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Bioethical challenges in the use of artificial intelligence in ophthalmology

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Abstract

The use of technology in medicine, especially in ophthalmology, is undergoing advances which, combined with artificial intelligence, are promising in the detection and diagnosis of eye diseases. Ophthalmology uses many images to offer accurate diagnoses, and artificial intelligence seems to provide a more assertive analysis due to its ability to process large data amounts and interpret medical images. These technological advances improve the chances of successful treatment and reduce diagnosis time, enabling more effective and agile care, with an impact on quality of life. However, such integration between technology and ophthalmology also raises concerns, and questions such as data privacy, equity of access to technological advances and the role of the physician in decision-making must be considered. In view of this, this literature review highlighted ethical challenges and future prospects for the use of artificial intelligence in ophthalmology.

Keywords: Bioethics. Ophthalmology. Diagnosis. Artificial intelligence.

Resumo

Desafios bioéticos do uso da inteligência artificial na oftalmologia

Atualmente, o uso da tecnologia na medicina, em especial na oftalmologia, passa por avanços, que, aliados à inteligência artificial, têm sido promissores na detecção e diagnóstico de doenças oculares. A oftalmologia utiliza muitas imagens para oferecer diagnósticos precisos, e a inteligência artificial parece oferecer uma análise mais assertiva pela capacidade de processar grande quantidade de dados e interpretar imagens médicas. Esses avanços tecnológicos melhoram as chances de tratamento bem-sucedido e reduzem o tempo de diagnóstico, possibilitando um atendimento mais eficaz e ágil, com impacto na qualidade de vida. No entanto, essa integração entre tecnologia e oftalmologia também traz preocupações, e devem ser considerados pontos como privacidade dos dados, equidade de acesso a avanços tecnológicos e o papel do médico na tomada de decisões. Diante disso, esta revisão da literatura levantou apontamentos sobre desafios éticos e perspectivas futuras do uso da inteligência artificial na oftalmologia.

Palavras-chave: Bioética. Oftalmologia. Diagnóstico. Inteligência artificial.

Resumen

Desafíos bioéticos para el uso de la inteligencia artificial en oftalmología

Actualmente, el uso de la tecnología en medicina, especialmente en oftalmología, viene experimentando avances que, combinados con el uso de la inteligencia artificial, son prometedores para la detección y el diagnóstico de enfermedades oculares. La oftalmología utiliza muchas imágenes para obtener diagnósticos precisos, y la inteligencia artificial puede contribuir a un análisis más asertivo por su capacidad de procesar muchos datos e interpretar imágenes médicas. Los avances tecnológicos aumentan las chances de un tratamiento exitoso y reducen el tiempo de diagnóstico, permitiendo una atención más eficaz y ágil, y calidad de vida. Esta integración entre tecnología y oftalmología también genera preocupaciones en cuanto a la privacidad de los datos, la equidad en el acceso a los avances tecnológicos y el papel del médico en la toma de decisiones. Esta revisión de la literatura destaca los desafíos éticos y las perspectivas futuras para el uso de la inteligencia artificial en oftalmología.

Palabras clave: Bioética. Oftalmología. Diagnóstico. Inteligencia artificial.

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Medicine and technology share a long history of collaboration, and recent years have seen a major evolution in this relationship. Such revolution is led by artificial intelligence (AI), a technology that is transforming the diagnosis, treatment and management of a variety of diseases, including ophthalmological diseases [1]. This is largely justified by AI's capacity to process vast amounts of clinical and medical data and interpret medical images with notable accuracy [2,3].

In addition, this technology is leading to significant changes in the structure of healthcare services and national healthcare systems, with substantial potential to improve quality and reduce costs in healthcare worldwide [4].

As the technology advances, it is implemented in several fields of medicine and, in the case of ophthalmology—which is one of the main specialties in the field of medical AI—it provides numerous benefits and efficiency to diagnosis. With abundant images, including photographs and other diagnostic resources, AI may provide a more personalized means to analyze pieces of information and transform them into a useful tool for clinical decision-making [5].

