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ARTIFICIAL INTELLIGENCE IN PULMONOLOGY: CLINICAL PERSPECTIVES AND LEGAL CHALLENGES

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Summary.
Artificial intelligence (AI) is reshaping pulmonology across diagnosis, personalized therapy, telemedicine, and outcome prediction. Deep learning accelerates interpretation of CT/MRI and chest radiographs; machine-learning models using raw spirograms, questionnaires, and digital inhalers improve early detection and exacerbation forecasting. Remote patient monitoring with wearables enables pre-emptive care, while multi-omics and digital twins open paths to precision medicine. High-risk regulatory frameworks (EU AI Act) and ethical oversight ensure transparency, safety, and human control. For Moldova, phased adoption–standards, PACS/EHR integration, AI literacy, and pilots for COPD, asthma, and tuberculosis–can reduce delays and inequities. This review synthesizes methods, governance, and pragmatic steps for trustworthy, locally adapted implementation at scale.
Keywords: Artificial intelligence, pulmonology, COPD, tuberculosis, telemedicine, digital twins, EU AI Act.

Rezumat. Inteligența Artificială în pneumologie: perspective clinice și provocări juridice.
Inteligența artificială remodelează pneumologia în diagnostic, terapie personalizată, telemedicină și predicția rezultatelor. Învățarea profundă accelerează interpretarea CT/RMN și a radiografiilor toracice, iar modelele de învățare automată bazate pe spirograme brute, chestionare și inhalatoare digitale îmbunătățesc depistarea precoce și prognoza exacerbărilor. Monitorizarea la distanță cu dispozitive purtabile permite îngrijire proactivă; multi-omica și gemenii digitali deschid medicinii de precizie. Cadrul pentru sisteme cu risc înalt (AI Act al UE) și supravegherea etică asigură transparență, siguranță și control uman. Pentru Republica Moldova, adoptarea etapizată – standarde, integrarea PACS/EHR, alfabetizare în AI și proiecte pilot pentru BPOC, astm și tuberculoză – poate reduce întârzierile și inechitățile și sprijini implementarea la scară.
Cuvinte cheie: Inteligență artificială, pneumologie, BPOC, tuberculoză, telemedicină, gemeni digitali, AI Act UE.

Резюме. Искусственный интеллект в пульмонологии: клинические перспективы и правовые вызовы.
Искусственный интеллект меняет пульмонологию по всему циклу: от диагностики и персонализированной терапии до телемедицины и прогноза исходов. Глубокое обучение ускоряет интерпретацию КТ/МР и рентгенограмм, а модели машинного обучения по «сырым» спирограммам, анкетам и данным цифровых ингаляторов улучшают раннее выявление и предсказание обострений. Дистанционный мониторинг с носимыми датчиками позволяет проактивную помощь; мультиомика и цифровые двойники приближают медицину точности. Для высокорисковых систем регуляторные рамки (EU AI Act) и биоэтический надзор обеспечивают прозрачность, безопасность и «человека в контуре». Для Молдовы поэтапное внедрение – стандарты, интеграция PACS/EHR, AI-грамотность и пилоты по ХОБЛ, астме, туберкулезу – снижает задержки и неравенство и поддерживает масштабирование.
Ключевые слова: Искусственный интеллект, пульмонология, ХОБЛ, туберкулез, телемедицина, цифровые двойники, EU AI Act.

Introduction.

Respiratory diseases remain among the leading causes of mortality and disability worldwide, and their socioeconomic burden is increasing amid population aging, urbanization, air pollution, and the impact of the COVID-19 pandemic. The pandemic crisis has revealed both the vulnerabilities of traditional models of care and the potential of digital solutions: telemedicine has mitigated gaps in continuity of care and accelerated the adoption of proactive protocols, while machine learning and deep learning have demonstrated the ability to extract useful patterns from medical images, signals, and clinical documentation texts. The regulatory environment is actively catching up with technological progress: the European AI Act codifies requirements for "high-risk" medical AI systems, including the diagnostic and monitoring solutions described in this paper; In the US, E.O. 14110 served as a guideline for federal agencies, after which it was repealed by the

new administration in January 2025. However, this does not negate the market's ongoing transition to practices of safety, transparency, and post-marketing surveillance. At the clinical services level, the UK is scaling up lung screening as part of Targeted Lung Health Checks, where AI elements are increasingly integrated into image assessment and patient routing workflows, while the US FDA AI/ML device registry continues to be updated and serves as a guide for selecting solutions with proven clinical and regulatory soundness. These examples set standards for quality and safety and are relevant for resource-constrained countries, where implementation should be phased, with an emphasis on interoperability, staff training, and auditing of real-world effectiveness.

