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Revolutionizing Diabetic Retinopathy Screening: Integrating AI-Based Retinal Imaging in Primary Care

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ABSTRACT

Diabetic retinopathy (DR) is a public health issue affecting millions in the United States and Europe. However, despite strong recommendations for screening at regular intervals by many professional societies, including the American Diabetes Association and the American Academy of Ophthalmology, screening rates remain suboptimal, with only 50–70% of patients with diabetes adhering to recommended annual eye exams. Barriers to screening include lack of awareness, socioeconomic factors, health care system fragmentation, and workforce shortages, among others. Artificial intelligence (AI)-based retinal screening tools offer promising solutions to improve DR detection in primary care settings. We describe a quality improvement and continuing medical education programme, starting in 2020, which has so far deployed 198 AI-equipped cameras in 5 health systems, covering approximately 151,000 patients with diabetes. To date, over 20,000 screenings were completed, with more than mild DR detected in more than 3,450 people, leading to specialist referrals for follow-up care. Notably, negative screenings potentially represent deferred specialist care. While AI adoption in healthcare presents challenges, its potential benefits in improving patient care and optimising resources are significant. Integrating AI-based DR screening with a comprehensive education and process improvement initiative in primary care practices warrants serious consideration, promising to enhance patient outcomes.

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Introduction to AI in Medicine

Integrating artificial intelligence (AI) into medicine marks a pivotal shift, transforming AI from basic decision rules into a powerful tool that analyzes complex medical data, aids in diagnoses, and predicts outcomes. Although AI's journey has seen challenges – such as IBM Watson's ambitious yet mixed implementation in oncology – its evolution and current use, particularly as in our intervention, demonstrates its utility to assist in delivery of patient care while alleviating specialist burden.

Today's advanced AI systems can enhance diagnostic accuracy, streamline workflows, and personalise care across medical specialities. One critical application is in diabetic retinopathy (DR), a leading cause of blindness that requires timely screening for effective intervention. Despite recommendations for regular screening from organisations like the American Diabetes Association (ADA) and the American Academy of Ophthalmology (AAO), and the European Society of Retina Specialists (EURETINA), DR screening rates remain suboptimal.

This manuscript examines the "Saving Sight: Vision Protection & Blindness Prevention in Diabetes" initiative, which integrates AI-based DR screening in five health systems' primary care offices, along with primary care clinicians' continuing medical education. We explore the initiative's design, implementation, and outcomes, emphasising the educational framework and AI's role in improving DR screening.

Diabetic Retinopathy

DR is a significant public health issue in the United States. As of 2021, an estimated 9.6 million people were living with DR, with 1.84 million of those cases being vision threatening [1,2]. Despite the high prevalence of DR, screening rates in primary care settings remain suboptimal. Only about 50–70% of patients with diabetes adhere to the recommended annual eye exams [3–5]. Specifically, in 2020, only 58.3% of adults diagnosed with diabetes had an eye exam within the last year, a decrease from 64.8% in 2019 [6]. Screening

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rates are even lower among specific demographics, with annual eye exams being less common among Black (48.9%) and Hispanic (48.2%) individuals compared to non-Hispanic White individuals (55.6%) [3].

Multiple factors can contribute to the low screening rates for DR, including lack of awareness and education, socioeconomic and geographic barriers, health system barriers, and delayed referrals and access issues [7]. Many patients with diabetes are unaware of the importance of regular eye exams and the asymptomatic progressive nature of early DR [3,4], but patient education has been shown to increase screening [5]. The fragmented nature of the US healthcare system complicates the establishment and funding of centralised screening programmes. Lastly, delayed referrals from primary care physicians (patients skipping referrals due to lack of insurance) and limited access to eye care providers further hinder timely screening [3,4].

The ADA and the AAO have similar but slightly different guidelines for screening people with diabetes for DR. Both recommend that patients with type 1 diabetes have their first dilated eye examination within five years of diagnosis and patients with type 2 diabetes have their first dilated eye examination at the time of diagnosis of their diabetes [7,8]. However, the recommendation for the interval for screening is every 12 months per the AAO and up to every two years for patients with no or minimal retinopathy upon prior screening per the ADA [7,8]. Both also recommend prompt referral to an ophthalmologist for patients with any level of macular oedema, severe non-proliferative DR, or proliferative DR [8,9].

