0008-0853-5495

⁴Department of Business Administration (Cybersecurity), California state university San Bernardino, 5500 University Pkwy, San Bernardino, CA 92407, USA. Email: 008794273@coyote.csusb.edu, ORCID ID: 0009-0009-8609-3570

^{5*}College of Business, Westcliff University, 17877 Von Karman Ave, 4th floor, Irvine, CA 92614, USA.

Email: o.faruq.123@westcliff.edu, ORCID ID: 0009-0005-8093-0957

⁶Department of Business Administration, International American University, 3440 Wilshire Blvd, Los Angeles, CA 90010, USA. Email: kazisanwarulazim@gmail.com, ORCID ID: 0009-0001-0145-2135

⁷College of Business, Westcliff University, 17877 Von Karman Ave, 4th Floor, Irvine, CA 92614, USA.

Email: m.islam.9094@westcliff.edu, ORCID ID: 0009-0004-9835-6765

Correspondence

Omar Faruq

Email: o.faruq.123@westcliff.edu

ABSTRACT

Background: The epidemiology of diabetes in the United States is an acute topic of concern in community health and the economy that has some constraints in infrastructure such as the absence of specialists, ineffective glycemic control. A special opportunity, the introduction of Artificial Intelligence (AI) and Machine Learning (ML) into digital health will allow transferring the process of care delivery to the more proactive and personalized intervention and decrease the constantly increasing healthcare expenditures.

Research Objective: This project will focus mainly on examining the utility of an artificial intelligence system in the delivery of diabetes solutions. The research will also focus on the technology's impact on glycemic outcomes, patient activation, and clinical workflow.

Research Methods: The present review was carried out in accordance with the Preferred Reporting Items of Systematic Review and Meta-Analysis (PRISMA 2020) methodology. The question of the research was formulated on the basis of the PICO framework (Population: Persons with Diabetes (PWDs) in the US; Intervention: AI-Powered Integrated Technology Solutions, including Automated Insulin Delivery (AID), Clinical Decision Support Systems (CDSS), etc.

Conclusion: In spite of this clinical potential, scalable use is limited by fundamental issues, such as the continued absence of standardized device inter-operability and extreme cyber-security risks, especially the susceptibility of ML models to manipulation (e.g. inference-time attacks). Strict regulatory adherence to HIPAA (data privacy) and the Good Machine-Learning Practice (GMLP) of the FDA, which requires Explainable AI (xAI) to provide transparency and accountability to adaptive systems, is required for secure implementation.

KEYWORDS: Artificial Intelligence, Healthcare Information Systems, Diabetes Management, Clinical Decision Support Systems, Predictive Analytics, Patient Engagement.

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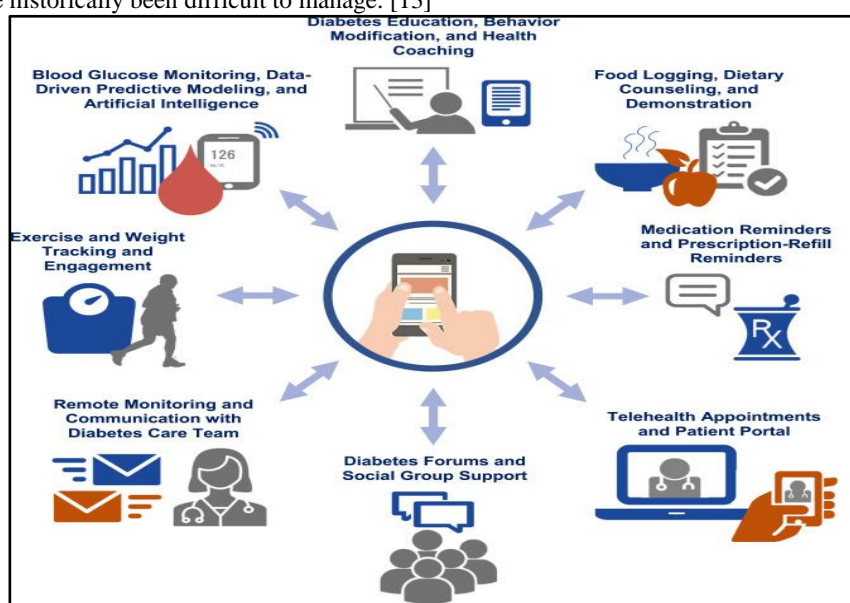
INTRODUCTION

The increasing prevalence of diabetes globally and in the United States has made it an increasingly serious public health challenge for the 21st century. The considerable burden of avoidable morbidity and mortality, and the substantial economic costs associated with the disease and its complications, necessitate the prompt and effective improvement of care delivery. [1] This challenge is compounded by significant infrastructural constraints of the US healthcare system, including the availability of diabetes specialists in the workforce; inequitable distribution and access to medical care; and continuing patient-centered obstacles to compliance to aggravate adherence to activity, diets, and medications for good glycemic control and to overall quality of care. Recent technological advances, especially with developments in digital health, particularly AI and ML, position an opportunity

to address these systematic inefficiencies and improve clinical outcomes. [2] By capitalizing on the computational affordability of AI, medical care providers can expect efficiencies in their delivery of diabetes management over time that translates to a variety of cost-containment estimates with respect to healthcare costs associated with diabetes care and complications, by migrating diabetes care delivery away from a purely reactive treatment model and toward proactive and personalized treatment paradigms. Effectiveness in US Diabetes Care Delivery

