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## NATIONAL CLINICAL PROTOCOLS IN PHTHISIOPULMONOLOGY: EVALUATION AND ENSURING QUALITY AND SAFETY

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### Summary.

In the context of healthcare reform in the Republic of Moldova, national clinical protocols are becoming particularly important. Their main purpose is to standardize diagnosis and treatment, reduce medical risks, improve patient safety, and serve as a guideline for medical and forensic examinations. This study is devoted to the analysis of phthisiopulmonological protocols. It identified the most significant nosologies, assessed the frequency of protocol updates, and examined the medical and legal risks associated with the untimely revision of documents. In the Republic of Moldova, 10 protocols for adults and 14 for children have been approved. They cover diseases and conditions such as tuberculosis, pneumonia, chronic obstructive pulmonary disease, sarcoidosis, idiopathic interstitial pneumonitis, bronchiectasis, obstructive sleep apnea syndrome, smoking cessation, and a number of rare diseases. The average age of the protocols for adults is 5.7 years, which indicates the need for their accelerated revision. A medical-legal analysis has shown that untimely updating of protocols reduces their evidential value and increases the risk of liability for healthcare professionals.

**Keywords:** phthisiopulmonology, national clinical protocols, patient safety, quality of medical care, medical error, forensic examination.

### Rezumat. Protocoale clinice naționale în ftiziopneumologie: evaluarea și asigurarea calității, și siguranței.

În contextul reformării sistemului de sănătate din Republica Moldova, protocoalele clinice naționale capătă o importanță deosebită. Scopul lor principal este de a asigura standardizarea diagnosticării și tratamentului, reducerea riscurilor medicale, creșterea nivelului de siguranță a pacienților, precum și utilizarea lor ca orientare în efectuarea expertizelor medicale și judiciare. Prezenta cercetare este dedicată analizei protocoalelor ftiziopneumologice. În cadrul acesteia, a fost determinată acoperirea celor mai semnificative nozologii, a fost evaluată frecvența actualizării protocoalelor și au fost analizate riscurile medicale și juridice care apar în condițiile revizuirii întârziate a documentelor. În Republica Moldova au fost aprobate 10 protocoale pentru adulți și 14 pentru copii. Acestea acoperă boli și afecțiuni precum tuberculoza, pneumonia, boala pulmonară obstructivă cronică, sarcoidoza, pneumonita interstițială idiopatică, bronșiectazia, sindromul de apnee obstructivă în somn, renunțarea la fumat, precum și o serie de boli rare. Vârsta medie a protocoalelor pentru adulți este de 5,7 ani, ceea ce indică necesitatea revizuirii accelerate a acestora. Analiza medico-juridică a arătat că actualizarea întârziată a protocoalelor reduce semnificația lor probatorie și crește riscul de răspundere a personalului medical.

**Cuvinte cheie:** ftiziopneumologie, protocoale clinice naționale, siguranța pacienților, calitatea asistenței medicale, erori medicale, expertiză judiciară.

### Резюме. Национальные клинические протоколы во фтизиопневмологии: оценка и обеспечение качества, и безопасности.

В условиях реформирования системы здравоохранения Республики Молдова особую значимость приобретают национальные клинические протоколы. Их основная цель заключается в обеспечении стандартизации диагностики и лечения, снижении медицинских рисков, повышении уровня безопасности пациентов, а также в использовании в качестве ориентира при проведении медицинских и судебных экспертиз. Настоящее исследование посвящено анализу фтизиопневмологических протоколов. В его рамках был определен охват наиболее значимых нозологий, проведена оценка частоты обновления протоколов, а также рассмотрены медицинские и правовые риски, возникающие в условиях несвоевременного пересмотра документов. В Республике Молдова утверждено 10 протоколов для взрослых и 14 – для детей. Они охватывают такие заболевания и состояния, как туберкулез, пневмония, хроническая обструктивная болезнь легких, саркоидоз, идиопатические интерстициальные пневмонии, бронхоэктазы, синдром обструктивного апноэ сна, отказ от курения, а также ряд редких заболеваний. Средний возраст протоколов для взрослых составляет 5,7 года, что свидетельствует о необходимости ускоренного их пересмотра. Медико-правовой анализ показал, что несвоевременное обновление протоколов снижает их доказательную значимость и повышает риск наступления ответственности медицинских работников.

