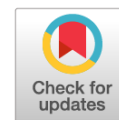


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# Организация диспансерного наблюдения пациентов с патологией макулярной области сетчатки с использованием систем искусственного интеллекта

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## АННОТАЦИЯ

**Обоснование.** Несмотря на то, что в приказе Министерства здравоохранения Российской Федерации «Об утверждении порядка оказания медицинской помощи взрослому населению при заболеваниях глаза, его придаточного аппарата и орбиты» сказано про оснащение медицинского консультативно-диагностического отделения поликлиники оптическим когерентным томографом, динамическое наблюдение пациентов с патологией сетчатки после начала лечения осуществляется чаще всего в медицинском офтальмологическом центре, что снижает доступность лечения для пациентов со впервые выявленной (первичной) патологией, требующей как можно более раннего начала лечения. Имеющаяся технология нуждается в изменении и интенсификации, в том числе — с применением технологий искусственного интеллекта.

**Цель** — разработка методических основ организационной технологии диспансерного наблюдения пациентов с патологией заднего отрезка глаза с использованием систем поддержки принятия врачебных решений на основе искусственного интеллекта.

**Материалы и методы.** Оценка существующей нормативной базы проведена на основе анализа Конституции Российской Федерации, федеральных законов, подзаконной нормативной базы и судебной практики. Создание структурированного медицинского документа описания снимка оптической когерентной томографии проведено с использованием экспертного метода: анкетирования 100 врачей-офтальмологов, имеющих соответствующий уровень образования, в том числе дополнительное профессиональное, занимающихся оказанием медицинских услуг — специализированной медицинской помощи пациентам с патологией заднего отрезка глаза. Структурированный медицинский документ послужил основой для формирования предикторов искусственных нейронных сетей. Обучение нейронных сетей проведено с использованием 60 000 медицинских изображений с помощью метода классификации и сегментации в зависимости от признака.

**Результаты.** Экспертным методом отобрано и описано 123 бинарных признака, позволяющих описать структуру макулярной области сетчатки в норме и при патологии, из которых выявлено 26 признаков, которые могут быть интерпретированы в качестве предикторов ухудшения клинического течения заболевания.

**Заключение.** Разработанный классификатор позволил создать и обучить на основе 60 000 медицинских изображений систему поддержки принятия врачебных решений, которая в качестве информационного сервиса, без постановки диагноза, может позволить изменить организацию процесса динамического наблюдения. Формирование маршрутизации пациентов — первичная услуга разработанной системы поддержки принятия врачебных решений. При наличии признаков ухудшения клинической картины предполагается маршрутизация в медицинский офтальмологический центр для оценки динамики и оказания специализированной, в том числе высокотехнологичной, медицинской помощи.

**Ключевые слова:** система поддержки принятия врачебных решений; искусственный интеллект; оптическая когерентная томография; патология; макула.

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# Organizing follow-up care for patients with macular retinal pathologies using artificial intelligence systems

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## ABSTRACT

**BACKGROUND:** The Order of the Ministry of Health of Russia “On Approval of the Procedure for the Provision of Medical Care to the Adult Population for Diseases of the Eye, Appendages, and Orbit” provides for equipping consultation and diagnostic departments of outpatient clinics with optical coherence tomographs. However, case follow-up of patients with retinal pathology is most commonly performed in ophthalmology centers, limiting treatment accessibility for patients with primary (newly diagnosed) pathologies requiring immediate treatment initiation. The available approach requires modification and intensification, including the use of artificial intelligence technologies.

**AIM:** To develop methodological foundations for organizing follow-up care for patients with posterior segment eye diseases using an artificial intelligence-based clinical decision support system.

**MATERIALS AND METHODS:** The existing regulatory framework was analyzed based on the Constitution of the Russian Federation, federal laws, by-law framework, and judicial practice. A structured medical document describing an optical coherence tomography image was created using an expert method: a survey of 100 ophthalmologists with an appropriate education level, including additional professional training, engaged specialized medical care for patients with posterior segment eye diseases was performed.

**RESULTS:** Using an expert method, 123 binary features were selected to describe the structure of the macular area of the retina under normal and pathological conditions, with 26 features identified as predictors of a worsening clinical course of the disease.

**CONCLUSION:** The proposed classifier enabled the creation and training of a medical decision support system based on 60,000 medical images, which, as an information service, without making a diagnosis, can change the case follow-up process. Routing of patients is a primary service of the proposed system. If the clinical picture shows signs of deterioration, a referral to an ophthalmology center is considered to assess the course of the disease and provide specialized services, including high-tech medical care.

