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ОРИГИНАЛЬНОЕ ИССЛЕДОВАНИЕ

Development and application experience of the clinical and organizational management algorithm for tuberculosis medical care at the regional level

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Abstract. Relevance. The high incidence, prevalence and mortality in tuberculosis determines the relevance of improving clinical and organizational processes in terms of algorithmization. *The aim* of the study was to develop and evaluate the effectiveness of the clinical and organizational management algorithm for tuberculosis medical care at the regional level. *Materials and Methods.* The object of the study (2007—2021) were the tuberculosis medical care system of the Sverdlovsk region, Russian Federation. The scientific and methodological bases were Department of Health Organization, Drug Supply, Medical Technologies and Hygiene of the Peoples' Friendship University of Russia topic SRW № 214791-3-000. The development of the algorithm was carried out on the basis of a scientifically proven universal clinical management system. The epidemiological tuberculosis author data and of Rosstat in the Sverdlovsk region for 2007—2020 were used — general and structural morbidity, prevalence, mortality, as well as the number of 3, 4 and 6 groups of dispensary registration of patients. The efficiency of the algorithm was evaluated by the dynamics of the complex of epidemiological indicators of tuberculosis. Research methods were applied: content analysis, analytical, statistical, comparative, expert. Significance was assessed using the t-White test. Differences in the compared parameters were considered significant at $p < 0.05$. *Results and Discussion.* The effectiveness of the developed algorithm for managing regional tuberculosis medical care, including the components of needs analysis, systematization, automation and telecommunications, interdisciplinary integration, resource provision and performance evaluation, was confirmed by a significant decrease in the Sverdlovsk region for the period 2007—2020 general incidence by 2.05 times (from 119.9 to 51.7 per 100 thousand of the population), the incidence of children 0—14 years old by 1.48 times (from 18.7 to 12.6 per 100 thousand children of the corresponding age), prevalence in the population by 1.8 times (from 258.6 to 143 per 100 thousand of the population) and mortality from tuberculosis by 2.675 times (from 21.4 to 8.02 per 100 thousand of the population) ($p < 0.001$). The COVID-19 pandemic (2020—2021) did not worsen the epidemiological situation for tuberculosis in the region. In 2020, an active form of tuberculosis was detected in 2201 people, which is 16 % less than in 2019 ($p < 0.05$). The prevalence of epidemiologically dangerous bacillary forms of the disease for the period 2019—2020 decreased by 15.4 %, from 73.2 to 61.9 per 100 thousand population ($p < 0.05$). *Conclusion.* Clinical and organizational management of tuberculosis medical care based

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on the algorithmization of scientifically evidence processes increases the effectiveness of therapeutic and preventive measures and the social and epidemiological well-being of the population.

Key words: tuberculosis; algorithm; morbidity, mortality, prevalence, clinical and organizational management

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Introduction

Management of the incidence and prevalence of infectious diseases, including socially important tuberculosis, HIV infection and COVID-19, is an actuality public health problem in all countries of the world [1—6].

The high prevalence of HIV-associated forms of tuberculosis, the disability of children and the working-age population caused by tuberculosis infection, the high frequency of acute and antibiotic-resistant forms of the disease determine the relevance of improving anti-tuberculosis care as a strategy to combat global socially dangerous phenomena [5, 6].

Management of tuberculosis medical care in a «manual» mode, through an exclusively analysis of epidemiological coefficients and mathematical modeling of tuberculosis measures, is not an effective process. Most of the developed algorithms for managing the epidemiological coefficients of tuberculosis are of

an analytical nature and are not always effective in practice [7, 8].

Scientifically and practically proven effective resource technologies, including tuberculosis vaccination, laboratory and radiation diagnostics, and treatment of latent forms of tuberculosis, which allow managing epidemic trends, are used at the regional level with varying degrees of effectiveness [1, 7—11].

Despite the positive dynamics of the decrease in the overall incidence, prevalence and mortality associated with tuberculosis infection in the Russian Federation, the incidence of tuberculosis in the children's population and men of all age groups by 2013 exceeded similar indicators of European countries by 5 times or more [3—6].

The Sverdlovsk region is a subject of the Russian Federation characterized by high rates of incidence and prevalence of tuberculosis, exceeding the national average by 1.3—1.5 times. The tense epidemiological situation with respect to tuberculosis in the Sverdlovsk

region is due to a number of factors, including high rates of HIV infection for the period of December 2012 prevalence — 1347.5 cases per 100,000 population, morbidity — 136.4 cases per 100,000 population, the presence in the region of a significant number of institutions of the Main Directorate of the Federal Penitentiary Service, the social, economic and geographical characteristics of the region in the national economic positioning and health care in general [13].