Except for the UK, the situation in Europe is similar. Screening rates for DR vary significantly across the five major European countries, reflecting differences in healthcare systems, access to specialised care, and national initiatives. The UK leads with the highest screening rate, achieving approximately 80–88% coverage through its well-established national programme and the integration of advanced technologies like teleretina models and AI-assisted screening. According to the WHO, while most countries in the EU region have some sort of DR screening in place, it essentially is unorganised/unsystematic and predominantly carried out by ophthalmologists, and that some countries/regions lack equipment for effective screening and treatment [10]. The European Society of Retina Specialists (EURETINA) guidelines recommend DR screening that includes annual screening visits, as allowed by local EU country healthcare authorities and patient risk factors. They also highlight the need for patient education and systemic management of diabetes to prevent vision loss [11].

A 2023 study estimated that 9.6 million people in the United States live with DR, translating to a 26.4% prevalence among those with diabetes, with 5.1% experiencing vision-threatening DR (VTDR) [12]. The global prevalence rate among individuals with diabetes is estimated at 30–40% [13]. Another 2023 study found a high DR prevalence with about 5–10% of patients with diabetes advancing to vision-threatening stages, underscoring the need for early screening and risk factor management [14].

Addressing the barriers to screening, such as improving patient education and enhancing the coordination of care, is crucial to increase adherence to screening guidelines, potentially reducing the effects of the socioeconomic and geographic disparities, and prevent vision loss associated with DR. By implementing AI-based retinal screening in the primary care setting, we set out to improve screening rates and outcomes for patients with diabetes.

AI-Based Retinal Screening Tools Currently Available

In recent years, AI-based tools for DR screening have gained FDA approval, marking considerable progress in autonomous detection technology for healthcare. Notable among these are IDx-DR (LumineticsCore), EyeArt by Eyenuk, and AEYE Diagnostic Screening (AEYE-DS). The EyeArt tool has been extensively validated in both multicenter trials and real-world clinical settings, achieving high sensitivity (95.5%) and specificity (86%) in detecting referable DR and vision-threatening DR. Its rapid, in-clinic screening capability has made it valuable for point-of-care diagnostics. The AEYE-DS tool is a portable, FDA-approved tool that supports screening in diverse settings, including remote locations, using a handheld device [15,16]. The LumineticsCore™, initially called IDX-DR uses a Topcon fundus camera, which does not always require that the pupils are dilated, to capture retinal images. The images are then analysed by AI diagnostic software to detect the presence of DR. To train the AI for detecting DR, large datasets of retinal images were collected and annotated by medical experts. These images are then used to train a convolutional neural network through supervised learning, optimising the model's parameters to accurately identify DR. The model's performance was validated and tested using metrics such as accuracy, sensitivity, and area under the receiver operating characteristic curve, ensuring robust detection capabilities when deployed in the LumineticsCore™ system. The sensitivity and specificity for detecting more than mild DR are 87.4% and

89.5%, respectively, which exceeded the superiority endpoints defined in the study [17,18]. In real time, the algorithm assesses the images and creates an alert with either "No Diabetic Retinopathy Detected" or "Diabetic Retinopathy Detected". When the system cannot analyse provided images accurately, a message that says "Exam Quality Insufficient" is generated. The patient's need for subsequent expert follow-up is determined by the AI-based system within moments of capturing the image [19]. In Europe, LumineticsCore™ is certified as a Class IIa medical device, meeting the Medical Devices Regulation requirements for diagnosis software [20].

The Saving Sight Programs

Methods

DKBmed developed *Saving Sight*, a continuing medical education and quality improvement (QI) initiative designed for primary care clinicians (MD/DO, NP, PA, and RN) treating patients with diabetes. The first iteration of the activity, which began before the FDA authorisation of the AI-based device, used a retinal camera that sent images via software that maintained patient privacy to a remote ophthalmologist, who read the images and returned results. However, subsequent interventions have used AI-equipped cameras. The initiatives were supported by independent medical education grants received from Regeneron Pharmaceuticals.

Since its inception, the Saving Sight initiative has been implemented at many healthcare systems; the first five using AI-equipped cameras are described in this review. The initiative employs a multimodal approach that is illustrated in the figure below (Figure 1).

Clinician education focuses on the pathophysiology of DR and the importance of regular screening and prompt referral for DR. The educational content also covers the burden and risk factors for DR, current therapies, and the implementation of retinal screening using AI-equipped cameras in clinical practice. The learning objectives of the activity were: (1) Describe ADA/AAO screening recommendations, (2) Explain the pathophysiology of DR and the importance of regular screening for DR, and (3) Describe the benefits of current treatment options for DR, including VEGF inhibitors.