Advanced glucose management devices rely on artificial intelligence algorithms as the underlying intelligence. Specifically, Hybrid Closed-Loop systems have been found in studies to be superior to Standard Insulin Management systems by using AI to estimate glucose in the future to determine what insulin to deliver. [3], [7] The primary outcome measure for HCL systems is Time-in-Range (TIR), which is the time spent in the target glucose range. In meta-analyses of studies, TIR improved for HCL systems by about 8-12%. Moreover, HCL systems have been associated with improved TIR, decreased the time spent in hyperglycemia, and no decrease or less time spent in hypoglycemia to show a net positive benefit of improved algorithm safety and effectiveness. [9]

While these new technologies, inclusive of HCL systems and real-time factory-calibrated Continuous Glucose Monitors (CGM), are being used with more prevalence and adoption, the effects on population health outcomes are more nuanced. [4] A recent significant registry analysis from the United States showed a substantial increase in CSII pump usage 57%-63% and a staggering increase in CGM usage 7%-30% both of which occurred from 2010-2012 and from 2016-2018. [5], [11] In turn, the HbA1c adjusted mean for the overall T1D population increased from 7.8% to 8.4% within this time frame with the differential increase being most pronounced in adolescents and young adults. This difference implies that AI-supported treatments are clinically efficacious for individuals who are engaged in their care, however, there remains a lag between the potential of population health benefit and implementation, access and adaptability across the continuum of patients, eventually this may include those individuals who have historically been difficult to manage. [13]



Source: Ashrafzadeh (2019)

Figure 1: Patient Driven Diabetes care using AI

Autonomous Diagnostics

AI has demonstrated a promising capacity to translate clinical knowledge into diagnostic screening, particularly for complications of diabetes. Diabetes is the leading cause of adult onset blindness in the USA. It is estimated that 98% of vision loss due to Diabetic Retinopathy (DR) is preventable with more accurate prediction and early detection. [6], [2] Deep learning algorithms have shown a high degree of accuracy when screening and diagnosing diabetic retinopathy. Studies report that deep learning AI-grading of retinal images has a sensitivity and specificity of over 90% at detecting DR. The FDA's approval of IDx-DR, the first autonomous AI-based diagnostic algorithm that provides design or rule-based evidence of DR greater than mild without the need for a clinician to interpret the results, represents a major regulatory approval in the USA and demonstrates an important transition towards the deployment of autonomous diagnostic aid systems in primary care environments, thereby creating increased access and efficiency to care. [7], [12] AI-enabled solutions are also in development for early detection and diagnosis of other complications of diabetes, including diabetic nephropathy, neuropathy and diabetic foot ulcers.

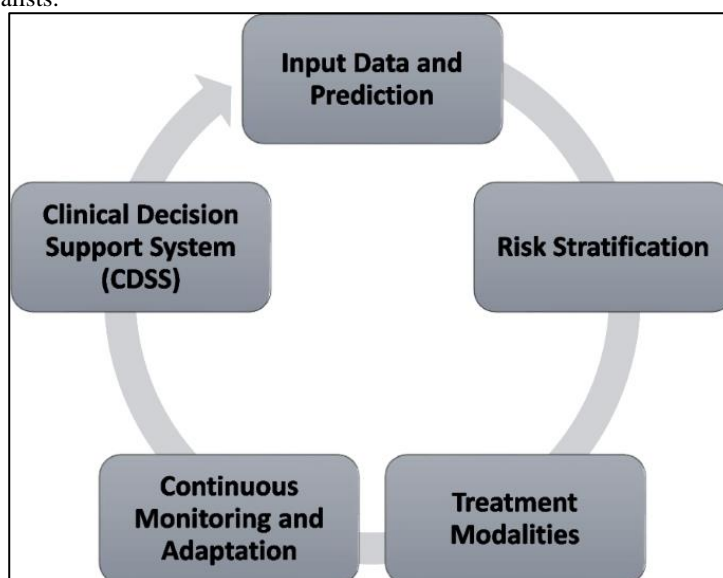
Remote Patient Monitoring (RPM)

Predictive models and remote patient monitoring (RPM) have a major impact on diabetes management by being more engaged, proactive in targeted delivery of care. The capability of collecting the high volume of data based on wearable, mobile applications and other health devices allows engagement of AI models to identify patients at risk blowing their blood glucose who could have worsened conditions before worse complications and more uncontrolled diabetes. [8] An example of an RPM model for diabetes monitoring (RDMP) that utilizes large-scale data streams such as blood glucose (BG), medication fills, and health signal data to dynamically predict patient outcomes.[9] The predictive machine learning (ML) models were able to predict outcomes, such as

specified recall between 70%-94% for observable, at risk observations (around participants). Similarly, deep learning based predictive analytic models using photo-plethysmo-graphy (PPG) signals along with clinical data yielded 97.8% predictive accuracy for possible complications and 91.2% predictive accuracy continuous glucose monitoring (CGM) based in real-time monitoring.[15]

Clinical Decision Support Systems (CDSS)

Clinical Decision Support Systems that utilize artificial intelligence (AI-CDSS) possess a unique capacity to aggregate multiple and complex fields of information (such as Electronic Health Records (EHRs), genomic information, and lifestyle) to create comprehensive profiles of the health of populations of patients. [17], [4] The aggregation of this information improves risk stratification and the ability to make personalized treatment recommendations. Systematic reviews have established the benefit and safety of the use of AI-CDSS framework as an adjunct, in the management of diabetes. None of the studies reported increased occurrences of hypoglycemia. AI-CDSS may be particularly useful in supporting newer clinicians, or providing care for patients with limited access to specialists.



Source: Kokori et al (2024)

Figure 2: CDSS Using AI for Diabetes Management

Furthermore, AI allows patients to gain more agency through the provision of better self-management devices. For example, the Sugar. IQ mobile smart assistant with AI functionality tracks everyday patient interactions relative to the various parameters that can affect the patient's glycemic profile (foods eaten, insulin doses taken, activities done) and offers unique insights that the patient can act on.