In the context of the observed epidemiological tension caused by tuberculosis infection, not all risk factors can be eliminated or their influence weakened.

Management of clinical and organizational processes based on algorithms has been scientifically proven in various diseases. The effectiveness of the developed clinical and organizational systems is widely presented in the available scientific literature [8, 9, 13].

Strategically effective is the systematic management of tuberculosis medical care based on the processes of algorithmization and automation, primarily tuberculosis dispensaries, a process-oriented approach and efficient use of resource opportunities available to regional healthcare [1, 7, 10, 11].

The aim of this study was to develop a clinical and organizational management algorithm of the regional tuberculosis medical care and analyze and evaluate its effectiveness in terms of a set of evidence-based epidemiological monitoring coefficients.

Materials and methods

The object of a comprehensive milestone study conducted in 2007—2021 was the system of tuberculosis medical care in the Sverdlovsk region. The base and scientific and methodological support was carried out by the Department of Health Organization, Drug Supply, Medical Technologies and Hygiene of the Peoples' Friendship University of Russia in accordance with the Research topic No. 214791-3-000. The development of the algorithm was carried out on the basis of a scientifically proven universal clinical management system [9]. Epidemiological data on tuberculosis of Rosstat in the Sverdlovsk region for 2007—2020 were used. The regional indicators of general and

structural morbidity and prevalence of tuberculosis, mortality, as well as the number of groups 3, 4 and 6 of dispensary registration of patients with tuberculosis were studied. The analysis and evaluation of the clinical and organizational effectiveness of the algorithm was carried out according to the dynamics of the complex of epidemiological indicators of tuberculosis. Research methods were applied: content analysis, analytical, statistical, comparative, expert. Statistical processing of the material was carried out on the basis of the Statistica 6.0 package. Significance was assessed using the t-White test. Differences in the compared parameters were considered significant at $p < 0.05$.

Results and discussion

The study found high incidence, prevalence and mortality rates due to tuberculosis in the Sverdlovsk region, 1.3—1.8 times higher than the average for the Russian Federation for the period 2008—2012. The region during the study period is characterized by an increase in the incidence of children aged 7—14 years to 46.2 per 100 thousand of the population, a high proportion of newly diagnosed tuberculosis patients in the age group of 25—44 years, including those with lung tissue decay of more than 36 %, and high numbers of multidrug resistant infections.

To develop an algorithm for clinical and organizational management in tuberculosis at the regional level, a model of clinical management at the level of the health care system was created, which is shown in Figure 1 (Fig. 1).

Clinical management of tuberculosis at the level of the health care system and medical organization is based on the processes of effective clinical practice and continuing medical education of specialists.

Tuberculosis medical organizations, including dispensaries, offices and departments, are structural and functional components of the model of clinical management of tuberculosis medical care, on the basis of which a database of epidemiological coefficients is created and monitoring indicators are introduced, and the medical, economic, clinical and analytical aspects of medical care are implemented.