**Keywords:** clinical decision support system; artificial intelligence; optical coherence tomography; pathology; macular.

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# 利用人工智能系统组织对视网膜黄斑病变患者的防治观察

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## 摘要

**论证。**根据俄罗斯联邦卫生部命令《关于向成年居民提供眼部、眼部附属装置和眼眶疾病医疗服务的程序批准》，综合医院的医疗咨询和诊断部门都配备光学相干断层扫描仪。然而，视网膜病变患者在开始治疗后的动态观察通常是在专门眼科医疗中心进行。这就降低了对首次发现（原发性）病变患者的治疗机会，因为这些患者需要尽早开始治疗。需要改变和加强现有技术，包括使用人工智能技术。

**目的。**本研究旨在利用基于人工智能的医疗决策支持系统，为眼后段病变患者的防治观察组织技术奠定方法论基础。

**材料和方法。**在对《俄罗斯联邦宪法》、联邦法律、附属法规和司法实践分析的基础上，对现有管理框架进行了评估。使用专家方法编制了描述光学相干断层扫描图像的结构化医学文件：对100名具有适当教育水平的眼科医生进行了问卷调查，包括额外的专业教育。所有医生都从事医疗服务工作，即为眼后段病变患者提供专业医疗服务。结构化医学文件是形成人工神经网络预测器的基础。利用基于特征的分类和分割方法，使用60000张医学图像对神经网络进行了训练。

**结果。**通过专家方法选取并描述了123个能够描述正常和病理下视网膜黄斑区结构的二元特征。其中，26个特征被确定为疾病临床过程恶化的预测器。

**结论。**所开发的分类器可以在60000张医学图像的基础上创建和训练一个医疗决策支持系统。该系统可用作信息服务。它可以在不做出诊断的情况下改变动态观察过程的组织结构。患者路径选择是已开发的医疗决策支持系统的主要服务。如果临床症状有恶化的迹象，患者就会被转诊到眼科医疗中心，以接受动态评估及包括高科技在内的专业医疗服务。

**关键词：**医疗决策支持系统；人工智能；光学相干断层扫描；病变；黄斑。

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## BACKGROUND

The National Artificial Intelligence Development Strategy adopted in the Russian Federation determined the artificial intelligence (AI) to be used in increasing the efficiency of organizations.<sup>1</sup> This can be achieved by automating routine (repetitive) production processes and operations.

In accordance with current guidelines, if risk factors for disease progression are present in patients with diabetes mellitus-induced retinal pathology and age-related macular degeneration, regular follow-ups by an ophthalmologist are recommended to monitor changes and start adequate treatment if necessary [1, 2]. Retinal examination using a computer analyzer, i.e., structural optical coherence tomography (OCT), is included in the standard of care for primary specialized medical care of patients with diabetic retinopathy and age-related macular degeneration and is a recurring service.<sup>2</sup> The frequency of doctor visits is determined individually depending on the planned management strategies and clinical signs. According to domestic studies, the minimum number of OCT examinations of the macular retina performed in medical institutions during follow-ups in patients with age-related macular degeneration and diabetic macular edema is 1,629,429 per year.

Foreign analytical studies have shown the willingness of patients to switch to controlled self-medications during follow-up (up to 54% of respondents according to 2019 data, STADA Health Report 2020) and to receive part of the medical services using telemedicine technologies, i.e., without face-to-face visits to a healthcare professional [3–5]. In a study by the Russian Public Opinion Research Center, 48% of Russians are open to follow-up and treatment using telemedicine services [6]. Thus, organizational and clinical prerequisites have been established for the provision of medical services using AI, including the use of telemedicine technologies, for patients who require repeated diagnostic appointments as part of the follow-up for posterior eye segment pathology.

The Order of the Ministry of Health of the Russian Federation dated November 12, 2012, No. 902n, On Approval of the Procedure for the Provision of Medical Care to the Adult Population for Diseases of the Eye, Appendages, and Orbit refers to equipping medical consultative and diagnostic departments of outpatients clinics with optical coherence tomographs. However, patients with retinal pathology most often receive follow-up care in a medical ophthalmology center once they have started treatment, and this reduces the availability of treatment for patients with newly diagnosed pathology, which must be treated the earliest time possible.

Existing technologies need changing and intensifying, including through the use of AI technologies.

## AIM

To develop the methodological basis for an organizational system for the follow-up of patients with posterior eye segment pathology using AI-based clinical decision support systems (CDSS).

## MATERIALS AND METHODS

Content analysis was performed to assess the existing regulatory framework. To create a structured directory, sociological and expert methods were used. Artificial neural networks (ANNs) were trained using segmentation and classification methods.