A study utilizing the Sugar IQ system recently reported a statistically significant increase in Time-in-Range (TIR) with average glycemic improvements of 36 minutes/day, along with a decreased time in hyperglycemia and in hypoglycemia. Importantly, 90% of the patients exhibited substantial engagement to conclude and there was strong evidence that AI-supported individualized guidance is translatable to sustainable adherence and engagement.

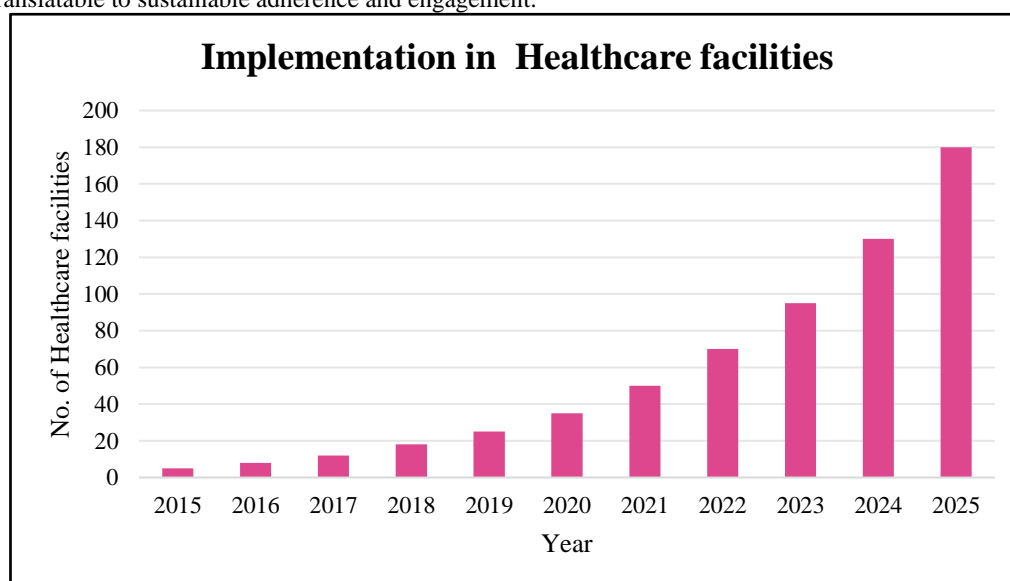


Figure 3: Number of Healthcare facilities implementing AI for Diabetes care

AI now even allows one to safely provide simplified individualized resources for education (ideas for meal plans, recommendations for exercise) developed in compliance with HIPAA via text messaging. Patients receive communication pertinent to their needs within a timely manner on an astonishing number (tens of patients!) amount of patients. [8], [12], [19] The current healthcare system in the United States is increasingly primed for advancement through similar new technologies with the growing focus on value-based care and digital health innovation. [14] The development and use of AI-enabled healthcare information systems for diabetes management raises concerns and challenges. Addressing issues of data privacy, algorithmic bias, interoperability, and clinician trust will require consideration of this ethical and effective incorporation of care technologies. Our purpose is to systematically review and synthesize the current evidence regarding AI-integrated healthcare information systems in the clinical context of diabetes care in the United States. More specifically, in this systematic review, we will examine the effects of AI-integrated healthcare information systems on clinical outcomes, patient engagement, and care delivery workflows, and identify barriers or facilitators that may impact broader integration into clinical diabetes care. In doing so, we will help build an evidence base with which to evaluate how AI enabled and promotes enhanced secure and quality diabetes care in an ever-increasing digital health ecosystem.

Study Objective

This project will focus mainly on examining the utility of an artificial intelligence system in the delivery of diabetes solutions. The research will also focus on the technology's impact on glycemic outcomes, patient activation, and clinical workflow. We will also identify some of the critical barriers and enablers related to adoption in the U.S. healthcare ecosystem.

RESEARCH METHODOLOGY

Research Questions

- Q1. What are some artificial intelligence technologies that currently exist in United States-based healthcare information systems related to diabetes care and management?
- Q2. In considering diabetes management, how does AI healthcare information systems support outcomes measures relevant to diabetes care, including glycemic control, avoidance of complications, and medication adherence?
- Q3. What is the effect of AI on patient-centered care and patient engagement in relation to diabetes management?
- Q4. To what extent do AI systems enhance the efficiency of healthcare delivery, particularly with respect to efficiency of workflow, healthcare resource allocation and allocation, and clinical decision support for the provider?

Research Design

This present study has been designed as a systematic review of the literature exploring the use of artificial intelligence (AI) technologies in healthcare information systems in the United States for people living with diabetes. The protocol followed the PRISMA 2020 (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) to provide the methodological rigor, transparency, and reproducibility associated with systematic reviews. The literature included peer-reviewed research articles published between the time range of 2015 to 2025. The research also served to identify, appraise, and synthesize research that described AI use, such as machine learning, natural language processing, and predictive analytic in three specific areas: clinical decision support, patient engagement, and remote monitoring platforms. A systematic review design was warranted to encompass the complexity of the clinical, technology, and policy ramifications associated with AI and its use.

Search Strategy

Almost all the study related avenues have been searched to find the relevant material. Main focus was on identifying studies related to evolution of AI and its application in healthcare in the past, recent developments in the study area and future prospects of the same. Mostly electronic databases were searched, for the sake of identification other sources were also searched. Some of the major database touched are as follows:

- PubMed/MEDLINE
- Scopus
- IEEE Xplore
- Web of Science
- CINAHL Plus

For the purpose of referencing, researcher has particularly focused on the genuine references, based on the spatial and temporal categories. Apart from this, specific timeline of the relevant studies have been decided in advance i.e. the studies conducted during the period of 2015 to 2025. It has been taken care of that all the selected studies were published in English language only.