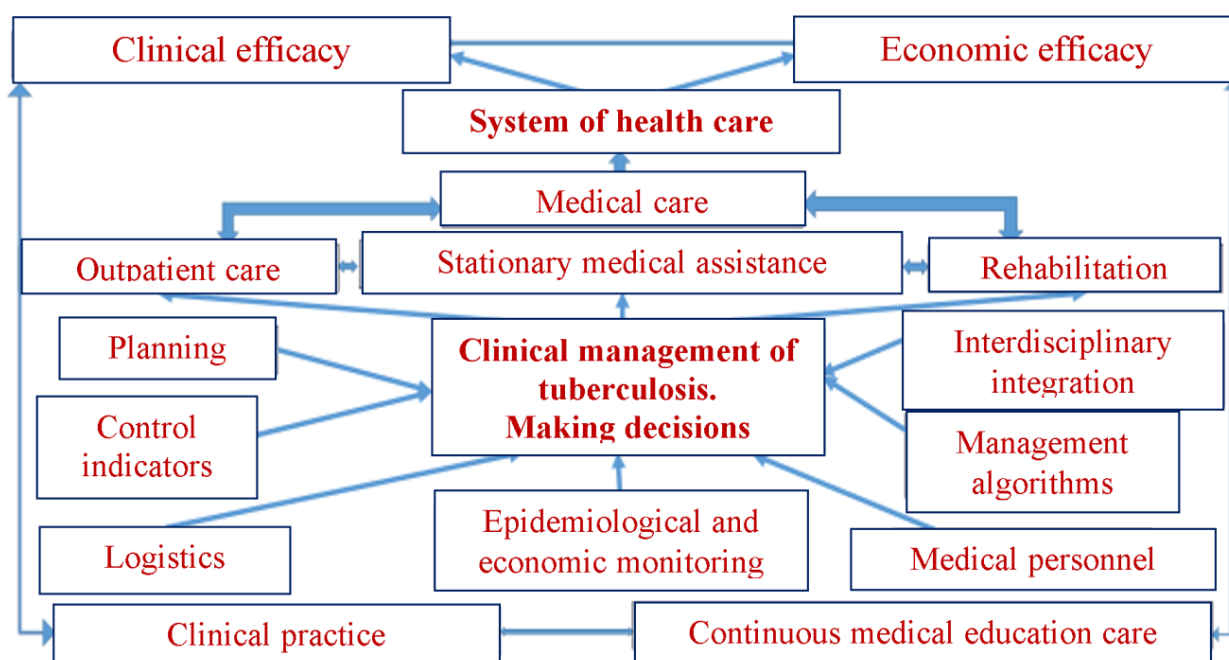


Fig 1. Clinical management model for tuberculosis medical care

Medical and economic planning, development of patient routing, interdisciplinary integration, implementation of indicators for monitoring and evaluating the effectiveness of tuberculosis medical organizations, continuous epidemiological and economic analysis of the effectiveness of tuberculosis activities and integrated personnel improvement are established as integral processes of the clinical management model for tuberculosis at the level of a medical organization.

The role of medical personnel is strategically important for solving the problems of clinical management of a complete and objective continuous formation of a base of the tuberculosis epidemiological coefficients for evidence-based clinical and economic monitoring of the effectiveness of tuberculosis medical organizations at the stage of primary health care, including outpatient care and rehabilitation and inpatient care.

Based on the universal model of clinical management, an algorithm for managing regional tuberculosis medical care has been developed as a system for integrating evidence-based and proven best clinical and organizational processes, including components of analysis, systematization, automation

and telecommunications, interdisciplinary integration, resource provision and performance evaluation. The Clinical and organizational management algorithm of regional tuberculosis medical care is shown in Figure 2.

The effectiveness of the implementation of clinical and organizational algorithm for managing regional tuberculosis medical care is confirmed by the results of a significant decrease in the Sverdlovsk region for the period 2007—2020 the overall incidence of tuberculosis by 2.05 times (from 119.9 to 51.7 per 100 thousand of the population), the incidence of tuberculosis in children aged 0—14 by 1.48 times (from 18.7 to 12.6 per 100 thousand children of the corresponding age), prevalence of the disease in the population by 1.8 times (from 258.6 to 143 per 100 thousand population) and mortality from tuberculosis in the region by 2.675 times (from 21.4 to 8.02 per 100 thousand population), $p < 0.001$.

The COVID-19 pandemic (2020—2021) did not affect the deterioration of the epidemiological situation for tuberculosis in the region, and reasonably led to an increase in the number of performed lung examinations using computed tomography.