In this context, the diagnosis of complex eye diseases—such as cataracts, diabetic retinopathy, age-related macular degeneration, glaucoma and retinopathy of prematurity—became significantly more standardized and accurate with the use of AI, becoming more effective and precise [3,6].

As in any technological intervention that affects health, the incorporation of these new tools is fundamental for the advancement of medicine; however, the use of AI in healthcare is not without challenges, especially those involving ethical issues. Health data privacy, accountability in algorithmic errors, and equitable access to AI's benefits are concerning issues that require a serious approach [5].

This study is an exploratory literature review based on previous research. Thus, it leaves gaps for possible comparisons and conception of new ideas on the proposed theme: bioethical challenges in the use of AI in ophthalmology.

Method

The analyzed materials, such as scientific articles published in journals, were found by surveying bibliographic data in the PubMed, ScienceDirect and Google Scholar databases. To this end, we used the following descriptors: "ethics in the application of AI in health," "application of AI in ophthalmology," "challenges in medical AI," and "bioethical challenges in AI implementation." Only bibliographic materials that addressed issues related to the ethical challenges involved in the use of AI in medicine were selected, disregarding the technical and/or technological challenges.

Based on the literature review, we present the definition of AI and its use in healthcare, especially in ophthalmology. In addition, we contextualize and analyze bioethical challenges involved in the use of AI in medicine and ophthalmological care, as well as bioethical governance criteria in the use of AI in ophthalmology, which should consider patients and healthcare professionals.

Implementation and use of artificial intelligence in medicine

Also known as "machine intelligence," AI is a computer science branch based on algorithms and data processing in search of theories, methods, technologies, and application systems to simulate, understand, and expand human intelligence in machines [5,7]. That said, it is important to note that one AI branch that explores the study and construction of computational algorithms through data learning, rather than pre-programmed instructions, is machine learning (ML) [8].

ML seeks an intersection of mathematical and statistical techniques with computational algorithms that employ the concept of AI. This technology is applied when seeking patterns in a set of variables to predict a reliable and interesting result [8,9].

In this context, computers are programmed to learn how the human brain works. This learning is developed based on neural networks fed by a large amount of data (big data), entered into the system to train the machine in the ability to find

solutions related to this data, seeking a variety of new combinations [9].

The term big data refers to a large data set, which none of the traditional data management tools can process efficiently, but it can also refer to a type of technology, such as storage facilities, tools, and processes [8].

Thus, increasing computing power, expanding storage capacity, and compiling health big data have helped implement AI in medical practice and health research [10]. The application of ML and AI is mainly focused on the handling of consolidated databases with heterogeneous information, for which the use of conventional statistical techniques is limited. Thus, the contribution of these technologies can range from the early diagnosis of a given disease to drug infusions [8].

Thus, AI progresses rapidly in several interdisciplinary and multiprofessional fields of healthcare, related to disease prevention, diagnosis and management, significantly improving clinical flows, including the field of ophthalmology [7].

This medical specialty—dedicated to the study and treatment of eye diseases—has undergone significant advances in recent decades, largely driven by multiple digital technologies and innovations. In addition to AI, these digital innovations include fifth-generation (5G) telecommunication networks and the internet of things (IoT), creating an interdependent ecosystem that provides opportunities for the development of new eye care models [3].

Ophthalmology is a medical specialty leading the application of AI in screening, diagnosis, and treatment. The first autonomous diagnostic system approved by the Food and Drug Administration was used to diagnose and classify diabetic retinopathy. AI has also been implemented for other ophthalmologic diseases, such as age-related macular degeneration, glaucoma, retinopathy, and congenital cataracts [10].

The field of eye disease diagnosis is promising for the study and advancement of this type of technology, and health data increase by approximately 50% each year, making this one of the fastest-growing digital areas. Given the ambulatory nature of the practice and the common use of various imaging modes, ophthalmology is suitable for AI implementation, since it employs numerous digital techniques – such as color fundus photography, optical coherence tomography (OCT), computerized visual field (VF) testing—and the huge database they provide [11,12].