### Study design

The existing regulatory framework was assessed based on an analysis of the Constitution of the Russian Federation, federal laws, sublegislative acts, and judicial practice. The methodology for a structured medical document describing an OCT image was created using an expert method: i.e., 100 ophthalmologists with the appropriate educational level, including advanced professional education, engaged in specialized medical care for patients with posterior segment pathology were included in a survey. The structured medical document was used as the basis for ANN predictors. As a result of annotation, 60,000 medical images were described. For each image, a json file describes the presence of features after mapping. To analyze and classify binary features in an image, neural networks with the DenseNet121 architecture without pretrained weights were trained. The Mask R-CNN architecture was used for the segmentation task.

### Eligibility criteria

A sign was added to the significant factors that indicated disease deterioration when the agreement between respondents reached 70%. A sign was added to the CDSS output when its accuracy (mean sensitivity and specificity) reached a value of  $\geq 0.7$ .

### Study conditions

A database was constructed based on the anonymized data from clinical studies (retinal examinations using OCT) conducted in the Orenburg and Tambov branches of the S.N. Fyodorov Eye Microsurgery Complex of the Ministry of

<sup>1</sup> Decree of the President of the Russian Federation dated October 10, 2019 No. 490 "On the Development of Artificial Intelligence in the Russian Federation" (together with the "National Artificial Intelligence Development Strategy for the period until 2030"). Access: [https://www.consultant.ru/document/cons\\_doc\\_LAW\\_335184/1f32224a00901db9cf44793e9a5e35567a4212c7/](https://www.consultant.ru/document/cons_doc_LAW_335184/1f32224a00901db9cf44793e9a5e35567a4212c7/) Access date: November 22, 2023.

<sup>2</sup> Order of the Ministry of Health of the Russian Federation dated December 24, 2012, No. 1492n "On Approval of the Standard of Primary Health Care for Diabetic Retinopathy and Diabetic Macular Edema." Access: <https://base.garant.ru/70344052/53f89421bbdaf741eb2d1ecc4ddb4c33/> Access date: November 22, 2023.

Health of the Russian Federation. The ANN was trained at the Research Institute of Digital Intelligent Technologies of the Orenburg State University (Russia).

### Study duration

Clinical studies (retinal examinations using OCT) were performed between 2015 and 2023. The structured binary classifier directory for describing the macular retina was created in 2022, and the ANNs were trained in 2022–2023.

### Medical intervention

For the database, retinal examinations involved OCT scans of the macular retina.

### Primary outcome

The methodological basis for the use of AI in the regular follow-up of patients with posterior segment pathology was developed and evaluated.

### Subgroup analysis

The follow-up methodology was based on an assessment of the medical care organization and clinical data of patients diagnosed with age-related macular degeneration (ICD-10 code: H 35.3) or diabetic macular edema (ICD-10 code: H 35.8).

### Outcome measures

Sensitivity and specificity are statistical parameters of a diagnostic test used to identify patients with pathology and healthy individuals derived from type I and II errors in the binary classification.

### Statistical analysis

For the sample size calculation, the minimum volume of the sample study was determined considering the validity criterion and maximum error (product of the confidence interval and specified accuracy).

Statistical procedures included descriptive statistics, calculation of the mean values and relative values, and mathematical modeling. The statistical significance of differences in the studied data according to qualitative characteristics was analyzed through mathematical calculations and subsequently evaluated using Pearson's chi-squared test. Quantitative variables were described during the preliminary assessment for compliance with Gauss's law (normal probability distribution).

## RESULTS

### Study objects

The study focused on organizing ophthalmological care for the adult population as part of their follow-up for posterior segment pathology. In the content analysis, 22 records were analyzed. The database included 60,000 records of retinal examinations using OCT for which a medical image (scan) and a result interpretation in accordance with the developed binary classifier are available.

### Primary outcome results

In accordance with Federal Law dated November 21, 2011, No. 323-FZ "On the Fundamentals of Public Healthcare of Citizens in the Russian Federation," medical care in the Russian Federation was organized and provided:

- 1) In accordance with the regulations on the organization of medical care by type of medical care
- 2) In accordance with the procedures for the provision of medical care approved by the authorized federal executive body and mandatory for execution in the territory of the Russian Federation by all medical organizations
- 3) Based on guidelines
- 4) Considering the standards of medical care approved by the authorized federal executive body.<sup>3</sup>

In addition, Paragraph 15 of Article 2 of this law defines "attending physician," who is a doctor responsible for organizing and directly providing medical care to a patient during follow-up and treatment. In the provision of primary specialized medical care, certain functions of the attending physician may be delegated to nursing staff in accordance with the approved procedure; however, the provision of primary specialized medical care, including medical services specified in the professional standard of an ophthalmologist, should not be delegated.<sup>4,5</sup>

Results of imaging studies cannot be interpreted by nursing staff independently when providing medical services. This is only possible with the use of registered medical devices.

