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VISION ACADEMY VIEWPOINT

The Vision Academy is a partnership between Bayer and ophthalmic specialists, established with the aim of addressing key clinical challenges in the field of retinal diseases

Current Status and Impact of Artificial Intelligence Use in Screening, Diagnosing, and Managing Retinal Diseases

Background

The application of artificial intelligence (AI) technologies in screening, diagnosing, and managing retinal diseases has the potential to shape modern healthcare ecosystems within ophthalmology. These promising new technologies may be able to improve the efficiency of existing healthcare pathways for screening and diagnosis and provide personalized treatments and risk scores for various retinal diseases. Furthermore, the establishment of AI-enabled technologies may provide better patient-centered services, minimize the impact of labor shortages, and bridge the healthcare gap between urban and rural areas.

A review of the literature and available evidence[1,2] was conducted to:

- Define the "state-of-the-art" in AI technologies in the field of retinal disease
- Provide recommendations on applying such technologies in diagnosing and managing retinal diseases

Endorsed by the Vision Academy in August 2023.

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Viewpoint

The Vision Academy recognizes the advantages of AI technology and has outlined the capabilities of AI to predict functional and structural changes during retinal disease, as well as treatment outcomes.[1,2] The use of AI technology should be of additive and synergistic value to the current standards of care.

The key domains surrounding the application of AI-enabled technology for diagnosis, screening, and disease management in real-world practice include data standardization, sharing, and safety; practicability of AI in clinical trials and telemedicine; the regulatory environment; and balancing profit and cost. The Vision Academy makes the following recommendations for applying such technologies in diagnosing, screening, and managing retinal diseases:

Recommendation 1: Integration of meta-data* and data sets for diagnosis and screening

The integration of meta-data, including multimodal images and structured clinical information from multiple data sets with different ethnic groups, and the establishment of a digital data processing and sharing system will empower data-driven AI technologies in ophthalmic practice. Ongoing research will be needed to build up data storage and sharing systems in a cybersecurity framework for broader use.

Recommendation 2: Use of AI in disease management

The Vision Academy recommends the application of AI medical devices to improve treatment outcomes and alleviate treatment burden for both patients and healthcare providers. The technology should be cost effective, with additive value and synergy for the healthcare system. These technologies should be implemented into everyday clinical practice for screening, quantification of biomarkers to guide treatment, prognosis of retinal pathology, and prediction of treatment outcomes via anatomical and functional biomarkers.

*Meta-data are data that describe and give context to other data.

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The Vision Academy is funded and facilitated by Bayer. This document was prepared on behalf of the Vision Academy by the Vision Academy Retinal AI Workstream, which comprises Yu-Bai Chou, Carla Danese, Aditya U. Kale, Tariq Aslam, Paolo Lanzetta, Jane Barratt, Bora Eldem, Nicole Eter, Richard Gale, Jean-François Korobelnik, Igor Kozak, Xiaorong Li, Xiaoxin Li, Anat Loewenstein, Paisan Ruamviboonsuk, Taiji Sakamoto, Daniel S.W. Ting, Peter van Wijngaarden, Sebastian M. Waldstein, David Wong, Lihteh Wu, Miguel A. Zapata, and Javier Zarranz-Ventura. The opinions expressed, and guidance laid out, by the Vision Academy are developed independently by the members and do not necessarily reflect the opinions of Bayer.
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Recommendation 3: Transparency surrounding data privacy and from regulatory authorities

While AI technologies could reidentify biometric information in retinal images, care should be taken when collecting and processing images. Some novel learning tasks can obscure bioidentical information or even provide unsupervised models for small-scale data sets. Standardizing data formats will be one of the key factors for extending the scalability and generalizability of AI-enabled technologies. An adequate balance between data privacy and transparency should also be maintained.

More transparency from regulatory authorities through publicly accessible databases is desired, and more prospective studies are needed for the validation of AI medical devices. It would also be advisable to increase transparency around the composition of training AI algorithms; they should be representative of the overall population, of adequate quality and quantity, and accessible to regulators. The end user running each AI medical device and their degree of responsibility need to be specified, especially in the event of errors or litigation.