Moldova's specific characteristics include a shortage of primary care equipment (especially spirometry and modern imaging), a significant rural population, and a fragmented legal framework for telemedicine, where regulations are scattered across various acts and do not form a single codified instrument for scaling. At the same time, piloting in eight medical and social centers (Caritas Czech Republic in collaboration with the Homecare Association) has demonstrated the practical feasibility of video consultations and remote monitoring, especially for elderly and immobile patients, which creates a basis for expanding programs in COPD, asthma, and tuberculosis, provided that standards for interoperability, data protection, and sustainable financing are in place.

In theoretical terms, AI in medicine is not limited to neural networks. For the purposes of this paper, AI refers to a wide range of methodologies: from symbolic AI and production rules that enable reproducible clinical triage and solution support, to probabilistic graphical models, evolutionary and swarm optimizers for planning tasks, and finally, machine learning methods including decision trees, ensemble methods, SVMs, linear and Bayesian models, as well as deep architectures for images, audio signals, time series, and multiomics. This broad definition is important because each direction solves its own set of problems: CNNs and transformers work well with visual and acoustic data, but interpretable ensemble models often perform better with tabular clinical datasets and risk assessment, and explainable and drift-resistant algorithms are often required for regulatory reporting and expert review.

Materials and methods.

A literature search was conducted in the international indexed databases PubMed/MEDLINE, Cochrane Library, Scopus, and Web of Science, followed by the addition of specialized sources, including EUR-Lex, Federal Register, NICE resource on TLHC programs, FDA public list of AI/ML devices, and full-text publications in PMC. Keyword combinations reflecting the target domains were used: artificial intelligence in pulmonology, machine learning in COPD, asthma, and tuberculosis, detection of interstitial patterns on CT, CAD for chest radiography, digital spirograms and deep learning for time series, telemedicine and remote monitoring, digital inhalers, predictive outcome models, multi-ome integrations and digital twins, as well as ethics and regulation, including the AI Act and E.O. 14110. The selection included original research, systematic reviews, and regulatory papers.

Results and discussion.

Diagnosis and early detection

Artificial intelligence (AI) is becoming a key tool in the X-ray diagnosis of lung diseases, increasing both the speed and reliability of interpretation. Deep learning algorithms, particularly convolutional neural networks (CNN), are capable of detecting minimal pathological changes in images that often go unnoticed during visual analysis. The CheXNet and CAD4TB systems have proven effective in diagnosing pneumonia, tuberculosis, and lung cancer, which is especially valuable for mass screening programs. The use of AI reduces the burden on specialists and provides higher diagnostic reliability in conditions of staff shortages and healthcare overload.

The scalability and reproducibility of image analysis have become one of the main factors in the introduction of AI into pulmonology practice. CNN algorithms for high-resolution computed tomography (HRCT) demonstrate 70–80% sensitivity and up to 90% specificity in recognizing interstitial patterns and UIP patterns, which is comparable to expert assessment and significantly faster. Such solutions are already being integrated into clinical processes: in the UK, the Targeted Lung Health Checks program uses AI for risk stratification and early diagnosis, speeding up patient routing, and in the US, there is a continuously updated registry of certified AI/ML devices, which includes modern CAD systems and software products for analyzing CT and X-ray images. For the Republic of Moldova, this opens up the possibility of reducing diagnostic delays at the regional level, provided that PACS/EHR is implemented, interoperability is ensured, and sufficient communication channel bandwidth is available.

For tuberculosis, an independent branch of CAD for chest X-rays has developed over the past decade. Early work showed that deep learning automatically

extracts characteristic features of infiltration and cavitation; more recent publications in high-impact journals have confirmed reproducibility in complex cohorts, including screening in prisons and regions with a high TB burden. Meta-reviews and practical guidelines have emerged to help select thresholds and interpret the sensitivity-specificity spectrum, taking into account program objectives, whether triage at the primary care level or verification in TB centers. In Moldovan practice, CAD on CXR can be the first filter in the TB detection chain and refer patients for confirmatory bacteriological diagnosis, relieving bottlenecks in the routing process.