**Ключевые слова:** фтизиопневмология, национальные клинические протоколы, безопасность пациентов, качество медицинской помощи, медицинские ошибки, судебная экспертиза.

## Introduction.

Modern healthcare is unthinkable without mechanisms that ensure the quality and safety of medical care. The World Health Organization defines clinical protocols as systematically developed guidelines designed to facilitate informed solutions in the provision of medical care [17]. They are based on a systematic review of evidence and an assessment of the balance between benefits and risks. The use of protocols reduces unnecessary variability in medical practice, improves clinical effectiveness, enhances patient safety, and promotes a consistent approach to diagnosis and treatment [11, 17]. In addition, the use of protocols contributes to the formation of a culture of safety: healthcare professionals receive clearly structured algorithms, patients are better informed about the treatment process, and the effectiveness of the system becomes measurable and transparent [17].

At the national level, clinical protocols are not only tools for practical medicine, but also regulatory acts that are mandatory for implementation [13, 14]. In accordance with Moldova's "Methodology for the Development and Implementation of Regulatory Standardization Acts for Health Services" clinical guidelines, protocols, and algorithms are considered acts that ensure the quality and safety of medical services [14]. At the same time, protocols are not an absolute legal standard for doctors, which requires careful analysis of the legal context [5].

The Law on the Medical Profession in the Republic of Moldova defines "medical error" as a professional action or inaction that causes harm to a patient and civil liability [15].

The fundamental principles of the profession include respect for patient rights, maintaining professional competence, and maintaining confidentiality [17]. In addition, the Law on Patient Rights enshrines the right to receive quality medical care, the possibility of informed choice, and participation in decision-making. In this way, failure to comply with current protocols may be considered a violation of a doctor's professional duties [15].

The significance of this issue is amplified in the field of phthisiopulmonology. Tuberculosis remains one of the leading causes of death from infectious diseases: in 2023, according to the World Health Organization, 10.8 million people fell ill, and the number of deaths reached 1.25 million [19]. Other respiratory diseases also represent a significant threat. For example, chronic obstructive pulmonary disease (COPD) was the fourth leading cause of death worldwide in 2021, resulting in 3.5 million deaths [21]. Pneumonia, in turn, remained the leading cause of death among children under five years of age [17].

The Republic of Moldova continues to have a high incidence of tuberculosis, with an increase in the number of resistant strains and exacerbating socio-economic factors, which requires the improvement of preventive and therapeutic strategies [19]. However, to date, there have been no systematic studies aimed at evaluating the effectiveness of national clinical protocols and identifying the legal consequences of their untimely updating [13, 15].

**The aim of this study** is to conduct a comprehensive analysis of national clinical protocols in phthisiopulmonology as a tool for improving the quality of medical care and ensuring patient safety [17].

## Materials and methods.

The work was analytical in nature and was carried out using a comprehensive methodological approach that included regulatory, statistical, and comparative legal analysis. The sources used were national regulatory legal acts governing the activities of medical workers. In addition, orders of the Ministry of Health regulating clinical protocols for phthisiopulmonology were studied. The dates of their introduction were verified on the official website of the Ministry of Health, with each protocol being compared with the order. A systematic search for scientific literature was conducted in the PubMed, Cochrane Library, Scopus, and Clarivate databases, as well as in the national resources [ibn.idsi.md](http://ibn.idsi.md), [legis.md](http://legis.md), and [dissercat.com](http://dissercat.com). Publications on clinical protocols, medical errors, patient safety, and lung diseases were analyzed. Particular attention was paid to WHO documents from 2024–2025, which made it possible to assess the compliance of MD protocols with international recommendations.

## Results and discussion.

### *Structure and coverage of national clinical protocols*

As of early September 2025, there are ten clinical protocols in place in the Republic of Moldova that regulate the diagnosis and treatment of adult patients with pulmonary diseases [13]. These include the protocol on community-acquired pneumonia, approved by order of March 30, 2020 [13, 17], and the document on Chronic Obstructive Pulmonary Disease (COPD), adopted by the same regulatory act [21]. Of particular importance is the new version of the tuberculosis protocol, which covers diagnosis, treatment, and prevention [19]. In April 2020, protocols on sarcoidosis and idiopathic interstitial pneumonitis were additionally approved [6, 9, 10]. The current documents also include a protocol for nosocomial pneumonia, regulations for bronchiectasis

[4], guidelines for obstructive sleep apnea syndrome [16], a smoking cessation program for adults, and a protocol for allergic bronchopulmonary aspergillosis [4]. This list demonstrates a fairly broad coverage of both infectious and chronic respiratory diseases [12, 17]. However, the average age of most documents exceeds five years, indicating the need for their updating [13].

