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MAIN DIRECTIONS FOR IMPROVING THE ORGANIZATION OF LIFETIME PATHOLOGICAL AND ANATOMICAL DIAGNOSTICS (USING NOVOSIBIRSK REGION AS AN EXAMPLE)

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INTRODUCTION

Relevance of the selected topic

Lifetime pathological and anatomical studies of biopsy and surgical material are an important tool in solving diagnostic, social and preventive public health problems, in particular, in the early diagnosis and treatment of cancer. Lifetime pathological and anatomical studies of biopsy and surgical material are used to reliably detect a tumor, determine the degree of its malignancy, histological type and select individual treatment.

An increase in the primary incidence of malignant neoplasms in the Russian Federation (for the period from 2011 to 2021 by 7.7% (from 368.1 to 396.3 per 100 thousand population) [149; 154; 176] predetermines an increase in the volume of lifetime pathological and anatomical diagnostics of biopsy and surgical material. At the same time, an increase in the proportion of newly diagnosed oncological pathology in the launched stage IV (from 20.3% in 2018 to 20.5% in 2021), the heterogeneity of oncological diseases, a change in priorities in the therapeutic tactics of malignant neoplasms from polychemotherapy to targeted therapy, purposefully affecting the identified genetic mutations, lead to an increase in the requirements for the quality of lifetime pathological and anatomical studies of biopsy (surgical) of material [3; 149; 176].Untimely or incorrect diagnosis leads to errors in determining therapeutic tactics, irrational use of practical health care resources.

One of the problems of the pathological and anatomical services of Russia is the personnel deficit. In the Russian Federation, the shortage of pathologists in 2018 amounted to 3,134 people, in 2022 - 4,192 people. In the Novosibirsk Region, the shortage of pathologists in 2018 amounted to 71 people, in 2021 - 83 people, in 2022 - 78 people with a percentage of staffing with occupied rates - 80,4% in 2018, 83.7% in 2021 and 86,7% in 2022. The deficit in the average medical personnel in Russia as a whole in 2018 amounted to 1 744 people or 40.7% of the staff, in 2022, the size of the shortage of personnel in this category of personnel amounted to 2 163 people.

The personnel shortage leads to systematic overloads of personnel (on average, the

workload per pathologist for conducting research in Russia in 2018 amounted to 2.09 rates, in 2022 - 1.67 rates, in the Novosibirsk Region in 2018 - 1.78 rates, in 2021 - 1.88 rates, in 2022 - 1.85 rates). The staff shortage is exacerbated by the uneven distribution of staff between urban and rural health care and the increasing proportion of category V complexity studies. For 2016-2018 the number of studied cases of the category difficulty V increased in Russia by 23.3%, in the Novosibirsk Region - 5 times. In the period from 2018 to 2022, the share of research of the category difficulty V increased in Russia from 21.08% to 29.22%, in the Novosibirsk Region - from 19.66% to 26.45% [3; 48; 146; 147; 148; 150].

A significant problem is the insufficient level of material and technical equipment of pathological and anatomical services with basic technological equipment. The average indicator of equipment of pathological and anatomical services with basic technological equipment in 2018 in Russia as a whole amounted to 32.7%, in the Novosibirsk region - 53.4%, in 2021 - in Russia - 39.1%, in the Novosibirsk region - 52.4%, in 2022 - in Russia - 43.5%, in the Novosibirsk region - 49%. The lowest provision in the Novosibirsk region in 2022 is noted by stations for macroscopic study and cutting - 17.6%, machines for concluding cuts under cover glass - 19.6%, stations for pouring into paraffin - 47.1%, machines for wiring carousel type - 50%.

The share of obsolete equipment is growing, with a service life of more than 10 years: in 2018 in Russia it was 23.7%, in the Novosibirsk Region - 26.2%, in 2022 - in Russia - 25.9%, in the Novosibirsk Region - 33.4%. Of the 36 rotational microtomes operating in the Novosibirsk Region in 2022, 11 (30.6%) have a service life of more than 10 years. The share of outdated equipment among carousel-type wiring machines (34.8%) and binocular universal microscopes (32.1%) is quite high in the Novosibirsk Region. The lack of equipment for conducting molecular genetic studies in state medical organizations of the Novosibirsk Region, even if the diagnostic capabilities of regional private health organizations are used, does not exclude analytical errors in establishing a diagnosis and determining the prognosis of treatment [3; 146; 147; 148; 150].