About 30 million OCT exams are performed annually in the United States, which highlights ophthalmology as one of the areas that produces the most health data [11]. In addition, the diagnosis of many diseases is currently more efficient and effective when using AI, as in the case of retinopathy, one of the main causes of vision loss in children and adults diagnosed with diabetes, considered a serious public health problem. Early diagnosis and treatment are essential to improve visual acuity, but a percentage of patients still progress to irreversible vision loss [13].

Although the impact of the results of diagnosis and treatment of this disease are known, access to specialized physicians may be limited, especially in developing countries such as Brazil. This conjuncture, in addition to high rates of variations in diagnosis among specialists, encouraged researchers to study the use of AI in these cases [12].

Brown and collaborators [14] developed a software that uses deep learning AI technology and a database of 5,511 fundus images obtained with RetCam fundus camera and reported 93% sensitivity and 94% specificity in determining the presence of additional disease. The software developed by Redd and collaborators [15], based on the same technology, presented 0.96 and 0.91 values of area under the sensitivity and specificity curve, respectively, in the identification of retinopathy. These studies demonstrated that deep learning AI significantly helps in the diagnosis of retinopathy and impacts the quality of life of patients affected by it.

In cases of age-related macular degeneration (AMD), there is an increasing number of studies employing AI software for diagnosis. These studies use optical coherence tomography

databases to validate this technology in the diagnosis of the disease.

Ting and collaborators [11] examined a database of 72,610 images and classified patients into two groups: those with intermediate to advanced disease and those without the disease, according to the Age-Related Eye Disease Studies (AREDS). The authors reported sensitivity and specificity of 93.2% and 88.2%, respectively. Burlina and collaborators [16] classified patients with software that used 130,000 images of 4,613 patients and reported a 91.6% accuracy rate in the identification of patients with moderate and advanced AMD.

Grassmann and collaborators [17] tested an algorithm developed based on 120,656 fundus photographs of 3,654 patients according to parameters of the AREDS database and reported an accuracy rate of 84.2% in differentiating early and late disease and 94.3% accuracy rate in identifying healthy individuals. These results demonstrate the effectiveness of the use of AI in the diagnosis of AMD at more advanced stages.

In cases of glaucoma diagnosis, a disease that is among the leading causes of vision loss worldwide, initial studies used deep learning AI to evaluate fundus photographs. In research that used a database of 125,189 fundus photographs, Ting and collaborators [11] reported 96.4% sensitivity and 87.2% specificity.

Considering these data, the importance of the use of AI in ophthalmology is undeniable, notably the benefits that seem indisputable for a more accurate diagnosis. Based on individual patient data and their specific characteristics, AI algorithms can help determine the best treatment plan, whether through surgery, pharmacological therapy or other interventions, maximizing the chances of success.

Bioethical challenges in the implementation of artificial intelligence in medicine

The integration of AI in ophthalmology has been effective and promising for the early diagnosis and effective treatment of eye diseases, providing undeniable benefits for eye care patients and professionals. However, as this technology becomes more widespread, bioethical concerns arise that cannot be ignored.

Over the past decade, bioethical challenges in the implementation and use of AI in healthcare have become a significant concern in both the academic and business communities. Several organizations and hospitals are recruiting AI bioethics experts to compose their teams to comply with AI ethical guidelines [18].

Bioethical concerns associated with AI-based medical interventions are related with all disease management cycles, from diagnosis to treatment, considering that the technology is applied to patient data. Clear limits must be established on patient data ownership or management, and patients need to be aware of where their data is kept and how secure they are [18].

According to Abdullah and collaborators [10], bioethical challenges involving the implementation of AI in medicine were classified into six main categories: 1) machine training ethics; 2) machine precision ethics; 3) patient-related ethics; 4) physician-related ethics; 5) shared ethics; and 6) regulators' roles.

The application of AI in ophthalmology raises fundamental questions about privacy, accountability, algorithmic biases, and equity in access to eye care. In this context, this study addresses the ethical challenges in the use of AI in ophthalmology, emphasizing the importance of informed discussion and appropriate regulation to ensure that the use of this technology is responsible and beneficial for society.