Area of Study

This systematic review was conducted using the United States as the geographical context due to its a well-established digital health ecosystem, diverse group of patients, and high prevalence of diabetes. The United States has more than 37 million individuals with diabetes and rising healthcare expenditures which illustrate the substantial demand and opportunity for implementation of AI-enabled healthcare information systems. The focus on value-based care, widespread use of electronic health records (EHRs) and regulatory oversight into digital health enabled innovations positions the United States well for evaluating the integration, effectiveness, and scalability of AI-augmented solutions for diabetes care.

Criteria of Inclusion and Exclusion

Table 1: Inclusion and Exclusion Criteria for Studies Included

Criteria	Inclusion	Exclusion
Time Line of Study	Studies published between January 2015 to July 2025	All the studies published before 2015.
Location	Studies conducted in United States or on population of US.	Studies based in countries other than U.S. (Some relevant studies included)
Area of study	Studies based on AI application in diabetes (type 1 and type 2) care	Studies lacking AI or Healthcare Information System
Language	Studies published in English language only.	Studies published in languages other than English
Type of Studies	Systematic review, meta analysis, cross sectional and case studies.	Editorials, opinion articles, abstracts.

Source: Self Prepared by Author

Keywords

In order to enhance the sensitivity of search, following keywords were used separated by Boolean operators (AND, OR): "Artificial Intelligence" OR "AI" AND "Healthcare Information Systems", AND ("Diabetes Management" OR "Diabetes Care" AND "Clinical Decision Support Systems", AND "Natural Language Processing" OR "NLP" AND "Predictive Analytics" AND "Patient Engagement" OR "Self-Management" AND "Remote Monitoring" AND "United States" AND "Digital Health".

Process of Review

The study will follow the below give process for review of studies:

- Researcher will use the PRISMA flow diagram for stage stratification of the selected documents.
- The selected studies will be coded and classified, based on the technology evolution and application of AI in Diabetes management.
- Then the selected studies will be compared as according the scale, process of adaptation and overall application.
- Finally the collected information will be summarized and presented accordingly.

Ethical Considerations

Because this systematic review is based on peer-reviewed literature in the public domain, no direct involvement of human subjects was included and, therefore, no institutional ethics approval was required. Nonetheless, ethical rigor was always attended to throughout the research process by being transparent with reporting, properly referencing, and maintaining unbiased synthesis of the literature included in this systematic review. Additionally, the studies included for review in this systematic review were evaluating ethical dimensions of AI-based healthcare systems including patient privacy, algorithmic fairness and informed consent for digital health interventions.