To date, the processes of taking and primary processing of biological material

have not been standardized enough, which affects the correctness of the morphological diagnosis.

Weak resource support of the pathological and anatomical services of the Novosibirsk Region, personnel shortage, insufficient level of training of medical personnel make it difficult to carry out an increasing volume of studies of lifetime pathological and anatomical diagnostics of biological material [3; 20; 108; 107; 109]. Resource deficit, combined with insufficient standardization of processes during intravital pathological and anatomical diagnostics, contributes to an increase in the need to obtain a "second opinion," which consists in revising histological preparations in order to confirm a previous diagnosis or establish a new one. Currently, obtaining a "second opinion" on drugs is provided by commercial organizations, as well as federal research institutes that have the status of "Reference Centers" of immunohistochemical and pathomorphological research methods [3].

Often in the pathological and anatomical services there are many problems associated with the transfer of research results to consumers and the exchange of data between the customer and the investigator. The degree of informatization and the use of the capabilities of the Medical Information System in the activities of the pathological and anatomical services of the Novosibirsk Region until 2020 was limited to the formation of automated workplaces for the registrar and pathologist. Optimization of the functionality of the Medical Information System of the Novosibirsk Region in the period from 2020 to 2022 made it possible to ensure the integration of electronic documents filled out by doctors of clinical specialties, instrumental diagnostics and pathological services. The development of remote diagnostics of drugs (telepathology) is closely related to the equipment of pathological and anatomical services with modern equipment and automation of the processes of lifetime pathological and anatomical diagnostics of biopsy (surgical) material [75; 108].

The above problems require finding new ways to solve them, which at the lowest cost will increase efficiency pathological and anatomical services [175; 177]. World practice has proven that the best solution is centralization, which allows you to rationally use personnel resources, equipment and consumables and improve the quality

of diagnostics. The quality control procedure in each individual medical organization is not centralized [47; 179]. Due to the growing importance of the expert role of intravital pathological and anatomical studies, the introduction and development of the reference approach becomes relevant [3; 170; 171].

Pursuant to the Decree of the President of the Russian Federation of 07.05.2018 No. 204 "On the national goals and strategic objectives of the development of the Russian Federation for the period up to 2024," a Passport of the national project "Healthcare" was developed, including eight federal projects, including "Fighting cancer." On November 13, 2017, within the framework of the V All-Russian meeting of the profile commission on the specialty "oncology," the professional community approved the National Strategy for Combating Cancer for the long term up to 2030 years.

In order to implement programs to combat cancer, the main strategic directions have been identified, including an information and communication campaign aimed at early diagnosis of cancer with an increase in the proportion of malignant neoplasms detected in the early stages. (I-II stages) from 55.6% by 31.12.2017 to 63.0% in 2024, increasing adherence to treatment, as well as the creation of Reference Centers for immunohistochemical, pathomorphological and radiation research methods (Currently, 18 reference centers are organized on the basis of medical organizations subordinate to the Ministry of Health of Russia).

At the regional level, the task of detecting malignant neoplasms at an early stage is ensured by the formation of new and increased volumes of medical care in the existing Outpatient Oncological Care Centers, organized on the basis of medical institutions with a full range of equipment and the necessary specialists: by the end of 2024, it is planned to organize 420 outpatient oncological care centers in 85 constituent entities of the Russian Federation, as of 01.11.2023 it operates 479 centers in 81 regions.

The main directions of the Reference Centers for pathomorphological research are consulting expert and educational activities, which are carried out remotely in online and offline modes. The vertical competence system is built using digitized histological

data (telepatomorphology). Digitization of histological glasses allows them to be examined remotely, without directing histopreparations and paraffin blocks [3, 74, 152, 153,171]. Reference centers also perform repeated in-life pathological-anatomical, immunohistochemical and molecular-genetic studies. According to the routing scheme, the referral of oncological patients and micro-drugs to federal reference centers is carried out by oncologists of regional oncological dispensaries and outpatient oncological care centers with the registration of form No. 057/y-4 (in electronic form or on paper).