AI's increasing capacity to analyze large sets of patient and ophthalmic image data, as well as to make clinical decisions, raises significant concerns as to the privacy of medical data. As for information privacy, it is important to consider two aspects: data ownership, which indicates authority to control, process or access data; and the profitability of the right to sell data or receive compensation [19].

Thus, a major concern is to ensure that patient information collected to train computers and AI models is securely protected by hospitals, clinics, research organizations, large pharmaceutical companies, insurers, and technology companies that store this data [19]. Accordingly, the protection of sensitive patient information is essential, and stringent cybersecurity measures and compliance with data protection regulations are necessary to mitigate these risks [19].

An AI-derived algorithm is only as good as the medical data based on which it is applied [19], which are key to implementing AI in ophthalmology. In this context, algorithmic biases are also an important ethical concern. Therefore, it is extremely important that data are connected, standardized and uniformly formatted to become useful to drive the application of AI in the health care field [10].

If algorithms are trained on biased data sets, they can perpetuate existing inequalities in ophthalmic care, favoring certain demographic groups over others. Ensuring that algorithms are unbiased and equitable is crucial to avoid disparities in access to eye care [19].

Erroneous predictions made by AI algorithms due to poor data quality, for example, are unavoidable, which can lead to liability issues for physicians. Considering this premise, the issue of legal liability in the event of misdiagnosis or inadequate treatment is complex when AI plays an active role in medical decision-making. Who is responsible when an algorithm makes a mistake that results in harm to a patient? This issue needs to be addressed with transparency and fairness for all parties involved.

In this sense, when a medical error involves the use of AI technology, it is necessary to identify and inform the moral guardian and the legal guardian, two very important aspects to be considered. In addition, as to accountability, individual professional responsibilities for healthcare providers' proper and accurate interpretation of AI results, as well as technical/technological responsibilities, must also be taken into account.

These responsibilities may include, for example, proper physical design, employment of systems, and creation of correct algorithms for machine learning [7,19]. Therefore, professional and technological responsibilities from the perspective of the AI diagnosis and treatment process need to be further refined in future medical regulations.

Another important aspect to be considered is the relationship between physicians and patients, because, with the use of AI technologies, patients tend to spend more time communicating with autonomous devices than with their physicians. As a result, the bidirectional patient-physician relationship, which was built on trust, eventually shifts to a three-way relationship that includes patient, electronic medical device, and physician. Thus, core values of care—such as communication, trust, and confidentiality—can be easily deteriorated by AI and big data technologies [19].

When these important interactions are absent or reduced, the physician-patient dialogue can be affected, distorting the patient's knowledge and understanding of a given procedure or treatment, which can negatively affect their ability to make autonomous decisions [19].

In addition, equitable access to AI in ophthalmology is an essential ethical consideration, since most data fed into AI tools tend to be homogeneous as to patient characteristics, which may result in underrepresentation or overrepresentation of certain groups. The common practice is that minority populations are often underrepresented, making them vulnerable to misdiagnosis or ineffective treatment procedures as a result [19].

Importantly, the advantages of this technology should not be available only to those who can afford it, but also to less privileged communities. The principle of distributive justice advocates the distribution of resources in society and the nondiscrimination of individuals and groups. When employing AI in medicine, it is important to promote equity and remove discrimination from algorithmic decision-making about patient care and disease prevention [19].

The consent stage is another point of concern regarding the bioethical aspects of the use of

AI in ophthalmology. It is important to note that the approach to obtaining consent from patients who will receive AI-based medical care is (or should be) different from the approach employed with patients who will receive traditional health care—which involves serious ethical challenges [19]. Communicating and explaining truthful, knowledge-based information that conveys confidence to patients is a key value from the perspective of patient consent in AI-based medical care.