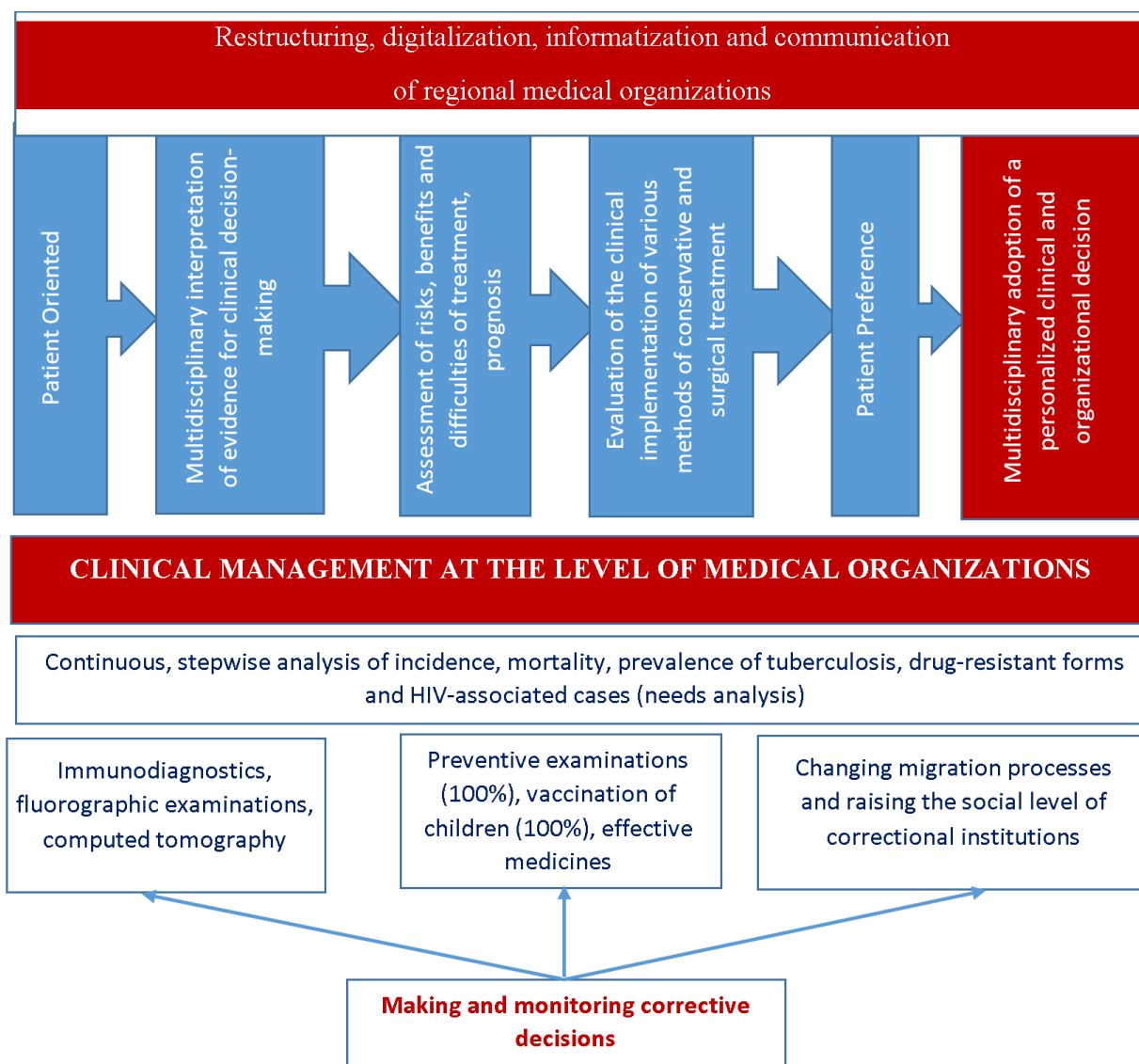


Fig 2. Clinical and organizational management algorithm of regional tuberculosis medical care

Mortality from tuberculosis in 2021 decreased to 7.2 per 100,000 population. In 2020, the active form of tuberculosis was detected in the population of the region in 2201 people, which is 16 % less than in 2019 ($p < 0.05$).

The prevalence of the most epidemically dangerous bacillary forms for the period 2019—2020 decreased by 15.4 %, from 73.2 to 61.9 per 100 thousand population ($p < 0.05$).

Among the positive epidemiological trends in tuberculosis in the Sverdlovsk region in 2020 after

the implementation of the algorithm, the following can be distinguished:

1. A downward trend in the overall incidence of tuberculosis. For the period 2019—2020 the overall incidence of tuberculosis in the region significantly decreased by 22.5 %, from 66.7 to 51.7 per 100,000 population ($p < 0.05$);

2. The downward trend in the incidence of children aged 0—14 years, which for the period 2019—2020 significantly decreased by 15.4 %, from 14.9 to 12.6 per 100 thousand children ($p < 0.05$);

3. The downward trend in the incidence of children aged 15—17 years, which for the period 2019—2020 significantly decreased by 20 %, from 19 to 15.2 per 100 thousand children ($p < 0.05$);

4. The downward trend in the prevalence of tuberculosis in the Sverdlovsk region, which for the period 2019—2020 significantly decreased by 16.3 %, from 170.8 to 143.0 cases per 100 thousand population ($p < 0.05$);

5. A downward trend in distribution prevalence of the most epidemically dangerous bacillary forms, which for the period 2019—2020 significantly decreased by 15.4 %, from 73.2 to 61.9 per 100 thousand population ($p < 0.05$);

6. A downward trend in the mortality of the population of the region from tuberculosis. For the period 2019—2020 tuberculosis mortality in the Sverdlovsk region decreased from 8.6 to 8.0 per 100,000 population.