Algorithms for early screening of COPD and asthma using non-medical data channels show particular dynamism. Questionnaire models, enhanced by gradient boosting and decision trees, achieve AUC in the upper range of 0.8–0.9 and above, allowing risk groups to be identified before the onset of severe symptoms and patients to be referred for spirometry. Approaches such as DeepSpiro go even further, working on raw volume-time curves and flow signals, applying smoothing blocks, feature encoders, and attention interpretations. They achieve an AUC of around 0.83 for current COPD and predict risk over a several-year horizon, while remaining robust to noise and variability in maneuver performance. Large genetic cohorts show that analysis of raw spiro signals improves not only phenotypic classification but also the identification of genetic associations, paving the way for the integration of functional phenotyping and multiomics into a single screening platform. For Moldova, it is critical that such solutions are potentially accessible at the level of smartphones and portable devices, which facilitates deployment "in the field."

Personalized therapy

In asthma, the age of targeted and biological drugs has increased the need for algorithms to select patients who truly benefit from a particular line of therapy. Random Forest and LASSO regression models, combining clinical features, biomarkers such as eosinophilia and FeNO, and genomic markers, demonstrate an AUC of approximately 0.71–0.74 in predicting response to inhaled steroids and biologics. The clinical value here lies not only in "accuracy for accuracy's sake," but also in preventing an inefficient escalation of treatment and saving resources when the algorithm suggests the likelihood of response and the time to expected effect. In registry systems and large centers, such models are complemented by integration with electronic medical records, where records of relapses, hospitalizations, comorbidities, and drug interactions are automatically pulled up.

COPD remains a heterogeneous umbrella diagnosis, where personalization is based on a clinical and functional profile, smoking index, comorbid burden, nutritional status, and individual history of exacerbations. Machine learning is good at combining these diverse characteristics, helping to select the combination of LABA/LAMA/ICS and determine thresholds for early rehabilitation. Digital inhalers and remote monitoring platforms deserve special attention. They record inhalation metrics and device usage patterns in real time and use gradient boosting models to predict aggravation 3–5 days before clinical manifestations. This gives the doctor a window of opportunity to adjust the dose, change the device, or provide enhancement to anti-inflammatory therapy, and gives the patient clear "signals for action."

For tuberculosis, personalization is largely related to drug resistance and treatment duration. Models trained on Mycobacterium tuberculosis genomic data, clinical and socio-demographic characteristics can predict resistance and the risk of treatment failure, thereby supporting the choice of regimen, especially for multidrug-resistant TB. At the same time, digital adherence monitoring technologies, from video-observed therapy (VOT) to smart pillboxes, increase the likelihood of completing a course of treatment, but require careful ethical considerations to balance public health and patient rights.

Monitoring and telemedicine

Remote monitoring of respiratory patients is increasingly based on multi-sensor platforms. Wearable devices—from watches and bracelets to chest vests—record respiratory rate, oxygen saturation, heart rate, heart rate variability, activity level, and sleep. Systematic reviews show that changes in these metrics appear several days before clinically significant aggravation, and combining multiple channels increases accuracy compared to single signals and reduces the risk of " alert fatigue." The limitations of individual sensors in real-world home settings are mitigated by multi-sensor integration and adaptive thresholds, and new work proposes using "novelty" and "anomalies" instead of hard rules, allowing for the detection of shifts in individual variability. In the EU and UK infrastructure, telemedicine is embedded in national strategies, and under the AI Act, remote monitoring solutions that influence clinical decisions are classified as "high risk" and require a comprehensive risk management system, logging, and human oversight. For the US, the conclusions from the COVID-19 period are clear: telemedicine is scalable, but without standardized protocols and trained personnel, the risk of errors

increases. For Moldova, this is an argument in favor of phased scaling from pilots to regional programs with uniform standards for quality, routing, and data protection.