Using the capabilities of the Reference Centers for Pathomorphological Research makes it possible to solve the following problems of the pathological and anatomical services of the Novosibirsk Region:

1) redistribution of personnel tasks, reducing the burden on pathologists. Slides processed by laboratory assistants are subject to "digitization" and can be sent through the medical information system directly to the Reference Centers;

2) implementation of a risk-based approach in morphology, development of digital pathology, telemedicine consultations, formation of a "second opinion," preparation of conclusions by a council of pathologists regarding samples of category V complexity, which contributes to the adjustment of the diagnosis and treatment plan, molecular genetic diagnostics of biological material delivered to the Reference Center, including using the new generation sequencing method (NGS) and the selection of personalized therapy [170];

3) development of personnel skills at "workplaces" through active use of mentoring, viewing of recorded multidisciplinary training sessions, gallery of images, participation in question-answer sessions;

4) participation of personnel of pathological and anatomical services of medical organizations of the Novosibirsk Region in the development and implementation of industry standards, increasing the readiness of pathologists of the Novosibirsk Region to monitor compliance with standardized processes for conducting lifetime pathological and anatomical diagnostics in the region;

5) reducing regional health care costs by centralizing the costs of conducting

expensive research (in particular, molecular genetic) by reducing reagent costs [3; 170; 171].

Degree of development of the dissertation topic

Currently, the activities of pathological and anatomical services are organized in accordance with the updated base of regulatory documents: by order of the Ministry of Health of Russia dated 24.03.2016 No. 179n "On the rules for conducting pathological and anatomical studies" and clinical recommendations "Standard technological procedures for conducting pathological and anatomical studies" approved by the Presidium of the Russian Society of Pathologists dated 25.06.2016 No. 30/1. The procedure for performing pathological and anatomical studies of biopsy (surgical) material has been standardized, the requirements for organizing the technological process in large centralized pathological and anatomical departments have been determined.

In the context of a personnel shortage, an insufficient level of provision of pathological and anatomical services with basic technological equipment, an increase in the number of cases of the V category of complexity, a dynamic study of digitized ones is considered by many authors (L. S. Urusova, E. E. Porubaeva, G. A. Melnichenko, N. G. Mokrysheva, O. I. Kit, A. Yu. Maksimov, I. A. Novikova) histological data in the Reference Centers using information resources. The implementation of the reference approach in the lifetime pathological and anatomical diagnosis of biopsy (surgical) material makes it possible to achieve the redistribution of tasks and reduce the workload on the staff of pathological and anatomical services, improve the qualifications of pathologists at the "workplace," standardize the processes of this type of diagnosis and reduce the costs of the health care system by centralizing the costs of conducting expensive studies [3; 170; 171].

A number of authors (G. S. Lebedev, I. A. Shaderkin, A. S. Tertychny, A. I. Shaderkina, E. O. Antsiferova, N. A. Lebedeva) indicate that when introducing a reference approach to lifetime pathological and anatomical diagnostics in the Russian Federation, the harmonious development of three vectors of the direction of financing

health care (state, compulsory medical insurance) is possible and covering expenses from personal funds of citizens) [171]. The authors note that digital pathomorphology is not only the digitization of micropreparations, but also the transfer to a single digital platform of all processes from the moment of diagnosis and surgical intervention to the study of digital images with the participation of clinicians, doctors of radiation diagnostics, pathologists and patients [171]. Currently, there are separate units of this single platform [171].

A modern quality control system for pathological and anatomical studies implies the mandatory participation of Reference Centers.

A number of authors (V. L. Kovalenko, V. N. Koksharov, L. V. Kaktursky, O. D. Mishnev, V. Z. Terekhov) proposed target quality indicators pathological and anatomical studies. In 2019, a team of authors (P. G. Malkov, D. V. Kalinin, N. M. Gaifullin, J. A. Hakobyan, N. O. Matytsin) formed approaches to quality control of in-life pathological and anatomical studies of biopsy (surgical) material and a system of indicators to assess compliance with all stages of research and standard technological procedures related to the conduct of the study and the design of its results. The system of indicators can be used within the framework of state control of the quality and safety of medical activities, as well as during internal quality control and external examinations of medical care [111].