The scientific and practical results of a comprehensive medical and social study, the introduction of which into the regional health care system of the Sverdlovsk region confirmed their scientific and practical significance for improving anti-tuberculosis care, made it possible to issue author's clinical and organizational inventions and protect patents for industrial designs, presented below:

1. Scheme of the study of patients with pulmonary tuberculosis dated April 16, 2014, № 87962;

2. Scheme of an integrated methodology in pulmonology and phthisiopulmonology dated February 16, 2014, № 87963;

3. Scheme of examination of patients for exercise therapy in pulmonology and phthisiopulmonology dated February 16, 2014, № 87964;

4. Scheme of the results of the study of patients with pulmonary tuberculosis in comparison between the main and control groups dated February 16, 2014, № 87965;

5. A set of pages of guidelines «Tactics of selecting a patient with drug-resistant tuberculosis for a course of second-line chemotherapy» dated December 27, 2016, № 101554;

6. A set of pages of the algorithm «Analysis of the activities of the tuberculosis dispensary based on the results of the quarter» dated December 27, 2016 № 101556;

7. «Algorithm of medical tactics in detecting tuberculosis of extra pulmonary localizations of their high-risk group» dated August 07, 2017, № 104472.

Conclusion

Clinical-organizational management using algorithms underlies the efficiency, safety and resource thrift of medical care processes. The choice of a strategy for clinical and organizational management in tuberculosis is a complex medical and economic task in the face of the difficulty of predicting the influence of numerous risk factors for the development, spread, progression and formation of drug resistance of tuberculosis infection. The algorithm for managing regional tuberculosis medical care is presented as a system for integrating evidence-based and proven clinical and organizational practices and processes, including components of needs analysis, systematization, automation and telecommunications, interdisciplinary integration, resource provision and performance evaluation, and as a result, making adequate management decisions. Analysis of the results of the development and implementation of an innovative clinical and organizational management algorithm for tuberculosis at the regional level testified to its effectiveness for a sustainable progressive reduction in the overall incidence, prevalence and mortality associated with tuberculosis.

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Опыт разработки и применения алгоритма клиничко-организационного управления при туберкулезе на региональном уровне

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Аннотация. *Актуальность.* Высокая заболеваемость, распространенность и смертность при туберкулезе определяет актуальность совершенствования клиничко-организационных процессов управления методом алгоритмизации. Цель исследования — разработать, внедрить и оценить эффективность алгоритма клиничко-организационного управления

противотуберкулезной помощью на уровне региона. *Материалы и методы.* Объектом исследования (2007—2021 гг.) явилась система противотуберкулезной помощи Свердловской области, база и научно-методическое сопровождение осуществлялось кафедрой организации здравоохранения, лекарственного обеспечения, медицинских технологий и гигиены Российского университета дружбы народов в соответствии с темой НИР № 214791-3-000. Разработку алгоритма осуществляли на основании научно доказанной универсальной системы клинического управления. Использована авторская информация и данные по туберкулезу Росстата по Свердловской области 2007—2020 гг. — структура заболеваемости, распространенности, смертность, а также численность пациентов 3, 4 и 6 групп диспансерного учета. Оценка эффективности алгоритма проводили по динамике комплекса эпидемиологических показателей туберкулеза. Применены методы исследования: контент-анализ, аналитический, статистический, сравнительный, экспертный. Для оценки достоверности применялся критерий t-Уайта. Различия сравниваемых показателей считали достоверными при $p < 0,05$. *Результаты и обсуждение.* Эффективность разработанного алгоритма управления региональной противотуберкулезной помощью, включающего компоненты анализа потребности, систематизации, автоматизации и телекоммуникации, междисциплинарной интеграции, ресурсного обеспечения и оценки эффективности, подтверждена достоверным снижением в Свердловской области за период 2007—2020 гг. общей заболеваемости в 2,05 раза (с 119,9 до 51,7 на 100 тыс. населения), заболеваемости детей 0—14 лет в 1,48 раза (с 18,7 до 12,6 на 100 тыс. детей соответствующего возраста), распространенности в популяции в 1,8 раза (с 258,6 до 143 на 100 тыс. населения) и смертности от туберкулеза в 2,675 раза (с 21,4 до 8,02 на 100 тыс. населения) ($p < 0,001$). Пандемия COVID-19 (2020—2021 гг.) не ухудшила эпидемиологическую ситуацию по туберкулезу в регионе. В 2020 г. активная форма туберкулеза выявлена у 2201 человек, что на 16 % меньше, чем в 2019 г. ($p < 0,05$). Распространенность эпидемиологически опасных бациллярных форм заболевания за период 2019—2020 гг. снизилась на 15,4 %, с 73,2 до 61,9 на 100 тысяч населения ($p < 0,05$). *Заключение.* Клинико-организационное управление противотуберкулезной помощью на основе научно-доказанных процессов алгоритмизации повышает результативность лечебно-профилактических мероприятий и социально-эпидемиологическое благополучие населения.

Ключевые слова: туберкулез, алгоритм, заболеваемость, смертность, распространенность, клинико-организационное управление

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