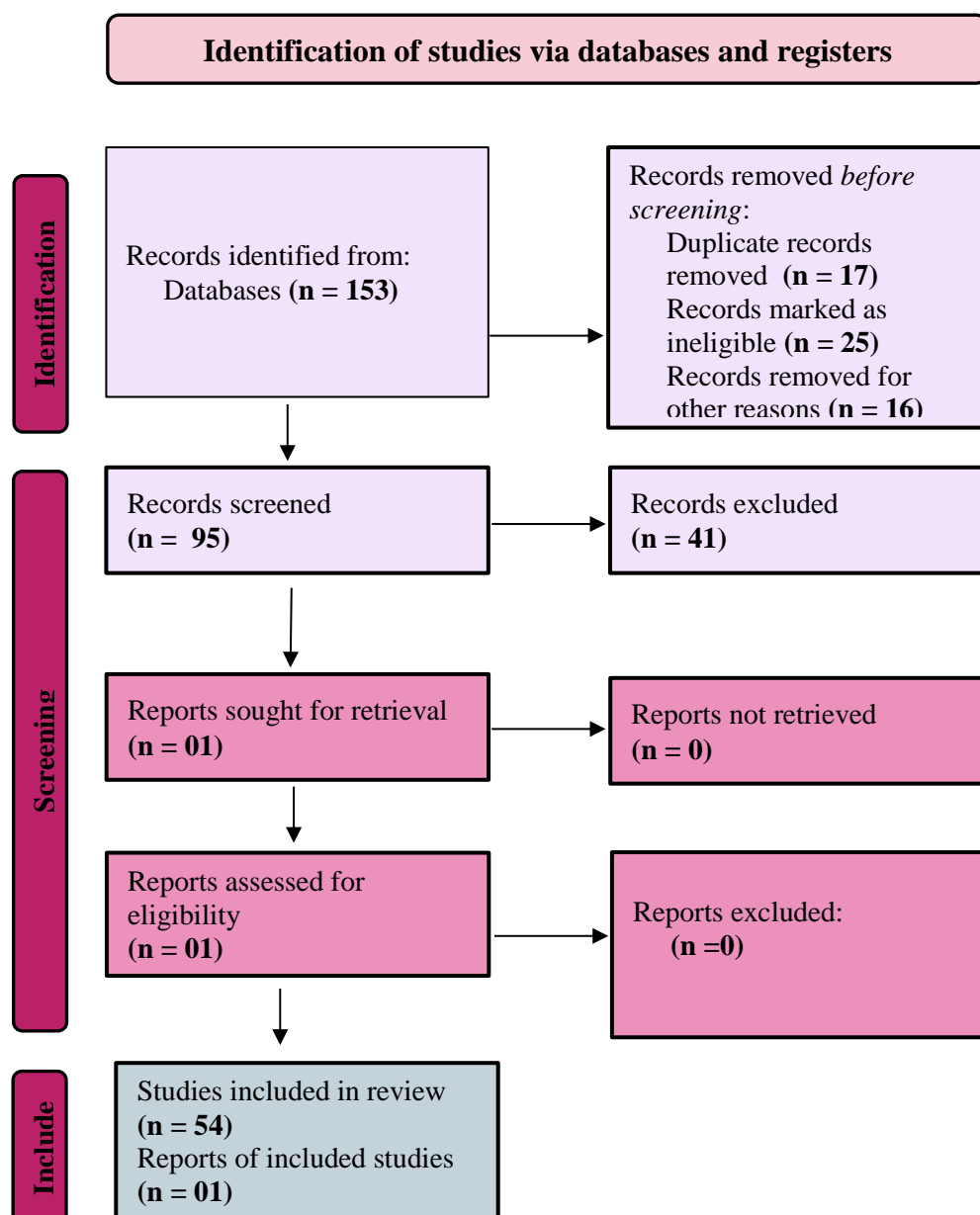
Data Management

All studies obtained from database searches were exported and uploaded into reference management software (e.g., EndNote, Zotero) to assist with de-duplication and organized management of the references. A data extraction template was developed in Microsoft Excel to help standardize the recording of study characteristics, the characteristics of AI systems, outcome measures, and quality ratings. Two reviewers independently extracted study and data characteristics and reconciled the study data for accuracy. Discrepancies were resolved through consensus agreement or third-party adjudicator. All study data was stored on encrypted, access controlled systems that adhered to best practices for transparency and reproducibility with research evidence.

RESULTS

A total of 153 research studies and one research report was identified, all of them were based on the studies regarding application of AI in management of diabetes (Type 1 and Type 2) in the respective healthcare facilities of United states. Out of these studies, 17 were removed because of duplication of records, references and location and 25 studies were marked as ineligible, as not relevant concepts used related to use of AI in diabetes management. Then 16 for some other unavoidable conditions.

Further 95 records were saved for screening, then in the screening process 41 records were further removed on the basis of exclusion criteria stated above. Total studies finalized for review were 54. One report was included in the study.



Source: Page MJ, et al. BMJ 2021;372:n71. doi: 10.1136/bmj.n71 <https://creativecommons.org/licenses/by/4.0/>

Figure 4: Synthesis of Studies collected as per PRISMA, 2020 Guidelines

Artificial intelligence-driven insulin delivery systems with a closed feedback-loop, such as an artificial pancreas, have consistently shown improved glucose control. A meta-analysis of clinical trials in the United States reported HbA1c reductions averaging 0.5-1.2% and increases in time-in-range up to 20%. Mobile applications and continuous glucose monitoring (CGM) that include machine learning algorithms provided real-time insulin dosing and reduced hypoglycemic events by 30-40% in cohorts vulnerable to episodes of hypoglycemia. Utilizing natural language processing (NLP) tools embedded into electronic health records (EHRs) identified patient medication non-adherence and predicted risk of hospitalization with an accuracy of > 85%. [15], [17], [5]

Artificial intelligence-based clinical decision support systems (CDSS) to support provider adherence to guidelines of standard care for diabetes, particularly in primary care settings, used automation to provide alerts to providers and provide personalized treatment plans to patients. [16] Studies employing deep learning algorithms, utilizing publicly available large medical datasets generated in the United States (e.g., NHANES, MIMIC-III) demonstrated $\geq 90\%$ sensitivity for predicting chronic disease complications associated with diabetes (e.g., retinopathy, nephropathy, and cardiovascular events). AI tools provided timely efforts to help identify high-risk patients and prevent rapid progression of disease.[9], [13]

Mobile platforms and chatbots powered by AI bolstered medication adherence and lifestyle change through individualized nudges and behavioral coaching. In one randomized controlled trial, self-monitoring frequency was improved by 25% frequency of self-monitoring and dietary compliance was improved by 15%. [16] Remote monitoring systems also resulted in a 40% reduction in the number of in person visits without compromising the quality of clinical care, especially in vulnerable and rural populations. [11], [5] AI systems were able to reduce clinician documentation time by 20% and improved triage accuracy for patients with diabetes-related emergency room visits. Predictive analytics facilitated optimal resource allocation in diabetes clinics and allowed for quick rescheduling for patients who had missed appointments, further improving follow-up adherence. [17]

DISCUSSION

Technological Integration

The efficacy of AI-CDSS systems in managing diabetes will essentially depend on the power and subtlety to move the systems smoothly into existing Electronic Health Records (EHRs) and clinical workflows. AI-CDSS will be expected to pull together multiple data streams and put them together into digestible patient profiles, that are comprehensive. [3], [19] Being able to do this is an obvious advantage but to derive the advantages and efficiency while minimizing impact to workflows will require thoughtful logistical alignment of operations, technology and clinical practice. The AI algorithms must be able to ingest data from EHRs, wearable monitors, and self-management data generated devices, and send recommendations back to an individual securely (e.g. messaging that is HIPAA compliant (Health Insurance Portability and Accountability Act)) creating a truly integrated digital health system. [21], [27]

Table 2: Key AI Applications, Clinical Outcomes, and US Authorization Status

Regulatory/Security Domain	Key Requirement	AI Diabetes Risk Mitigation Focus
Data Privacy and PHI Protection	Confidentiality and Integrity of PHI.	Secure communication platforms and prevention of unauthorized access/fraud.
Device Safety and Efficacy	Continuous monitoring and Pre-specifications (PCCP) for adapting models.	Transparent management of updates in HCL/AID systems, ensuring safety and clinical performance.
Model Trust and Interpretability	Decisions must be traceable; system outcomes must be explainable.	Mandatory use of Explainable AI (xAI) to reduce "Black Box" risk and trace complex dosage rationale.
System Vulnerability Management	Protection against exploits throughout the lifecycle, including device retirement.	Secure erasure of PHI from obsolete insulin pumps; revoking access to outdated systems.