Tuberculosis in the context of remote monitoring is a separate practical issue. Digital adherence monitoring tools reduce the risk of premature discontinuation of therapy, while video-monitored appointments and electronic reminders enable the implementation of hybrid monitoring models in communities with limited access to hospital-based services. However, a transparent informed consent process and a complaints mechanism are needed to minimize stigmatization and invasion of privacy. The Moldavian system could benefit from the gradual introduction of VOT and smart reminders based on mobile applications integrated with the tuberculosis registry and enabling two-way communication between doctors and patients.

Outcome prediction

The use of artificial intelligence in predicting clinical outcomes can significantly improve resource planning and the quality of care for patients with chronic and acute respiratory diseases. One key area is the assessment of the risk of hospitalisation and repeat visits in patients with COPD. Ensemble methods, such as random forests and gradient boosting, consistently demonstrate superiority over traditional clinical scales. Although an improvement in AUROC from 0.63 to 0.69 may seem modest, in practical healthcare, such an increase is significant. It allows for more accurate stratification of patients by risk level, timely prescription of prevention programs, including home visits and early pulmonary rehabilitation, and optimization of pharmacotherapy based on the individual patient profile.

In severe infections such as pneumonia and COVID-19, machine learning algorithms have also shown high clinical value. For example, models based on a naive Bayesian classifier achieved an AUROC of 0.78–0.79 in predicting 30-day mortality, which is comparable to the results of the best validated clinical scales. Despite the challenges associated with population variability and the evolution of virus strains during the pandemic, the overall conclusion remains unchanged: multiparametric models combining demographic characteristics, saturation indicators, laboratory markers of inflammation, and data on comorbidities allow for more accurate risk ranking and assist in the allocation of medical resources in crisis situations.

With regard to tuberculosis, predictive models are being actively developed to assess the likelihood of treatment failure, the risk of relapse, and the occurrence of side effects of therapy. These models are particularly valuable in public health programs, as they allow the identification of patients who are prone to treatment failure and the timely adjustment of management tactics. An important advantage is the ability to integrate data on treatment adherence, socioeconomic status, and living conditions of patients. This comprehensive approach provides a more realistic risk assessment and creates conditions for personalized intervention aimed at improving the effectiveness of disease control and reducing the level of multidrug-resistant tuberculosis.

In this way, AI models for predicting outcomes are gradually becoming an important tool in clinical practice and healthcare in general. They enable a shift from reactive to proactive risk management, improving resource allocation and strengthening preventive measures in pulmonology and phthisiology.

Fundamental and research aspects

Generative models open up new horizons in the analysis of complex physiological signals and medical imaging, enabling the creation of more accurate and reproducible tools for clinical practice. Variational autoencoders (VAEs) have proven their superiority over traditional methods in separating cardiac and respiratory sounds, especially in the presence of background noise. Their use ensures consistent extraction of acoustic features, which significantly improves the quality of early diagnosis and monitoring of respiratory diseases.

Another direction is generative adversarial networks, in particular BicycleGAN, which allow the formation of realistic four-dimensional simulations of respiratory movements in XCAT phantoms with the possibility of precise adjustment of amplitude and geometry. This approach speeds up the development and testing of imaging protocols, optimizes radiation therapy planning, and reduces dependence on expensive and difficult-to-reproduce physical experiments.

At the same time, multi-modal platforms are reaching new heights, forming clinical-genomic-radiomic “digital avatars” of patients. One example is the LANTERN project, where demographic, clinical, genomic, and radiomic data are combined into a single model for diagnosis, prognosis, and selection of optimal therapy for lung cancer. This architecture has universal potential: it can be adapted for chronic inflammatory diseases of the respiratory system and infectious processes, including tuberculosis. In the future, combining pathogen genomics, host immune profiles, respiratory tract microbiome data, and long-term clinical context will enable the creation of integrative predictive models that improve diagnostic

accuracy, personalize therapy, and enhance the effectiveness of preventive measures.

Ethical and legal aspects

The international regulatory framework for medical AI is growing, and there are already real-life cases where the use of AI systems has led to legal consequences. Current practice shows that doctors, even when acting in good faith and relying on AI systems, can be held liable for medical negligence if they follow the algorithm's recommendations without critical review, especially when the system has not been sufficiently tested or its operation is not transparent. At the same time, it is emphasized that in the case of autonomous solutions capable of independently generating recommendations or actions, responsibility cannot lie solely with the doctor. The creators of such systems also bear legal obligations, even if the device was used correctly and in accordance with the instructions. In this regard, there are increasingly insistent calls for professional liability insurance to cover not only healthcare professionals but also the manufacturers of such solutions.