Following the educational phase, Topcon fundus cameras equipped with LumineticsCore™ were installed in the health systems, and medical staff were instructed on its use. Simultaneously, the electronic health record was updated to include a reminder to prompt the medical staff to encourage DR screening when appropriate. In addition, a referral network was established to ensure proper follow-up, employing dedicated referral coordinators and patient navigators to facilitate consultations and collaborative care with ophthalmologists for all patients screening positive for DR or for those who otherwise warrant consultation (e.g. insufficient image capture using the AI-equipped device).

Concurrent with these clinical interventions, patient education about the asymptomatic progressive nature of DR and the importance of regular screening and, when warranted, early treatment was provided via posters and handouts.

The programme's educational effectiveness is measured using Moore's Level 1–5 educational outcomes for all learners, assessing changes in knowledge, competence, confidence, and practice strategies. Additionally, outcomes will be captured to measure

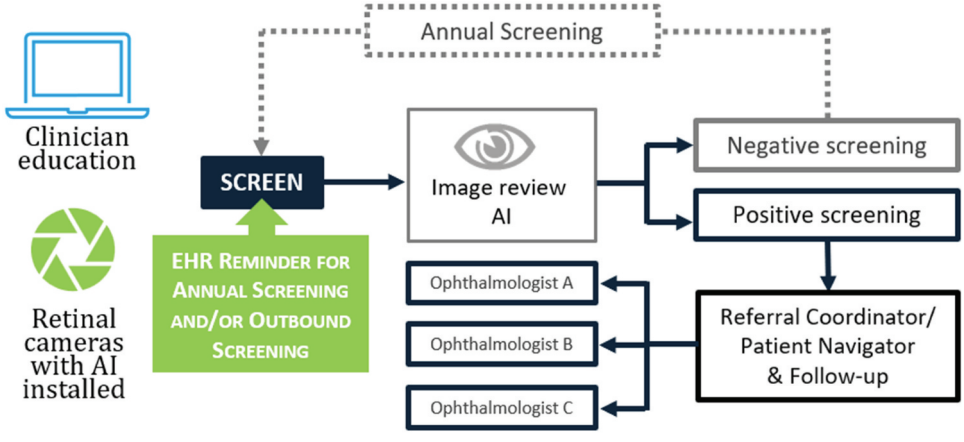

Figure 1. Overview of the program design. Patients with a positive screening result worked with a referral coordinator to set up a specialist appointment with a community ophthalmologist.

Moore's Level 6 outcomes of the programme's impact using EHR and claims data by treatment class for all patients [21]. The claims data assessment sought to determine whether the intervention led to a measurable increase in DR screenings, specialist referrals, and treatment rates for patients with DR or DME among each systems' population of patients with diabetes. The claims analysis employed rigorous methodological controls to ensure data reliability. A 1:1 matching protocol paired intervention patients with control patients based on multiple criteria, including demographics (age, gender, payment type, geographic location), previous DR screening history, and provider type. Random selection of control patients minimised potential biases, with additional controls implemented to ensure consistent data reporting across both cohorts. A historical review period (January 2022 – December 2022) examined claims data, establishing a baseline for comparison during the intervention period (January 2023 – December 2023).

Results

As of mid-2024, 198 AI-equipped cameras have been deployed in 5 health systems, covering approximately 151,000 patients with diabetes. For the purpose of this review, we will discuss the results of our education and screening intervention at one specific health system, which has one full year of data.

Education

Knowledge was assessed by asking learners specific questions (multiple choice, with one correct response) that addressed the identified learning objectives. Questions were asked both before and after the learners participated in the education, allowing us to measure any change in knowledge that occurred because of participation in the education.

For example, we asked, "How often should screening occur for patients with T2DM and no evidence of retinopathy on previous examinations, according to the American Academy of Ophthalmology (AAO) guidelines?" to measure knowledge of screening recommendations, and we asked, "Which of the following statements about anti-VEGF agents in patients with diabetic macular oedema is CORRECT?" to assess knowledge of current treatment options.

Educational outcomes from one health system with completed data, shown in the table below (Table 1), demonstrate that clinicians gained knowledge.

Screening

To date 20,160 patients have been screened. Of these screenings 14,553 (72%) were suitable for diagnosis; of those, 3,460 (24% of suitable screenings) cases of DR were identified, enabling timely referrals and interventions to prevent vision loss. Notably, the remaining 76% of suitable screenings potentially represent deferred specialist care.