Recommendation 4: Sensitivity, specificity, and validation

AI medical devices should have high sensitivity and specificity thresholds, and each algorithm in use should be validated. Validation and regulation should be defined according to international standards. Working parameters need to be well defined and the system should not be used outside of these parameters. Image data should be shared anonymously among various medical centers and countries, and such data sharing should be encouraged to overcome data poverty and ensure that AI medical devices are equally effective for all patient populations.

Recommendation 5: Implementation of AI in clinical practice

The role of AI-enabled technologies in the real world is not to replace ophthalmologists but to assist them and to hybridize both AI models and human experience to result in more efficient and accurate decisions. Such time-saving abilities could streamline medical procedures, giving clinicians more time to communicate with their patients. However, improper implementation of AI could harm doctor–patient relationships and could affect patients' trust if AI algorithms were used only for improving workflow but not patient care.

Recommendation 6: Non-retina specialist users and home monitoring

For AI devices that potentially do not need guidance from retina specialists, it is necessary to verify whether they can be deployed for use in the real world while maintaining high accuracy in clinical practice. Therefore, pathways for specialist referral and streamlined treatment need to be developed in parallel. Care pathways should ensure the capacity to follow up with and treat an increasing number of patients, and the workflow for the management of retinal diseases needs to adapt to new settings.

Recommendation 7: Ethical concerns and regulatory issues

A key hurdle in deploying AI-enabled technologies in clinical practice is the possibility of ethical and legal ramifications in the event that the algorithm makes a mistake in the diagnosis, prognosis, or treatment decisions and results in harm to the patient. Healthcare providers should thoroughly consider ethical and legal consequences and still take full responsibility for being aware of the capacity of AI models. Additionally, the degree of autonomy the AI medical device has in deciding the management of each patient should be discussed. In cases of poor predicted outcomes, adequate communication with the patient should occur.

The legal boundaries between developers and healthcare providers are still unresolved, and as the implementation of AI becomes more popular, legislative and governance systems need to be concretely established to refine liability rules and the regulatory environment. Policy and specific authorities should be set up not only for verification of AI models but for data security and legal liability. Cross-sector and cross-disciplinary collaborations will be important to ensure the integrity of AI healthcare ecosystems. The position of insurance companies regarding AI-based predictions should also be clarified.

Summary of current AI systems with regulatory approval for different retinal diseases[1,2]