The development of remote diagnostics, including in the Reference Centers, fully scanned micropreparations (telepathology) is closely related to the equipment of pathological and anatomical services with modern equipment and automation of the processes of intravital pathological and anatomical diagnostics of biopsy (surgical) material. Telepathology is most developed in the USA, Japan, and EU countries. In Russia, telepathology has been actively developing since the end of the 20th century, however, active use in a number of regions is limited by insufficient logistics (in particular, the lack of sanitizing microscopic equipment) [111; 112].

Purpose of the study

On the basis of social and hygienic research, develop and scientifically substantiate the improvement of the system of organization of lifetime pathological and anatomical diagnosis of biopsy (surgical) material in the Novosibirsk Region.

Research objectives

1) Analyze and investigate the features of the system for organizing lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk region in order to identify factors that reduce its effectiveness.

2) Assess satisfaction with the quality of lifetime pathological and anatomical diagnostics of biopsy (operating) material of doctors of clinical specialties and heads of medical organizations of the Novosibirsk Region.

3) Justify the choice of criteria for assessing the compliance of the execution of pathological and anatomical diagnostics procedures with technological standards, analyze the degree of agreement of the opinion of experts on the importance of components that ensure timeliness and quality intravital pathological and anatomical diagnosis of biopsy (surgical) material.

4) Develop an organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material at the regional level.

5) Evaluate the effectiveness of the implementation of the territorial organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region.

Scientific novelty

For the first time, the author applied the method of multi-criteria analysis of decision-making to determine priority criteria and corresponding indicators for assessing the compliance of procedures with lifetime pathological and anatomical diagnostics of biopsy (surgical) material to process standards, the degree of impact of non-conformities on the result or duration of the studies was investigated. For the first time, an integrated approach to the quality management system of this type of diagnostics was applied, consisting of three components: the quality of the structure, the

quality of the process and the quality of the result. Conditions and tools were developed and tested to form an organizational and functional model of the system for organizing lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region.

The previously developed model of final results, including indicators of the quality of use of resources, diagnostic processes and results [32], was first used to assess the effectiveness of the study object - a system for organizing lifetime pathological and anatomical diagnostics of biopsy (surgical) material in medical organizations of the Novosibirsk Region.

Theoretical and practical significance of the work

Based on a multi-criteria analysis of decision-making, the most significant criteria were determined for a phased assessment of the compliance of the procedures with the technological standards of lifetime pathological and anatomical studies of biopsy (surgical) material, which develops theoretical provisions for organizing quality control of this type of diagnostics.

Standard operating procedures and instructions formed for personnel in the provision of medical care on an outpatient basis and in a hospital (identification of a patient's biomaterial when taking biological material, performing histological technologies, using the functionality of the Medical Information System to form electronic Directions and Research Protocols) can be used as teaching aids in clinical units and pathological anatomical service of any medical organization.

Indicators of the quality of use of resources, diagnostic processes and results, combined into a model of final results, can be used to assess the activities of the pathological and anatomical service of a medical organization.

Technical assignments and flow charts were developed for the Medical Information System of the Novosibirsk Region, which made it possible to optimize the functionality and integrate the information blocks of the Protocol of Surgical Intervention, Endoscopic Diagnostic Examination, Referral for Lifetime Pathological and Anatomical Examination of Biopsy (operating) material of accounting form No. 014/y, Log of biopsy (surgical) material and issuance of the results of in-life

pathological and anatomical studies of registration form No. 014-2/y, Protocol of in-life pathological and anatomical study of registration form No. 014-1/y and Directions for cytological diagnostic study and study result "of registration form No. 203/y-02.

The practical significance of the study is confirmed by the introduction of its results into the diagnostic activities of healthcare institutions of the Novosibirsk Region (State Budgetary Healthcare Institution of the Novosibirsk Region "City Clinical Hospital No. 1" (implementation certificate dated 29.12.2018 No. 1-19-4997) and the State Budgetary Healthcare Institution of the Novosibirsk Region "Novosibirsk Regional Oncological Dispensary" (implementation certificate dated 20.05.2019).

Scope and structure of work

The dissertation is presented on 334 pages of typewritten text and consists of an introduction, 5 chapters, a conclusion, conclusions, practical recommendations, a list of abbreviations and conventions, a list of references, a list of illustrative material and applications. The list of references is presented by 190 sources, of which 13 are in foreign publications. The results obtained are illustrated by 51 tables and 10 figure.