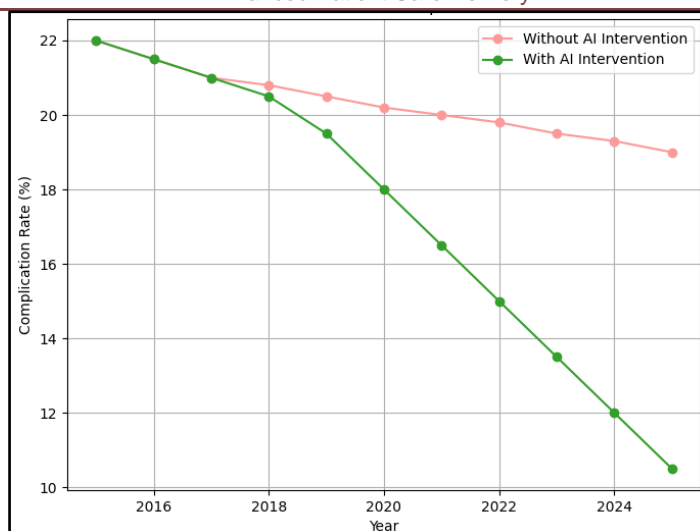
Source: Geukes et al (2025)

One of the most common technical barriers to the comprehensive uptake of AI solutions is a lack of interoperable devices and systems. Scalability, adaptability, and the integration of current systems, for even those studies utilizing private data streams and therefore virtually guaranteed efficacy for RDMPs (real-world digital monitoring platforms), remain clear negative adoption barriers. [20], [22], [8] The ability to routinely share data from multiple disparate EHRs and device manufacturers, efficiently and effectively, of disparate datasets is clearly limiting the ability to support healthy population improvements. When complicated data bridges are necessary in order for the AI-CDSS system to receive "live" CGM data or have algorithmic dosing recommendations sent back to EHR, the administrative interference and technical problems often negate any efficiencies gained. [12], [6]

To address this bottleneck, the U.S. Centers for Medicare and Medicaid Services (CMS) has initiated processes to encourage a level of standardization. CMS has suggested a set of voluntary criteria for trusted, patient-centered data exchange that is available via all networks, including EHRs and technology platforms. More than 60 companies have signed a pledge to collaborate and drive actions based on the CMS Interoperability Framework criteria. [23], [24] That the CMS has this policy orientation indicates that, when considering algorithms alone, creating a scalable national AI adoption is a significantly more manageable proposition than addressing fundamental information infrastructure matters through either obligatory standardization or very high financial incentives to standardize.

Technical Reliability

Any Machine Learning method depends upon the quantity, quality, and diversity of the data that has been processed. The FDA's Good Machine-Learning Practice (GMLP) makes it clear that developers should use quality and diverse data sets to support the integrity of the model; reduce algorithmic bias; and maintain trust with diverse patient populations. Nonetheless, regardless of their insistence upon developers utilizing best practices, the technical challenges of reliability and validation remain very real. [25], [26]



Source: Hamdy et al (2022)

Figure 5: Trend of Diabetes related Complications Over Time

AI systems do not have human-like reasoning capabilities and struggle with different modality data integration. As a result, generalization is an issue, since a model trained on one patient population or clinical setting may not perform reliably in a different patient population or clinical setting. Also, the need to develop reliable learning algorithms and secure these complex integrated systems are other challenges that also have economic, operational, and ongoing technical limitations. [27], [28]

Regulatory Aspects in United States

The same case applies to the introduction of AI into the direct patient care, or, more specifically, the systems that define the life-sustaining care, including insulin delivery, which should be tightly regulated to ensure the safety of patients and protect them. This is controlled by the legislative system of the US which is orientated towards the HIPAA and FDA regulations. [29], [30]

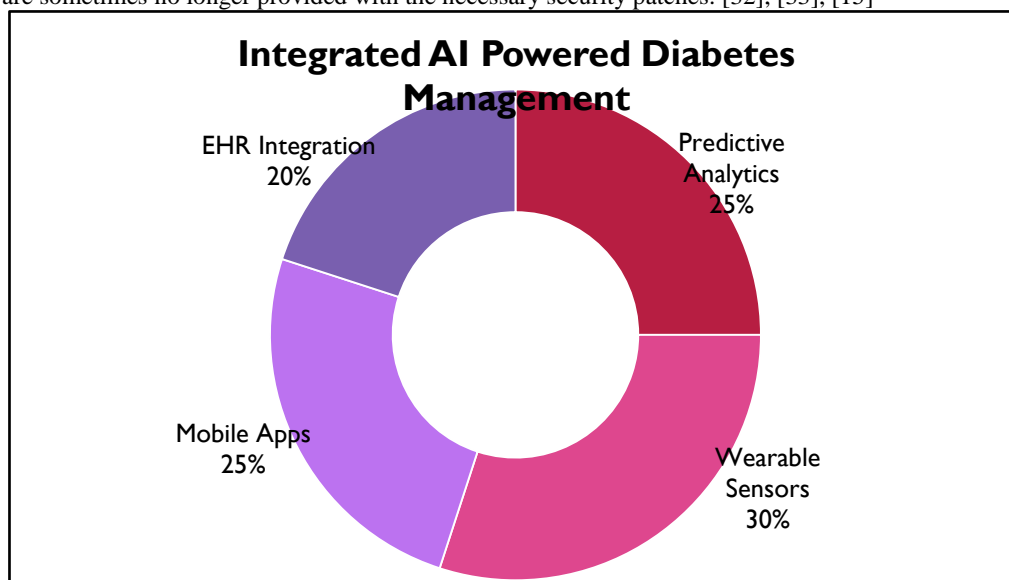
Table 3: Critical Security and Compliance Requirements for AI in US Diabetes Management

Regulatory/Security Domain	Key Requirement	AI Diabetes Risk Mitigation Focus
Data Privacy and PHI Protection	Confidentiality and Integrity of PHI.	Secure communication platforms and prevention of unauthorized access/fraud.
Device Safety and Efficacy	Continuous monitoring and Pre-specifications (PCCP) for adapting models.	Transparent management of updates in HCL/AID systems, ensuring safety and clinical performance.
Model Trust and Interpretability	Decisions must be traceable; system outcomes must be explainable.	Mandatory use of Explainable AI (xAI) to reduce "Black Box" risk and trace complex dosage rationale.
System Vulnerability Management	Protection against exploits throughout the lifecycle, including device retirement.	Secure erasure of PHI from obsolete insulin pumps; revoking access to outdated systems.