AI system (company)	Year approved	Target disease	Imaging modality	Impact on prognosis	Regulatory status in the United States, Europe, and elsewhere
Intelligent Retinal Imaging Systems[3,a,b] (IRIS; Intelligent Retinal Imaging Systems, Pensacola, FL, USA)	2015	DR	Fundus photography	NA	FDA clearance (class II)
Automated Retinal Disease Assessment[4,a,b] (ARDA; Google LLC, Mountain View, CA, USA)	2016	DR	Fundus photography	NA	CE mark
SELENA+[5,a,b] (EyRIS Pte Ltd, Singapore)	2019 and 2020	AMD, DR, glaucoma	Fundus photography	NA	CE mark, HAS approval (Singapore)
IDx-DR[6,a,b] (Digital Diagnostics Inc., Coralville, IA, USA)	2018	DR, including DME	Fundus photography	NA	FDA approval
Medios AI[7,b,c] (Remidio Innovative Solutions Pvt Ltd., Karnataka, India)	2023	DR, glaucoma	Fundus photography from smartphone-based camera	NA	CE mark
RetCAD[8,a,b] (Thirona Retina BV, Nijmegen, the Netherlands)	2022	AMD, DR	Fundus photography	NA	CE mark
EyeArt[9,a,b] (Eyenuk, Inc., Woodland Hills, CA, USA)	2015 and 2020	DR	Fundus photography	NA	FDA clearance (class II), CE mark
VUNO Med-Fundus AI[10,a,b] (VUNO Inc., Seoul, Korea)	2020	AMD, DR, glaucoma	Fundus photography	Strict follow-up	CE mark (class IIa), MFDS approval (Korea, class III), HAS approval (Singapore)
THEIA[11,a,b] (Toku Eyes, Auckland, New Zealand)	2020	AMD, cataract, DR, smoking status	Fundus photography, OCT-A	NA	In progress
iPredict[12,a,b] (iHealthScreen Inc., Richmond Hill, NY, USA)	2021 and 2022	AMD, DR, glaucoma	Fundus photography, OCT	Prediction of progression	CE mark, TGA approval (Australia)
Notal Home OCT[13,a,d] (Notal Vision, Inc., Manassas, VA, USA)	2018	Neovascular AMD	OCT	Early detection of fluid	FDA (Breakthrough Device Designation)
Notal OCT Analyzer[14,a] (Notal Vision, Inc., Manassas, VA, USA)	2018	DME, neovascular AMD, RVO	OCT	Automated detection of fluid	FDA (Breakthrough Device Designation)
OphtAI[15,a,b] (Evolucare/ADCIS, Villers-Bretonneux, France)	2019	AMD, DME, DR, glaucoma	Fundus photography	NA	CE mark, HC approval (Canada), FDA in progress
Retmarker[16,a,b] (Retmarker, SA, Taveiro, Portugal)	2010	AMD, DR	Fundus photography	NA	CE mark (class IIa), TGA approval (Australia)
Retmarker DR Biomarker[17,c] (Retmarker, SA, Taveiro, Portugal)	2010	DR	Fundus photography	Identification of the risk of complications	CE mark, TGA approval (Australia)
RetinaLyze[18,a,b] (RetinaLyze System A/S, Hellerup, Denmark)	2021	DR, dry AMD, glaucoma	Fundus photography, OCT	NA	CE mark (class I, self-certified)
RetinAI Discovery[19,a,b] (RetinAI Medical AG, Bern, Switzerland)	2022	AMD, DME, DR, RVO	Fundus photography, OCT	Strict follow-up	FDA clearance (class II), CE mark
RetInSight Fluid Monitor[20,a] (RetInSight GmbH, Vienna, Austria)	2022	AMD, DME	OCT	Automated detection of fluid	CE mark

[a]Cloud-based; [b]Target user is the healthcare provider; [c]Not cloud-based; [d]Target user is the patient.

AMD, age-related macular degeneration; CE, Conformité Européenne; DME, diabetic macular edema; DR, diabetic retinopathy; FDA, U.S. Food and Drug Administration; HAS, Health Sciences Authority (Singapore); HC, Health Canada; MFDS, Ministry of Food and Drug Safety (Korea); NA, not applicable; OCT, optical coherence tomography; OCT-A, optical coherence tomography angiography; RVO, retinal vein occlusion; SELENA, Singapore Eye LEsioN Analyzer; TGA, Therapeutic Goods Administration.

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Further considerations

More prospective and real-world studies are needed to validate AI medical devices, and adequate sensitivity and specificity thresholds should be set. While the integration of AI into clinical practice is highly desirable, the limitations of AI as well as the ethical and legal ramifications of its use should be understood, such as the absence of a common regulatory pathway and a lack of clarity regarding the applicability of AI-enabled medical devices in different populations. Continuing education, promotion of practical application, and user-friendly, understandable interfaces for healthcare providers are equally important to streamline the workflow and broaden the applicability of AI systems. Cross-sector and cross-disciplinary collaborations, including ophthalmologists, optometrists, computer scientists, statisticians, data scientists, patient organizations, and engineers, will be important to ensure the integrity of AI healthcare ecosystems and to have a positive impact on vision health and preservation through AI-enabled technologies. Nonetheless, AI has the potential to lead to profound change in ophthalmological care by providing better patient-centered disease management and possibly leading to a future of personalized medicine.

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