To obtain the benefits of AI and ensure bioethical compliance during medical care, physicians must understand and lead the technological progress of AI. According to Anom [19], physicians need to have fundamental knowledge and be always up-to-date in relation to technologies to be able to explain the basic nature of a given technology to their patients. Physicians lacking knowledge about AI systems may risk not providing patients with sufficient and/or understandable information and seriously affecting the quality or validity of the informed consent process.

To ensure bioethical compliance in care when there is implementation and use of AI tools in ophthalmology, it is important to seek to understand and comprehend the view of medical professionals on these technologies. Physicians are at the forefront of care and, in a way, largely assume the risks in relation to the responsibilities of using these technologies.

In this context, a study carried out by Martinho, Kroesen and Chorus [18] aimed to trace prospects of medical professionals in relation to the explanation of the use of AI in medicine and in their care. In short, professionals consider that AI should never be a "black box" and that physicians need to be able to explain how the results of AI tools are obtained. They also note that physicians are not the only ones who need to know how AI medical tools work, and that such tools should only be used by physicians who understand how AI decisions are made.

Another important aspect to be considered is the importance of physicians explaining and making patients aware of the specific roles that humans play in a step of the procedure *versus* the functions of the AI/robotics system or device [19]. It should also be noted that this explanation must be provided at the data consent and confidentiality stage, since, when concerned about breach of confidentiality in relation to a technology company or insurance company, patients may not provide complete information or avoid treatment, which leads to aggravated disease [20].

As AI continues to evolve in ophthalmology, it is imperative that the medical community, regulators, and technology developers collaborate to address these bioethical challenges appropriately. Ethical regulation and guidelines must be developed and improved to ensure that AI becomes a valuable resource in ophthalmology, without compromising medical ethics, equity, and patient privacy.

Bioethics governance in the use of artificial intelligence in ophthalmology

Despite the significant possibilities resulting from the implementation and use of advanced AI in health care, especially in ophthalmology, concerns on the ethical use of these applications have led to the need for a new form of bioethics governance. To ensure the reliability of AI applications, it is suggested the creation of a global multiprofessional bioethics governance framework, along with specific directives for the use of advanced AI in ophthalmology.

Bioethics governance in medicine plays a key role in ensuring quality health care and equity for all patients. Medical ethics is based on morally accepted principles and duties of physicians to their patients. In turn, governance involves the creation and implementation of policies and directives that govern the conduct of healthcare professionals, as well as the promotion of the provision of healthcare with ethics and quality.

It is important that healthcare professionals participate in bioethics governance, since AI-based healthcare application developers may have values that are not always aligned with the principles of ethical healthcare, as specified in the principles of healthcare ethics [19,20].

One of the important aspects of bioethics governance in the use of AI in ophthalmology concerns the protection of patient autonomy. Azambuja and Garrafa [21] report that, for Beauchamp and Childress, patient autonomy is at least self-rule that is free from both controlling interference by others and limitations, such as inadequate understanding, that prevent meaningful choice.

Governance should establish standards ensuring that, during the explanation and consent of procedures, patients are adequately informed about all steps involving the use of AI in healthcare. This enables patients to make informed decisions and actively participate in their own diagnosis/treatment process.

Another important role of bioethics governance is to ensure the beneficence for patients in the use of AI and technologies. The use and application of big data and AI technologies must firmly ensure the central importance of promoting patient well-being. It is important to measure the risk *versus* benefit ratio for patients in the use of big data and AI technologies. In addition, the use of technologies must be beneficial and ensure equity for all patients in the most diverse ways [22].

Thus, it is necessary to address and manage the bioethical risks presented by technologies and seek means to balance the benefits and risks they present to individuals and society [19,22]. As for data privacy, bioethics governance must recognize the ethical challenges associated with the lack or insufficiency of patient awareness. Their data are shared between healthcare stakeholders and big data repositories, as well as across the various social media platforms for technology companies [19].

Obtaining valid patient consent can be difficult when future uses of their data are not shared or are unclear to them, as well as to medical professionals themselves. In this sense, technology companies and healthcare organizations can help increase the trust of medical professionals in AI, as well as of patients themselves. This trust can be based on transparent information about data hosting and security, data ownership, and the purpose of their use [22].