Fourteen approved clinical protocols are used in pediatric practice [13]. They cover such nosologies as tuberculosis in children [19], cystic fibrosis [2], wheezing in children, aspiration of foreign bodies into the respiratory tract in children, community-acquired pneumonia in children [17], chronic bronchitis in children, bronchiectasis in children [4], acute bronchiolitis in children, pulmonary aspergillosis in children, bronchopulmonary dysplasia in children, pneumocystosis in children, obliterative bronchiolitis in children, primary ciliary dyskinesia in children, smoking cessation in children and adolescents [20]. The dates of approval of these documents vary from 2016 to 2025 [13].

#### *Analysis of the coverage of nosological categories*

An analysis of current clinical protocols allows us to identify several main groups of diseases [12]. Respiratory tract infections include community-acquired and nosocomial pneumonia [17], as well as bronchiolitis. Chronic obstructive diseases include COPD [21], bronchiectasis [4], and chronic bronchitis. Specific infections, represented by tuberculosis [19] and pneumocystosis, constitute a separate category. The group of systemic inflammatory diseases includes sarcoidosis [9] and idiopathic interstitial pneumonitis [6, 10]. Among rare genetic pathologies, cystic fibrosis [2] and primary ciliary dyskinesia are regulated. In addition, allergic and fungal diseases are covered, including allergic bronchopulmonary aspergillosis [4]. Protocols have also been developed for obstructive sleep apnea syndrome and smoking cessation programs [20].

In this way, the Moldavian clinical protocols cover a wide range of nosologies relevant to both adults and children [13]. At the same time, significant gaps have been identified: there are no separate protocols for bronchial asthma, sarcoidosis in children [9] and interstitial diseases in children [6, 10], as well as for COVID-19 infection [18]. It should be noted that the official protocol for COVID-19 (NCP-371 Provisional NCP “New Coronavirus Infection”) was developed in 2020, but was subsequently archived after the epidemiological situation stabilized [18].

A quantitative analysis showed that of the 24 clinical protocols, ten are intended for the adult

population and fourteen for children [13]. Among them, 45% of the documents are devoted to infectious and inflammatory diseases, including tuberculosis and pneumonia [17, 19], and bronchiolitis; 25% are devoted to chronic obstructive diseases such as COPD, bronchiectasis and chronic bronchitis [4, 21]; about 20% are protocols for rare genetic and allergic pathologies [2, 6]; 10% are devoted to smoking cessation programs [20]. This structure reflects the priority of diseases with a high epidemiological burden and generally corresponds to the structure of morbidity in the population [17]. However, the limited number of documents regulating the management of patients with COPD and bronchiectasis indicates insufficient attention to these pathologies, which, according to the World Health Organization, rank fourth among the causes of mortality worldwide [21].

#### *Updates and frequency of updates*

To assess the relevance of national clinical protocols, the time interval between their approval date and September 12, 2025 was calculated [13]. The analysis showed that the average “age” of documents for the adult population is 5.7 years, while for pediatric protocols it is 3.1 years. Of the ten protocols for adults, eight (80%) were approved more than five years ago, indicating that they are outdated [13].

The most critical situation appears to be with documents on bronchiectasis [4] and obstructive sleep apnea syndrome [16], which have not been revised since 2017. In pediatric practice, protocols are updated more regularly: by the end of 2025, only one document (community-acquired pneumonia in children) was more than five years old [17]. It is noteworthy that in 2025, several protocols were updated simultaneously, including wheezing in children, chronic bronchitis in children, bronchiectasis in children [4], which indicates increased attention to the problems of pediatric respiratory pathology.