Regulatory practice confirms these risks. There are known cases where devices approved by the competent authorities were subsequently recalled after being placed on the market. Often, the reason was that clinical trials did not cover all age or gender groups, or that the device functioned differently in real-world conditions than in controlled conditions. Such examples show that certification is not a guarantee of error-free operation, but rather a necessity for constant monitoring and refinement.

At the same time, experts note serious gaps in the post-marketing surveillance system. Many adverse events are not properly recorded, which prevents the timely detection of malfunctions and the adjustment of algorithms. This raises the question of the need for stricter monitoring, transparent reporting, and rapid exchange of information about risks.

Specific technical and organizational measures are also proposed, which could serve as a kind of legal "insurance" for all participants in the process: mandatory double-checking of solutions by a clinical specialist, maintenance of audit trails, systematic assessment of biases, implementation of data quality standards, and ensuring the explainability of algorithms.

In most cases, judicial practice still places the main responsibility on the doctor, even if the error was caused by an incorrect algorithm. Doctors are expected to exhibit the behavior of a 'reasonable specialist' and be able to recognize system errors. However, there are increasing calls to reform this model and recognize the share of responsibility of developers and manufacturers, especially when "black boxes" are used, whose solutions cannot be interpreted.

European regulation goes further: taken together, the requirements of the Medical Devices Regulation, the AI Act, and the revised Product Liability Directive create conditions under which manufacturers, importers, distributors, and even organizations that modify AI systems can be held liable for defects—including software defects. This creates a new legal reality where responsibility is shared among all participants in the chain and patient protection is placed at the center of regulation.

In this way, examples show that legal liability in real cases often falls on the doctor, but with a growing trend toward joint liability: manufacturing, certification, data quality, staff training, algorithm stability, transparency, and the regulatory environment are all taken into account. This experience is also important for Moldova: it shows that without an adequate regulatory framework, internal audit, and clear procedures for allocating responsibility, the use of AI can entail legal risks for all parties—patients, doctors, manufacturers, and healthcare institutions.

Recommendations for the Republic of Moldova

For the sustainable integration of artificial intelligence into pulmonary practice in the Republic of Moldova, coordinated progress is needed in several areas at once: regulatory, infrastructure, human resources, and organizational.

From a legal point of view, the priority should be the adoption of a single law on telemedicine and medical AI systems. This law should be harmonized with the European AI Act and GDPR regulations, provide for risk classification, rules for logging and transparency of algorithms, mandatory human oversight, and a system of regular staff training. Such regulation will reduce legal uncertainty, protect patients, and ensure predictability for medical organizations and developers.

In the infrastructure sector, the key task is to create a compatible digital ecosystem. It is necessary to implement national PACS and electronic health records (EHR), ensure secure channels for transmitting images and physiological signals, and integrate wearable devices and digital inhalers through international data exchange standards. Particular attention should be paid to the protection of personal information: data anonymization and encryption should become standard, especially for rural and remote areas.

Staff training is another critical element. It is important to institutionalize AI literacy by including it in educational programs for doctor students, as well as to organize ongoing professional development for practicing doctors and administrators. Medical staff must be able to recognize the limitations of algorithms, assess the risks of model drift, use incident escalation mechanisms, and participate in the periodic revalidation of AI systems.

At the operational level, existing pilot projects, such as the Caritas/Homecare program, should be scaled up, with a focus on patients with COPD, asthma, and tuberculosis. The introduction of video-observed medication (VOT), the use of digital inhalers, and home spirometry will enable the development of comprehensive remote monitoring programs. The effectiveness of such projects should be assessed not only in terms of clinical outcomes (frequency of complications, hospitalizations, mortality), but also in terms of economic indicators and patient quality of life.

To support personalized medicine, it is advisable to create national registries and multi-dimensional data collections similar to the LANTERN project, with mandatory compliance with the principles of confidentiality and ethics. At the same time, international registries such as FDA and CE marking should be actively used to select solutions with proven safety and clinical validity.