Claims and Electronic Health Record (EHR) Data

Data are not yet available for all included systems; therefore, we provide claims and EHR data for one system that has finalised outcomes.

The claims data revealed a marked increase in DR screenings, with a 118% increase in screening for patients visiting the system's primary care providers compared to baseline levels, with statistical significance at the 90% confidence level. The claims analysis also showed a significant 23% increase in referrals to ophthalmologists for the intervention group compared to the control group. Lastly, the initiative achieved a significant 27% increase in new anti-VEGF treatments for DME among the system's patients compared to controls.

Discussion

The programme successfully increased ophthalmologist referrals, aligning with its objective of ensuring appropriate care escalation for patients with DR. The integration of AI-based screening and structured follow-up procedures in primary care settings drove an increase in specialist referrals among intervention group patients. Additionally, a statistically significant increase (90% confidence level) in vascular endothelial growth factor (VEGF) inhibitor treatments for DME was observed among intervention group patients compared to controls.

Table 1. Educational outcomes.

Learning objective	Pre-activity	Post-activity	Change in knowledge
Describe ADA/AAO screening recommendations	65.1%	82.8%	27.2%*
Explain the risk factors for DR and importance of regular screening for DR	41.7%	74.0%	77.5%*
Describe benefits of current treatment options for DR, including VEGF inhibitors	50.1%	83.3%	66.7%*

*Denotes statistical significance, $p < 0.05$.

With the establishment of new workflows and educational practices during the initiative, the healthcare system plans to maintain these improvements post-intervention. Through continued optimisation of the referral process and permanent integration of AI-assisted screening devices in primary care settings, the system anticipates sustained improvements in screening rates and timely referrals.

AI has emerged as a powerful tool with the potential to improve patient care by integrating into existing workflows and EHR. The AI-based screening tools provide easy screening for DR, provide immediate feedback, and connect patients with specialist care as needed. However, the integration of AI-based screening tools in primary care settings faces a significant challenge: physicians' hesitancy to adopt innovative technologies. Despite being at the forefront of medical advancements, physicians are often slower to adopt innovative technologies, particularly AI. This phenomenon has been extensively studied using the Technology Acceptance Model, consistently highlighting two critical factors influencing adoption: perceived usefulness and ease of use [22,23]. While this initiative was not designed to study clinician adoption of this technology, it is also essential to consider other challenges faced by primary care physicians and ophthalmologists.

The burden of care placed on primary care physicians (PCPs) and ophthalmologists in the United States is highlighted by several critical issues, including high burnout rates, administrative burdens, workforce shortages, and underinvestment in primary care in general [24]. According to research published in 2024, 50% of PCPs and 37.8% of ophthalmologists reported experiencing burnout, compared to 42% in 2018 and 48% in 2023, respectively [24,25]. Key contributing factors to burnout among ophthalmologists include low work control and insufficient time allocated for necessary documentation tasks. However, for AI-based DR screening to gain traction among PCPs, it must not add to the burdens of their practice while demonstrating clear benefits to patient care. Conversely, ophthalmologists will benefit from a decrease in the screening burden for patients where screening is not warranted.

Implementing AI-based DR screening in primary care settings offers advantages that can significantly improve patient care and practice efficiency. Automated systems can integrate into existing workflows, generating reports directly into electronic health records. This streamlined process enhances efficiency and facilitates improved patient communication, as easily generated reports enable PCPs to discuss eye health with patients more effectively. The ease of use and instant readout of screening results provide immediate feedback, enabling timely interventions and enhancing patient education opportunities. Furthermore, AI-based cameras present a cost-effective alternative to traditional screening methods, making comprehensive eye care more accessible and economically viable for primary care practices and patients.

To encourage PCP buy-in and overcome adoption barriers for AI-based DR screening, a multifaceted approach is essential. Comprehensive education forms the foundation of this strategy, providing in-depth training on AI's impact on healthcare, including its rationale, benefits, and ethical considerations. This educational effort should be complemented by comparative analyses highlighting the improved outcomes and efficiency of AI-based retinal screening tools compared to standard care screening. Addressing privacy concerns is crucial, with focused training on AI systems' reliability, accuracy, and data security measures to alleviate concerns about patient privacy.

Studies comparing AI-based and manual clinician screening for DR provide valuable insights into efficiency, sensitivity, and practical outcomes. A study conducted in India evaluated a deep-learning algorithm alongside manual grading by trained clinicians and found the AI's performance to be on par with or superior to manual methods [26]. Several studies have documented the high sensitivity and specificity of AI-diagnostic retinal devices [17,18]. These results suggest that AI can match clinician accuracy in detecting referable DR, with the added benefits of speed and scalability, which are particularly useful in high-demand settings where physician availability is limited.