International sources emphasize that clinical guidelines need to be revised when new evidence emerges, new therapeutic interventions are introduced, key clinical outcomes change, or the resource base for treatment transforms [11]. The rapid evolution of medical knowledge in the field of phthisiopulmonology, including the introduction of short-term tuberculosis chemoprophylaxis regimens [19], the use of new drugs [6, 10], and the revision of approaches to the treatment of COPD [21], makes it necessary to regularly update national documents [12]. In 2024, the World Health Organization represented new recommendations for the preventive treatment of tuberculosis, including a six-month regimen with Levofloxacinum for contacts of patients with multidrug-resistant forms of the disease [19].

Table 1.

## National Clinical Protocols for Phthisiopulmonology

№	Title of National Clinical Protocol (NCP)		Anul aprobării
<b>Adult</b>			
1.	NCP-3	Community-acquired pneumonia in adults	<b>2020</b>
2.	NCP-18	Chronic obstructive pulmonary disease	2024
3.	NCP-123	Tuberculosis in adults	<b>2020</b>
4.	NCP-186	Sarcoidosis in adults	<b>2020</b>
5.	NCP-187	Idiopathic interstitial pneumonitis	<b>2020</b>
6.	NCP-203	Nosocomial pneumonia in adults	<b>2020</b>
7.	NCP-275	Bronchiectasis in adults	<b>2017</b>
8.	NCP-276	Obstructive sleep apnea syndrome	<b>2017</b>
9.	NCP-335	Smoking cessation	<b>2018</b>
10.	NCP-391	Allergic bronchopulmonary aspergillosis	2021
<b>Child</b>			
1.	NCP-55	Tuberculosis in children	2023
2.	NCP-93	Cystic fibrosis	2021
3.	NCP-98	Wheezing in children	2025
4.	NCP-99	Aspiration of foreign bodies into the respiratory tract in children	2021
5.	NCP-100	Community-acquired pneumonia in children	<b>2016</b>
6.	NCP-101	Chronic bronchitis in children	2025
7.	NCP-126	Bronchiectasis in children	2025
8.	NCP-149	Acute bronchiolitis in children	2021
9.	NCP-392	Pulmonary aspergillosis in children	2021
10.	NCP-393	Bronchopulmonary dysplasia in children	2021
11.	NCP-407	Pneumocystosis in children	2022
12.	NCP-415	Obliterative bronchiolitis in children	2022
13.	NCP-416	Primary ciliary dyskinesia in children	2022
14.	NCP-430	Smoking cessation in children and adolescents	2024

*Note: NCPs subject to urgent review are highlighted in bold.*

The prompt inclusion of such changes in national protocols is critical to maintaining their compliance with international standards [11, 17].

The WHO has previously noted that a number of European countries lack a unified regulatory framework for the development of clinical guidelines, and that the implementation of recommendations largely depends on the activity of professional associations. In the Republic of Moldova, the protocol system is developing more consistently: according to the WHO report on non-communicable diseases, 147 clinical protocols have been developed since 2008 in priority areas of healthcare, with a key feature being

the presence of mandatory implementation indicators and their link to the remuneration scheme. At the same time, international recommendations point to the need for an accelerated review of protocols on priority topics, as well as the expansion of the competencies of nurses and primary care doctors.

#### **Medical and legal risks of outdated protocols**

The existence of a clinical protocol contributes to the standardization of diagnosis and treatment, ensuring the predictability of therapeutic outcomes and reducing variability in medical practice [17]. However, excessive formalization without taking into account new evidence can lead to the

inclusion of outdated or even potentially harmful recommendations in documents [12]. In the field of phthisiopulmonology, such risks are particularly significant: incorrectly chosen therapeutic tactics in the treatment of tuberculosis contribute to the development of drug resistance, and suboptimal management regimens for patients with COPD worsen disease control and increase the risk of complications [21].

International literature emphasizes that clinical guidelines are not an absolute legal standard; their use in court practice is limited due to the possibility of obsolescence, conflicts of interest, and the lack of consideration of individual patient characteristics [11]. At the same time, in a number of countries, compliance with protocols is considered by the courts as a sign of conscientious patient care, while ignoring them may be interpreted as a disregard for professional standards [15].