Finally, each initiative should include a Health Technology Assessment (HTA) component, based on the recommendations of the World Health Organization and the OECD. This will allow for the assessment of not only the medical effectiveness but also the economic feasibility of implementing AI technologies. Only those solutions that have proven their usefulness and sustainability should receive long-term funding and be scaled up in the healthcare system.

In this way, Moldova's strategy should be based on a sequence of steps: from creating a legal framework and infrastructure to training specialists and scaling up proven pilot projects. This will not only allow Moldova to catch up with international standards, but also adapt them to the national context, ensuring the accessibility and fairness of digital medicine for all categories of the population.

Prospects for further research

The future of pulmonology is inseparably linked to the integration of digital technologies, where digital twins will play a key role. These virtual patient models will combine data from various levels — from physical and pathophysiological models of ventilation and perfusion to clinical and laboratory indicators, CT and MRI images, genomic and radiomic profiles, as well as information on exposure factors (air pollution, smoking, occupational risks) and behavioral habits. This approach will make it possible to predict the course of the disease on an individual basis, evaluate the effectiveness of therapy before it is prescribed, and adjust treatment tactics in real time.

An equally important area will be the introduction of explainable AI and causal inference methods. Modern algorithms should not only make predictions, but also ensure transparency in decision-making by demonstrating which specific factors were decisive. Verifiable causality and explainable attributions are the basis of clinical trust and legal stability of systems that directly affect the lives and health of patients.

Generative models will play an increasingly important role in creating synthetic data that closely resembles real physiological processes. Such data is necessary for testing and validating protocols, especially in conditions of limited access to large clinical samples or in rare diseases. They will allow the reproduction of scenarios that are difficult or impossible to model in real conditions, thereby accelerating the development and implementation of innovative methods of diagnosis and therapy.

At the same time, multisensory remote monitoring is also developing. In the coming years, protocols for integrating wearable and portable devices are expected to be standardized, which will allow for the formation of a unified digital ecosystem. Particular attention will be paid to the creation of "fatigue-resistant" alarm systems that minimize the number of false alarms and direct the attention of medical staff only to clinically significant events. In such systems, human experts must remain in the decision-making loop, maintaining a balance between automation and the need for medical control.

In this way, the prospects for further research in pulmonology are linked to the transition from individual digital solutions to integrated platforms capable of forming predictive and explainable models of patient health. This will lay the foundation for the proactive, personalized, and sustainable medicine of the future.

Conclusion.

Artificial intelligence is no longer an experimental add-on, but has become the technological foundation of modern pulmonology. At the diagnostic level, it increases the speed and reproducibility of CT, MRI, and chest X-ray interpretation, helps standardise the recognition of interstitial patterns and oncological findings, reduces the burden on overloaded links, and shortens the time to clinical solution. At the level of personalised therapy, AI combines clinical,

functional, and molecular characteristics, supports the selection of biological drugs for asthma, optimises LABA/LAMA/ICS regimens for COPD, and in tuberculosis, it guides tactics when there is a risk of drug resistance, combining pathogen genomic data with the patient's clinical context. Remote monitoring via wearable devices and digital inhalers shifts the focus to predictive, preventive medicine, allowing for prevention of aggravations days in advance and flexible routing of care.

However, the sustainability of results is determined not by the algorithms themselves, but by data quality, risk management, and process maturity. The European AI Act rightly classifies medical AI systems as high risk, and this sets the agenda: transparency, documented metrics, 'human in the loop', logging and post-marketing monitoring. Without these safeguards, automation creates new vulnerabilities, from automation bias to erosion of trust.

For the Republic of Moldova, the priorities are clear. There is a need for a unified law on telemedicine and medical AI, compatible PACS/EHR and secure transmission channels, institutionalised AI literacy for clinicians and IT services, as well as pilot studies that measure real outcomes rather than 'impressive' AUCs: reduced hospitalisations, shorter time to diagnosis, increased adherence to tuberculosis therapy, and improved quality of life. The next step will be to deploy registries and multimodal collections with privacy in mind, as well as to implement explainable AI and digital twins where they add clinical value. With this architecture, AI will become not a trend, but an infrastructure that provides equitable access, predictable quality, and consistent outcomes for patients with lung disease.

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