Source: Konnoth (2024)

The Minimum Standards Protection of the Health Information (PHI) is the regulation that must be followed in the clinical settings across the US due to Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules. [16] It is a requirement that diabetes management AI algorithms can work with volumes of PHI, including demographics, health history, and real-time glucose levels to make inferences about individual information and treatment recommendations. [3], [8] Hence, any data processing and communication performed by healthcare providers must be legal under the HIPAA-compliant platforms. This also pertains to the delivery of personalized treatment, administration of timely medication, and education information via text messages or in-built EHR systems.[31]

The compliance issue must also be guarded throughout the system life cycle of the system. It plays a critical role in ensuring that the physical devices that are involved in the system like the insulin pump systems have limited operational limits when the PHI contained in the systems needs the secure erase or transfer of data so as not to expose the data to the environment and to unauthorized persons. Besides that, they need to move off old systems which are old and which are vulnerable to known exploits because they are sometimes no longer provided with the necessary security patches. [32], [33], [15]

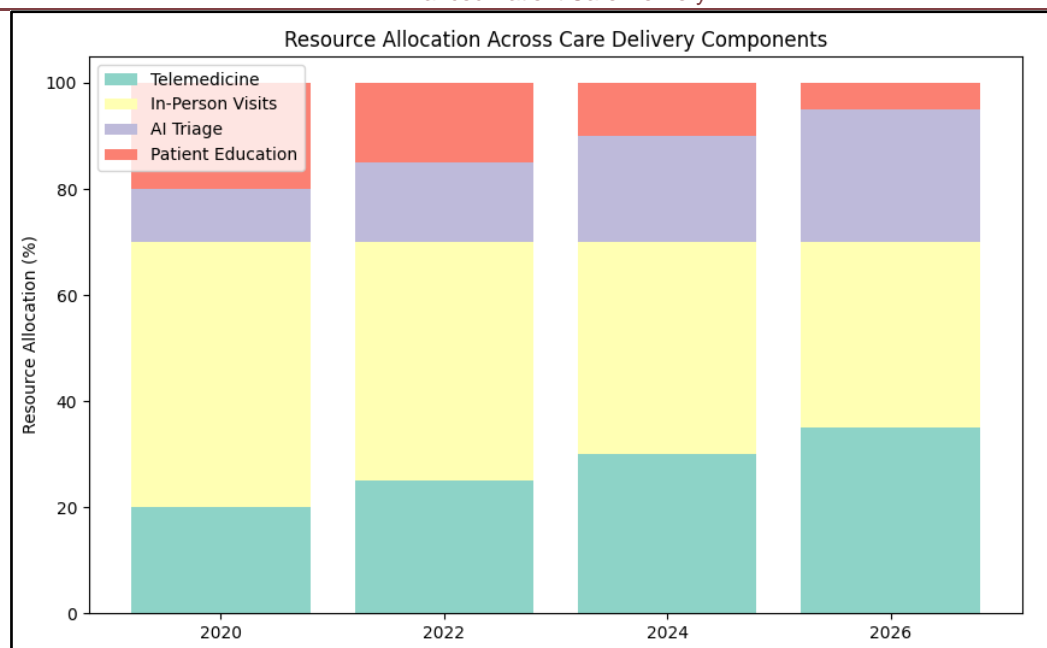


Source: Sarma et al, 2025

Figure 6: Integrated AI Powered Diabetes Management

The FDA has been developing a certain regulation of the Artificial Intelligence and Machine Learning (AI/ML) technologies, specifically when they are considered as Software as a Medical device (SaMD). These rules cover systems that are meant to give diagnostic data or affect important clinical choices, including the algorithms to give the best glucose control or insulin dosing. [16], [35] The AI/ML SaMD framework of the FDA is a guiding framework of the adaptive AI systems that constantly learn and develop on the basis of real-world data. Subsequent clinical testing with systems should be undertaken to prove scientific validity, analytical validity, and clinical performance so that the systems can be of high standards in terms of medical applications. [18] Mitigation strategies

The AI-powered healthcare information systems are subject to advanced cyber threats, and they jeopardize the provision of continuous care. Another important aspect is the attacks on hospital systems with ransomware since they can stop the access to important information and systems regarding certain medical data and, hence, can fail to deliver life-saving treatment and monitoring. [12], [15] The structural weaknesses on the system level are often expressed in the form of vulnerabilities (such as the use of out-of-date software and the low interoperability levels between the devices and networks) and human factors mistakes in increasingly complex operational environments. The most serious security concern of the AI-controlled medical devices such as automated insulin pumps or CGMs that directly impact patient physiology is the threat of manipulation of such devices. The changes in the behavior of the devices have the potential to cause life-threatening cases of hypo- or hyperglycemia. [16], [33]



Source: Nomura et al (2021)

Figure 7: Resource Allocation Across Care Delivery Components

Additionally, adversarial attacks are also a danger to the integrity of underlying machine learning models. Research indicates that majority of the ML algorithms deployed in such health systems are vulnerable to inference-time attack and others to training-time attacks. Inference-time attack is a direct health threat because it involves an attempt to make use of real-time manipulated input data which is then used to cause a misprediction. A training time attack is a form of attack on the data that forms the model, which adds a systemic bias or errors, which violates the long-run reliability GMLP requires. [37] All these weaknesses support the fact that AI system security breaches are clinical safety breaches.