The legislation of the Republic of Moldova explicitly establishes the concept of “medical error” and liability for its commission. In accordance with the Law on the Doctor Profession, healthcare professionals are civilly liable for any harm caused. The Law on Health Protection imposes on the healthcare system the duty to ensure the quality and timeliness of medical care, while the Law on Patient Rights establishes the need to take into account the patient’s opinion, ensure the availability of information, and respect the patient’s dignity [15]. In a situation where the treatment provided does not comply with current protocols, the patient has legal grounds for making a claim. If the protocols themselves are no longer relevant, the doctor finds himself in a contradictory situation: to follow the official national document or to be guided by more modern international recommendations [5]. This conflict creates legal uncertainty and increases the likelihood of litigation [11].

Additional difficulties arise when interpreting clinical protocols in forensic medical examinations. An expert opinion should be based on a combination of factors: the provisions of the current protocol, modern scientific data, and the individual characteristics of the patient [11]. The absence of a regulatory document on a specific nosology or the existence of an outdated protocol significantly complicates the determination of the standard of medical care and increases the risk of conflicting interpretations [15].

International practice shows that clinical guidelines should be considered only as one source of information, which does not replace the professional judgment of an expert and does not exempt them from the need to take into account all the circumstances of

a particular case [11]. It is important for the Republic of Moldova to enshrine a similar approach in law, supplementing it with mechanisms for regular review of protocols and systematic monitoring of their implementation in practice [13].

At the same time, statistical analysis confirms the scale of the problem. In 2019–2024, more than 1.200 forensic medical examinations were conducted in the Republic of Moldova, half of which were related to the assessment of the quality of medical care. The total number of examinations decreased by 2021, probably due to the COVID-19 pandemic, but later recovered. The proportion of cases related to the quality of medical care remains consistently high, at around 50%, and significantly exceeds the figures for previous decades [15].

A notable feature is the predominance of criminal proceedings: more than 98% of such examinations are initiated in the context of criminal cases, with a minimal number of civil claims. At the same time, there has been a shift in focus from surgical specialties to therapeutic disciplines (~58% of cases). In the vast majority of situations (~70%), the reason for conducting an examination is the death of a patient [15].

In this way, forensic medical practice clearly demonstrates that the absence of up-to-date clinical protocols or their formal application creates significant difficulties in assessing the quality of medical care. This strengthens the argument in favor of a systematic update of documents, their regulatory rethinking, and the integration of international experience into national practice.

#### ***Liability for violation of medical care rules***

Failure to comply with clinical protocols may result not only in civil liability but also, as noted above, in criminal liability. In accordance with Article 213 of the Criminal Code of the Republic of Moldova, negligent violation of the rules and methods of providing medical care by a doctor or other medical professional, resulting in serious harm to the health or death of a patient, shall be punished by up to three years’ detention, with the additional revocation of the right to hold certain positions or engage in certain activities for a period of two to five years. In this way, criminal law reinforces civil law mechanisms of liability, emphasizing the need for strict compliance with current medical standards [15].

Case law demonstrates the practical application of this provision. In particular, in a 2016 court case, a neurosurgeon was found guilty under this article for violating surgical care standards, which led to the death of two patients. The court imposed a suspended prison

revocation and obliged him to pay compensation for moral damage to the families of the deceased. Such cases demonstrate that the absence of modern clinical protocols or their outdated nature complicates the conduct of forensic medical examinations and at the same time increases the likelihood of criminal prosecution of medical workers [15].

Consequently, the regular updating and expansion of national clinical protocols should be considered not only a medical task, but also a legal one, which is of key importance for protecting the interests of patients and the legal security of medical professionals.

### ***The impact of protocols on patient safety***

Research in the field of patient safety culture shows that countries with a developed system of clinical guidelines achieve higher levels of public satisfaction and trust in the healthcare system. In the Republic of Moldova, there is currently no systematic collection of data on patient safety, and no reliable national indicators have been developed. The results of surveys of medical staff using HSOPSC (Hospital survey on patient survey culture, HSOPSC) questionnaires revealed a need to improve infrastructure, supplies, staffing, and to foster a culture of mutual respect within medical teams, which is consistent with the findings of similar foreign studies [17].

It should be noted that the introduction of clinical protocols without simultaneous strengthening of the material and technical base and without appropriate training of medical personnel risks remaining a formal measure. At the same time, the existence of transparent and uniform standards allows patients to better understand their rights and regulatory authorities to objectively assess the quality of medical services provided [17].