CDSSs require registration as a medical device for use by nursing personnel. When used by doctors, they can remain within the legal field of information services because the interpretation of results, diagnosis, and recommendations, including those in follow-up, remain within the competence of the attending physician, regardless of the legal status of the software.

<sup>3</sup> Federal Law "On the Fundamentals of Public Healthcare of Citizens in the Russian Federation" dated November 21, 2011, No. 323-FZ. Access: [https://www.consultant.ru/document/cons\\_doc\\_LAW\\_121895/](https://www.consultant.ru/document/cons_doc_LAW_121895/) Access date: November 22, 2023.

<sup>4</sup> Order of the Ministry of Health and Social Development of the Russian Federation dated March 23, 2012, No. 252n "On Approval of the Procedure for Assigning Certain Functions of the Attending Physician to a Paramedic or Midwife by the Head of a Medical Organization when Organizing the Provision of Primary Health Care and Emergency Medical Care for the Direct Provision of Medical Care to the Patient During Follow-up and Treatment, Including the Prescription and Administration of Medications, Including Narcotic Drugs and Psychotropic Drugs." Access: <https://base.garant.ru/70170588/> Access date: November 22, 2023.

<sup>5</sup> Order of the Ministry of Health and Social Development of the Russian Federation dated June 5, 2017, No. 470n "On Approval of the Professional Standard for Ophthalmologists." Access: <https://docs.cntd.ru/document/436744741> Access date: November 22, 2023.

Using the expert method, 123 binary features that allow describing the structure of healthy and abnormal macular retina were selected and characterized. The features were grouped into sections: general, vitreoretinal and retinal interface, retinal contour, retinal thickness, retinal structures, and choroid. In the survey of experts with appropriate education and professional experience, 75% of the doctors classified only 26 features out of 123 as predictors of worsening conditions in patients with age-related macular degeneration or diabetic macular edema (Table 1).

The selected features directly or indirectly indicated the onset of a pathological process, including neovascularization, which requires specialized and high-tech medical care in tertiary medical institutions (e.g., federal medical organizations). In addition, the features were consistent with the guidelines and current scientific literature describing medical care provision and interpretation of the results of imaging diagnostic studies [7, 8].

The binary classifier was divided into features suitable for use in ANN training by classification and segmentation methods. The ANN training based on 60,000 medical images made it possible to create a CDSS for follow-up in patients with posterior segment pathology. The accuracy of ANN models was assessed using the balanced accuracy metric to correctly account for the heterogeneous distribution of classes in the data. The mean balanced accuracy across features was 81%.

### Secondary outcome results

The developed version of the CDSS is in the open-access system: <http://retinadeepai.site/>. The system recognizes objects to be analyzed as predictors for each of the developed features and allows for the configuration of the analysis of various maps and modes, including those obtained using different devices. The recommended analysis mode is RetinaMap. The service has an ergonomic, intuitive interface

**Table 1.** Signs of clinical deterioration

Sign	Section
Moderate macular thickness increase ( $\leq 500 \mu\text{m}$ )	Macular thickness
Severe macular thickness increase ( $> 500 \mu\text{m}$ )	
Focal intraretinal edema identified	Retinal structure
Diffuse intraretinal edema identified	
Cystic intraretinal edema identified	
Abnormality: small ( $< 50 \mu\text{m}$ ) multiple cysts	
Abnormality: medium ( $50\text{--}150 \mu\text{m}$ ) multiple cysts	
Abnormality: large ( $> 150 \mu\text{m}$ ) multiple cysts	
Serous neuroepithelial detachment visualized	
Slit-like neuroepithelial detachment visualized	
Serous RPE detachment visualized	
Dome-shaped RPE detachment	
Flat wave-like RPE detachment visualized	
Flat RPE detachment visualized	
"Tabletop" RPE detachment visualized	
Hemorrhagic RPE detachment visualized	
Fibrovascular RPE detachment visualized	
Double-layer sign visualized	
Highly reflective opacity shadowing deeper layers (subretinal hemorrhage)	
Subretinal fluid visualized	
Hyperreflective focus visualized in inner retinal layers	
Hyperreflective focus visualized in outer retinal layers	
Hyperreflective focus visualized above RPE	
Hyperreflective focus visualized within RPE	
Hyperreflective focus visualized under RPE	
Hyperreflective focus shadowing the underlying layers visualized	

Note: RPE, retinal pigment epithelium.

that makes it possible to upload a report attached to the medical records. The service is not a medical device, but an information service; it does not store or process personal patient data. The service does not make a diagnosis or offer prompts for diagnosis. It describes the structure of the normal and abnormal retina, taking on part of the routine processes of an ophthalmologist during patient follow-ups.