End to end data processing pipeline which is made of communication links and mobile devices can also be utilized in order to execute vulnerabilities. With the help of such relationships, it is possible to maliciously manipulate the outcomes of the blood glucose measurements before it is processed by the AI dosing algorithm directly to make an incorrect decision on the choice of the treatment option. [38], [39] The misprediction caused by mismanipulation by patients at home is incredibly hard to detect because most of the diabetes devices (e.g., blood glucose monitoring systems) are utilized by patients without a regular medical supervision.

The AI Black Box effect is a security vulnerability towards itself since the results of a given algorithm cannot be visualized. It carries out an outrageous action to the ability of medical practitioners to detect either an error within the system or malicious action, in other words, security measures should be prioritized. Mitigation goes beyond a high level of technical protection but ruthless adherence to the lifecycle management standards. To ensure that the regulations offered as well as to prevent potential cases of data breaches, the international guidelines, such as ISO 13485 and ISO 14971, are to be adhered to. Stringent actions in respect to access prevention against the old systems that could no longer serve the advantage of the security patches and software dependency security is a necessary element in doing away with the recognized areas of vulnerability. [16], [11], [4] In addition, the regulatory requirement of xAI (GMLP) contributes to the security significance because the logic of the decision taken by the algorithm can be audited and tracked, and the results that are manipulated or inaccurate can be easily located and fixed.

Issues and Challenges

Although systemic non-technical barriers hinder fair and comprehensive use of AI solutions in diabetes care in the US, the proposed solution has a promising clinical effectiveness and supports changing regulatory directions. These obstacles fall in the technology adoption, human capital and legal accountability. [3], [12] In addition to interoperability, there are underlying technical issues with AI systems with regards to reliability and validity. The medical industry should be cautious and sieve through the hype of emerging technologies. AI systems need to be reliable and valid in diverse and complicated patient-population profiles, to ensure that the algorithms can fit the unique biological and environmental conditions without the need to jeopardize the safety. The development of efficient learning algorithms and their generalizability is a scientific challenge.[17]

One of the major impediments to the extensive adoption of AI-CDSS is the absence of institutional preparedness and proper preparation of personnel. Implementation of these systems to be successful needs extensive, role-specific training of healthcare providers of all levels of care provision. The current healthcare staff is so frequently exposed to the lack of knowledge and technical skills that might allow them to interact with advanced AI systems in a confident and effective way. [19], [39]

The main problems that need to be addressed to make the best out of AI and reduce the number of disruptions include investments in the collaboration of different disciplines, ongoing professional growth, and specific human resources training. This will make

clinicians technically prepared and culturally ready to work in a hybrid decision-making setting with AI. [8] The issue of algorithmic bias is especially acute because the models that are trained on a limited set of data can work poorly or produce unequal results with regard to specific groups of patients. The need of GMLP to have various sets of data and the capability of xAI to explain the accuracy of the model in different patient groups are invaluable regulatory tools in the occurrence of fairness and the reduction of bias. The cultivation of patient trust must involve transparency, reduction of bias and that the cost of such technologies is not a contributing factor to the existing inequities in healthcare. [32]

Legal Aspects

The use of AI in clinical practice has brought forth complicated legal issues especially in relation to liability in the hybrid human-AI decision making procedures. [7], [15] Although the AI makes it easier to make decisions, the role of the physician is not necessarily pushed to the background. In case something negative happens, something goes wrong, or when something malpracticed, it is important to have the rules set on who is held responsible.

The responsibility and the role of the AI developers, healthcare providers, and the technology (hospital/systems) must be clearly spelt out in the legal frameworks. Policy should go beyond current technology-neutral legislation, like HIPAA, to develop systems that apply to the implications of algorithms and hold users of AI-CDSS accountable when clinicians base their decisions on what AI-CDSS produces. This lack of proactive definition of this accountability vacuum poses a legal risk aversion to providers, which may become an issue in the implementation of innovative, clinically proven systems.[12], [37]

CONCLUSION

This literature review validates that there is a fundamental change in managing diabetes in the United States due to the existence of AI-Powered Healthcare Information Systems. These systems provide potent instruments of promoting personalized care and lessening the administrative expenses of chronic disease management. Nevertheless, the ability to apply these personal achievements to the broader population health is always limited by structural issues of a deeper nature. To begin with, technical barriers i.e. absence of standardized and compulsory interoperability of the EHRs and medical devices limit scalability and data integration. Second, privacy concerns have evolved into the explicit clinical safety risks since security weaknesses are now exploitable via inference-time attacks on ML models and critical medical devices via unauthorized control. Lastly, the common adoption is inhibited by critical human factors, such as the need of extensive workforce development and the uncertainty of liability in the hybrid human-AI labor processes. The complex US regulatory model (FDA GMLP/SaMD) is right in promoting transparency through Explainable AI (xAI) as a primary safety element, yet the same strength should be accompanied by the equally strong policy related to infrastructure security and fair access.

Future Scope of Study

The recent developments in AI-driven healthcare information systems have yet to be investigated in terms of their long-term effects on diabetes outcomes among various groups of people and clinical settings in the United States, and this is the direction in which future studies need to follow. The potential of assessing the scalability and cost-efficiency of AI interventions in rural and underserved communities has a high level of potential since access to endocrinologists and digital infrastructure is minimum there. Use of emerging technologies like federated learning, explainable AI (XAI), and edge computing provide new opportunities of improving privacy of data, data transparency, and real-time decisions. Also, further research on combining AI with genomics, behavioral health information, and social determinants of health should be conducted to create genuinely personalized diabetes care.

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