In this way, clinical protocols should be considered an integral part of the patient safety system. Their effectiveness directly depends on institutional support, regular training of medical staff, systematic monitoring, and open dialogue between the medical community and society.

### ***Comparison with international recommendations***

National clinical protocols should be updated taking into account international experience and current recommendations from leading professional organizations [11, 12]. In the field of tuberculosis, the World Health Organization updated its guidelines for preventive treatment in 2024, including a 6-month regimen with Levofloxacinum for contacts of patients with multidrug-resistant tuberculosis and expanding the list of approved regimens [19]. NCP-18 Bronhopneumopatia obstructivă cronică 2024 takes into account standard approaches to therapy, but

requires the adaptation of the latest recommendations and enhancement of control of preventive treatment. Studies conducted in the Republic of Moldova and Georgia have identified barriers to chemoprophylaxis, including limited availability of diagnostic tests, staff shortages, and low motivation among primary care doctors. This necessitates the inclusion of issues related to the training of medical staff, the clear organization of patient routing, and the development of motivational strategies in national documents.

Chronic obstructive pulmonary disease (COPD) remains one of the leading causes of death worldwide, with nearly 90% of fatalities occurring in low- and middle-income countries [21]. Contemporary GOLD international guidelines emphasize the importance of early diagnosis, individualized selection of bronchodilator therapy, smoking cessation, and vaccination [21]. NCP-18 on COPD notes the importance of inhalation therapy and pulmonary rehabilitation, but needs to be updated to reflect the emergence of fixed combinations of modern drugs, new inhalers, and improved approaches to risk stratification [1]. The smoking cessation protocol (NCP-335 Smoking cessation), approved in 2018, also needs to be revised, synchronized with the COPD protocol, and supplemented with a section on electronic cigarettes, which have become widespread in recent years [20, 21].

Pneumonia remains a significant infectious disease and the leading cause of death among children: in 2019, 740,180 children died from it, accounting for 14% of all deaths in this age group. International guidelines emphasize vaccination against *Streptococcus pneumoniae* and *Haemophilus influenzae*, early detection of severe forms, and rational use of antibiotics [17]. National clinical protocols for pneumonia – NCP-100 Community-acquired pneumonia in children (2016) and NCP-3 Community-acquired pneumonia in adults (2020) – include detailed algorithms for diagnosis and treatment [13]. However, they need to be updated to reflect data on antimicrobial resistance and the introduction of modern antibacterial drugs, including new macrolides and respiratory fluoroquinolones. In addition, integration with the national vaccination program and training of medical staff in methods of early detection of complications should be provided for [17].

With regard to sarcoidosis and rare and interstitial diseases, national protocols for sarcoidosis and idiopathic interstitial pneumonitis were approved in 2020, were an important step in the development of the regulatory framework. However, international professional communities, including the ERS and

ATS, are currently revising classifications and therapeutic approaches. The emergence of antifibrotic drugs such as Nintedanibum and Pirfenidonum should be reflected in national documents. The lack of protocols for children with interstitial diseases should be considered a significant gap that can lead to delays in diagnosis and uncertainty in the choice of therapeutic tactics.

#### ***The role of protocols in cost-effectiveness***

The use of clinical protocols affects not only the quality of medical care, but also the rational use of healthcare system resources. The World Health Organization report on noncommunicable diseases notes that the Republic of Moldova has actively linked the implementation of clinical protocols to performance indicators and the remuneration system for healthcare workers [17]. This approach encourages compliance with standards, optimizes medical practice, and reduces the number of unnecessary interventions [11]. At the same time, economic efficiency directly depends on the relevance of the protocols. The use of outdated treatment regimens not only reduces clinical effectiveness but also leads to irrational use of resources [12]. In this regard, timely updating of documents and systematic monitoring of their implementation should be considered as an investment in the sustainability of the national health system, ensuring its financial balance and long-term effectiveness [17].

#### **Recommendations.**

As a priority, it is necessary to accelerate the process of updating clinical protocols [13, 17]. A clear schedule for their revision should be approved, with a frequency of at least once every three to five years, in accordance with the recommendations of the World Health Organization and the principles of evidence-based medicine [17]. For areas where the evidence base is changing particularly rapidly, such as tuberculosis [19] or COVID-19 [18], it is advisable to provide for an annual review of documents [11]. The implementation of this task requires the formation of interdisciplinary working groups, including clinicians, pharmacologists, lawyers, and representatives of patient organizations.