Once trust is established in the physician-patient relationship, it is of utmost importance that the medical professional is aware of this information and trusts in the security of their patients' data. It is worth noting that bioethics governance must ensure that patients have the option to deny consent to use their data. In addition, physical property medical data must be covered by property laws and/or intellectual rights laws, which must establish ownership of this data, which can be public or private [10].

It has been reported that medical students and professionals understand the growing importance of AI in healthcare and have positive attitudes towards its clinical use. Despite positive attitudes toward AI, it is also reported that they are poorly trained in these technologies [20]. Therefore, bioethics governance in the use of AI in ophthalmology should foster the continuous training of healthcare professionals in technology, so they are able to use AI tools in medical care and, especially, ensure bioethical compliance.

It is worth noting that trends suggest that AI technologies will be increasingly applied in healthcare. Thus, it is extremely important that bioethics governance fosters the dissemination of knowledge already in the academic environment where these professionals are trained, and not only when they reach the labor market. Studies indicate that medical students who received AI education during academic training feel more confident when working with AI in the future compared to students who did not receive AI education [18,20].

Only with training in AI and new technologies will students and professionals be confident in effective decision-making, with learning based on clinical and technological knowledge, so they do not have to be afraid of being held accountable for having adopted or not the suggestion of AI. Using AI tools for diagnosis and treatment directly affect patient health. Thus, it is necessary to address potentially flawed results that can be produced by big data and AI technologies in ophthalmology [19,22].

Accordingly, it is important to emphasize that the health products of AI and new technologies should be tested in randomized clinical trials,

which are the most reliable source of medical evidence [20]. Bioethics governance should foster and encourage clinical trials, in addition to establishing the directives that these studies must follow and comply with.

In summary, to address some of the challenges and issues presented by technologies, bioethics and healthcare communities must establish sound data security, privacy, and governance strategies. These policies should be sufficiently established to ensure that all patients have full control over their own data and trust that they will not be used to harm or discriminate against them [2,22].

Some of the most important aspects include the role of governments in auditing the ethics and accountability of the different actors involved in the ethics governance system [2]. Government and healthcare stakeholders should consider investing in solutions that ensure security safeguards to protect patient data and privacy, as well as health information in general. In situations where policies and regulations already exist, there is a need to continually update them consistently with these rapidly evolving technologies [10].

Final considerations

The integration of AI in ophthalmology has been effective and promising for early diagnosis and effective treatment of diseases, promoting a more accurate approach. Ophthalmic care has substantial potential for the use of AI in several areas, given the ambulatory nature of the practice, since it employs numerous digital techniques, such as fundus photography, OCT and VF testing.

The ophthalmic disease diagnosis field is promising for the study and advancement of this type of technology, and health data increase by approximately 50% each year, making this one of the fastest-growing digital areas. However, as this technology becomes more widespread, bioethical concerns arise that cannot be ignored.

It is known that bioethical challenges in the use of AI in healthcare are important points to be considered so there is safe and beneficial advance, both for professionals and patients. As ophthalmic AI evolves, it is imperative that the medical community, regulators, and technology developers collaborate to appropriately address bioethical challenges, such as issues concerning data privacy, credibility, and diagnostic accuracy, trust, and potential impacts.

In addition, some points regarding access to this type of technology, when used correctly and beneficially, need to be considered and studied. Similarly, regulations and directives must be developed and improved to ensure that AI becomes a valuable resource in ophthalmology, without compromising data, patients, and professionals.

It is worth noting that trends suggest that technologies and AI will be increasingly applied in healthcare. However, it is extremely important that bioethics governance fosters the dissemination of existing knowledge in the academic environment where these professionals are trained, providing proper validation, encouragement, instruction and training.

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Cláudio do Carmo Chaves Filho and Jonas Byk chose the theme and the scientific articles, and drafted the manuscript. Luiz Carlos de Lima Ferreira supervised and critically and constructively reviewed all stages of the work.

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