### Adverse events

None identified.

## DISCUSSION

Currently, several AI-based systems are being developed globally for the early diagnosis of fundus pathology. For example, certain systems detect early signs of diabetic retinopathy using fundus images obtained from stationary and portable fundus cameras: the IDx-DR system (LumineticsCore, USA) and the Retina.AI platform (Digital Vision Solutions LLC, Russia).

In addition, several technological developments aimed at automated analysis of data obtained using medical devices.

- The Retina.AI platform is aimed at analyzing OCT images of the retina and identifying one of the specified syndrome complexes: subretinal fluid, intraretinal cysts, retinal pigment epithelial detachment, subretinal hyperreflective material, epiretinal membrane, retinal drusen, full-thickness macular hole, lamellar macular hole, and vitreomacular traction (<https://www.screenretina.com/>). Thus, the project is aimed at diagnosing conditions and assessing the course of the process. The project is not registered as a medical device.
- The Altris AI platform (USA) automates the selection of abnormal OCT scans and detection of >70 disorders and pathological signs, including epiretinal fibrosis, intraretinal cystoid fluid, pseudocysts, diffuse edema, fibrovascular detachment of the retinal pigment epithelium, and subretinal hyperreflective material (<https://www.altris.ai/>). The project aims to diagnose conditions (diseases) and train medical personnel. The project is registered as a medical device in the country of origin (US Food and Drug Administration).

The product we are developing contains a larger number of assessed features (123) and aims not at diagnosis but at changing the organization of the diagnostic and treatment process, i.e., delegating routine work from doctors to nursing staff, reducing research time, and increasing the availability of medical services.

It requires changing the professional standard of nursing staff by including the use of AI-based information services as part of patient follow-up. In addition, in the Order of the Ministry of Health of Russia dated March 15, 2023 No. 168n, "On Approval of the Procedure for Regular Follow-up of Adults," the regulatory framework must be updated for

the regular follow-up of patients with posterior segment pathology to include this pathology.

### Primary outcome summary

The methodological basis of the organizational technology for regular follow-up of patients with posterior segment pathology has been developed. A structural classifier for describing the retina has been prepared, and a CDSS has been developed for use in the regular follow-up of this patient population.

### Primary outcome discussion

The Order of the Ministry of Health of the Russian Federation dated September 7, 2020, No. 947n, "On Approval of the Procedure for Organizing a Document Flow System in the Field of Healthcare to Manage Medical Electronic Records" defines the procedure for using electronic medical records. To date, several structured electronic medical documents have been developed and approved and are currently used in Russia. The Center for the Development of Structured Electronic Medical Documents is part of the Central Research Institute for Organization and Informatization of Healthcare of the Ministry of Health of the Russian Federation. It ensures the implementation of the tasks of the Ministry of Health of Russia to improve the procedure for organizing document flow in healthcare by developing, updating, and modernizing guidelines for the implementation of structured electronic health records. The developed directory can become the basis for a medical protocol for an imaging study of the retina using OCT.

The accumulation of structured information will contribute to the improvement of the developed CDSS. Using AI-based CDSSs, changing the regulatory framework will help speed up the implementation of the organizational technology for regular follow-up of patients with posterior segment pathology.

### Study limitations

The results of the study are intended for follow-up in patients with posterior segment pathology. The results cannot be used in the primary diagnosis of eye, ocular adnexa, and orbit pathologies.

## CONCLUSION

In the legal framework of the Russian Federation, some of the physician's medical functions could not be delegated to nursing staff such as when interpreting the results of a medical examination. For example, in eye, ocular adnexa, and orbital disorders, the professional standard and regulatory framework must be amended. However, no uniform rules have been established for creating a structured electronic medical record containing the results of interpreting a retinal examination using OCT. The proposed classifier made it possible to create and train (based on 60,000 medical images)

a CDSS, which, as an information service not intended for establishing a diagnosis, allows for the reorganization of the follow-up process. The primary service of the developed CDSS is patient routing. If signs of deterioration are observed in the clinical presentation, referral to a medical ophthalmology center is warranted to assess the disease course and provide specialized, including high-tech medical care.

## ADDITIONAL INFO

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