Another study analysing the outcomes of AI screening in a U.S. telemedicine setting showed that AI screening could effectively identify cases needing referral, achieving a triage function that expedited care pathways [27]. This study found that AI-based systems also increased follow-up rates for DR-positive patients, likely due to faster reporting and streamlined workflows compared to traditional teleretinal programmes. These findings collectively indicate that AI not only supports manual efforts but may also increase screening efficiency and access to care in underserved or high-need areas, effectively complementing the role of human clinicians while maintaining high diagnostic standards.

These comparisons highlight AI's potential to relieve workload pressure on healthcare providers and enhance early intervention strategies, a critical component in managing the growing global DR burden. This synergy of AI and clinician-led care enhances the quality of care by combining human expertise with the consistency and speed of automated analysis.

Assumptions and Limitations

Important limitations of this initiative and its evaluation should be acknowledged. First, while the programme shows promising initial results, we lack overall long-term outcome data from all five systems. We did not collect

information on how often screening offers were declined and why screening may have been deferred/declined when offered. Additionally, we did not collect data on patient satisfaction or compliance with referrals, making it difficult to assess the initiative's impact across different patient populations. It is the intention of the programme developers to measure the value of an actual person vs. an electronic referral for specialist care in future iterations of this initiative.

From an implementation perspective, our analysis would benefit from a more detailed examination of resource requirements, failed implementation attempts, and specific challenges encountered across different practice settings. The financial sustainability of the programme beyond the initial grant funding remains uncertain, as we did not conduct a formal cost-effectiveness analysis or thoroughly examine reimbursement challenges. Future iterations of this initiative would benefit from addressing these gaps through more robust data collection and analysis, particularly focusing on patient-centred outcomes, implementation challenges, and financial viability in different healthcare settings.

Beyond the technical applications in DR screening, AI plays a transformative role in continuing medical education (CME) by personalising learning experiences, enhancing data analytics, and facilitating real-time skill development for healthcare professionals. Modern CME platforms are leveraging AI to tailor educational content based on individual learning preferences and performance data, making CME more targeted and effective. AI-powered systems analyse clinical data and identify learning gaps, prompting timely educational interventions. Additionally, advanced simulations using AI can recreate complex patient scenarios, allowing healthcare professionals to practice decision-making and procedural skills in a safe, controlled environment. This integration of AI ensures that CME remains responsive to the rapidly evolving medical landscape, equipping healthcare professionals with the knowledge and skills necessary to adapt to new technologies and treatment methodologies efficiently [28,29].

Continuing education and open dialogue about AI in healthcare will be essential in fostering acceptance of these valuable tools. As the healthcare landscape evolves, the integration of AI-based DR screening in primary care practices warrants broader adoption to enhance patient care and optimise healthcare resources [30].

Conclusion

In conclusion, our initiatives demonstrate that AI-based screening for DR can be effectively implemented and accepted in primary care practices, and it is a valid model for improving diabetic eye care. We emphasise the value of early intervention and multidisciplinary collaboration in preventing vision loss among patients with diabetes.

The advancements in AI-enhanced healthcare have significant implications for medical professionals and patients. As AI becomes more integrated into healthcare, practitioners must evolve their skill sets to interact with and interpret AI-assisted diagnoses and treatments effectively. This evolution will likely change traditional workflows, potentially increasing efficiency and reducing the daily burden on PCPs. However, it also requires medical professionals to navigate new ethical considerations, such as data privacy and algorithmic bias. Financial challenges, such as limited budgets, may persist as AI becomes more prevalent in healthcare. PCPs will need to stay informed about evolving resource allocation to advocate for increased AI utilisation within their practices. This shift, while challenging, has the potential to significantly improve efficiency, patient care, and outcomes, offering hope for the future of healthcare.

Continuous learning, as provided in our initiative, will become even more crucial as AI technology rapidly evolves, costs decrease, and implementation of AI becomes more widespread in clinical practice. While AI may manage routine tasks, the importance of human empathy and complex decision-making in patient care will likely increase, reshaping the nature of healthcare professional-patient interactions. As Eric Topol suggests, the AI revolution may allow medicine to become more human by freeing healthcare workers from administrative tasks, enabling them to focus on providing the empathy many patients expect [31].

Disclosure Statement

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