The next step is to expand the coverage of nosological categories [12]. In particular, it is necessary to develop separate protocols for bronchial asthma [1, 8], childhood sarcoidosis [9], interstitial lung diseases in children [6, 10], long COVID syndromes [18], and multifactorial rehabilitation after severe forms of pneumonia [12]. Such documents are already presented in international guidelines and are clinically relevant for the conditions in Moldova [7, 21].

It is important to integrate the legal aspect into the national protocol system [5]. Regulatory documents should include provisions establishing the legal status of clinical protocols: they should be considered as recommended standards based on the best available empirical evidence, without replacing clinical judgment. Failure to comply with a protocol without sufficient medical justification may be interpreted as a breach of professional duty [15]. To ensure uniform practice, guidelines should be developed for forensic medical experts on the use of protocols in assessing cases of medical errors [11].

Monitoring of implementation and the reporting system require special attention. The Ministry of Health should guarantee free access to protocols [13], conduct regular audits of their application, and publish reports on compliance with key indicators [17]. It would be rational to create an electronic platform where healthcare institutions can track the implementation of recommendations and the timeliness of their updates [11]. Implementation indicators should be integrated into the financial incentive system, as has already been done for programs aimed at combating non-communicable diseases [17].

Finally, training and transforming professional culture are of particular importance. Systematic training of doctors and medical staff in the application of clinical protocols [13], the adoption of modern therapeutic approaches, and effective communication with patients will contribute to the formation of a culture of safety. Compliance with protocols should be seen as part of professional ethics, not just a formal requirement. Educational programs for medical professionals should include courses on evidence-based medicine, clinical guidelines, and bioethics, as well as develop mechanisms for feedback from patients.

#### ***Prospects for further research***

This study represents only some of the issues related to the development, updating, and implementation of national clinical protocols. Further empirical research is needed to assess their practical impact. Of particular interest is the analysis of the impact of protocol use on clinical outcomes, mortality rates, and patient satisfaction with the medical care provided [17]. Another promising area is a comparative study of court cases related to medical errors before and after the implementation of protocols. Such an analysis will allow for an objective assessment of their role in shaping law enforcement practices and reducing the legal vulnerability of healthcare professionals [15].

The development of digital tools to support clinical decision-making, integrated into electronic medical

records, is gaining importance. The use of such technologies can improve protocol accuracy, reduce the likelihood of errors, and ensure a personalized approach to patient care [10, 11]. It is equally important to study the attitudes of patients toward treatment standards and their level of involvement in the medical decision-making process [17]. Taking into account the cultural and social characteristics of the Republic of Moldova will increase the level of trust in protocols and adapt them to the expectations of society, which will be an important condition for the successful implementation of the strategy to improve the quality and safety of medical care [13].

### Conclusion.

National clinical protocols represent a key tool for ensuring patient safety, improving the quality of medical care, and strengthening legal certainty in the healthcare field. An analysis of the Republic of Moldova's phthisiopulmonological protocols has shown that significant progress has been made in recent years in establishing a regulatory framework that covers a wide range of diseases, including tuberculosis, chronic obstructive pulmonary disease, various forms of pneumonia, and rare genetic and allergic pathologies.

At the same time, a significant part of the documents regulating the provision of care to the adult population has become outdated. The average age of the protocols exceeds five years, and more than half of them have not been revised since 2017, which reduces their clinical value and increases the probability of legal conflicts. International organizations emphasize the need for regular and dynamic updating of guidelines, taking into account new scientific evidence and the introduction of innovative technologies.

Patient safety and legal protection for healthcare professionals should be viewed as complementary components of a single system. The patient has a legal right to receive modern and high-quality medical care, while the state is responsible for ensuring the availability, accessibility, and relevance of clinical protocols. Achieving these goals requires a comprehensive approach that includes regulatory consolidation of the status of protocols, regular review and expansion of the range of nosologies covered, systematic training of medical staff, introduction of digital decision support tools, and active patient participation in the development and evaluation of standards.

Only if these measures are implemented will national clinical protocols become an effective mechanism for improving the safety and quality

of medical care and helping to strengthen public confidence in the healthcare system.

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