Methodology and methods of dissertation research

The methodology was based on an interdisciplinary approach integrating the stages and methods of socio-hygienic research, the principles of the quality management system and the basic provisions of health economics [66; 67; 77]. Study period from 2015 to 2022, included four stages, which are presented in Table 1.

Table 1 - Study and methods of research

Investigation phases	Research techniques	Sources of information, object and scope of the study
1. Study and analysis of modern domestic and foreign scientific sources of literature	Information and analytical	190 scientific sources, including 13 foreign, 8 regulatory legal acts. Analytical reports on the status and main tasks of the development of the pathological and anatomical service of the Russian Federation for 2015-2022
2. Comprehensive analysis of the activities of the pathological and anatomical services of medical organizations of the Novosibirsk region based on the results of sociological research, statistical indicators, results of multi-criteria analysis of decision-making on selection of criteria for assessing compliance of research processes with technological standards, calculation of Kendall's concordance coefficient to assess the degree of agreement of experts on the importance of factors in the system of organization of lifetime pathological and anatomical diagnostics of biopsy (surgical) material. Development of organizational and functional	Analytical, sociological, statistical, method of expert assessments, multi-criteria analysis of decision-making, organizational modeling	Analytical reports on the state and main tasks of the development of the pathological and anatomical service of the Russian Federation for 2015-2019 (edited by G. A. Frank) for 2020, 2021 and 2022 (edited by G. A. Frank and V. I. Starodubov), on the state of oncological assistance to the population of Russia in 2015-2018, (edited by A. D. Kaprin, V. V. Starinsky, V. Petrova),in 2019-2022 (edited by A. D. Kaprin, V. V. Starinsky, A. O. Shakhzadova), Forms of Federal Statistical Observation No. 30 "Information on a Medical Organization," No. 14 "Information on the activities of units of a medical organization providing medical care in inpatient conditions," No. 12 "Information on the number of diseases registered in patients living in the service area of a medical organization," No. 17 "Information on medical and pharmaceutical workers,"350 questionnaires for assessing satisfaction with the quality of filling out Protocols of intravital pathological and

model of the system of intravital pathological and anatomical diagnostics of biopsy (surgical) material		anatomical studies, for doctors of clinical specialties, 100 cards for interviewing heads of medical organizations, cards for interviewing expert doctors on the profile "pathological anatomy," referrals for lifetime pathological and anatomical study of biopsy (operating) material of the accounting form No. 014/y and Protocols of lifetime pathological and anatomical examination of biopsy (operational) material of accounting form No. 014-1/y in the amount of 500 units for internal audits, Logs of biopsy (surgical) material and issuance of the results of in-life pathological and anatomical studies of registration form No. 014-2/y (in the amount of 7). Regulatory documents on quality control of medical care
3. Implementation and scientific substantiation of the organizational and functional model of the system of intravital pathological and anatomical diagnostics of biopsy (surgical) material based on the process approach	Organizational modeling method, statistical, analytical, system analysis	6 orders on the organization and conduct of internal quality control and safety of medical activities; 4 orders on the organization and conduct of lifetime pathological and anatomical studies of biopsy (surgical) material, on the introduction of electronic registration forms during intravital pathological and anatomical diagnostics; 122 reports on internal quality control; 72 acts of external examinations of the quality of medical care of medical insurance organizations; 53 measures to ensure the quality of diagnostic processes; 12 standard operating procedures (patient identification when taking biological material for intravital pathological and anatomical research, performing procedures of histological technologies, using

		the functionality of the Medical Information System to form electronic Directions and Research Protocols); 8 letters to the Ministry of Health of the Novosibirsk Region with proposals for the introduction of registration forms during intravital pathological and anatomical studies of biopsy (surgical) material into the Medical Information System of the Novosibirsk Region, a mechanism for integrating information from the Protocol of surgical intervention and the Protocol of instrumental research into the corresponding columns of the Direction for intravital pathological and anatomical study of registration form No. 014/y.
4. Assessment of the medical and economic effectiveness of the organizational and functional model of the system of intravital pathological and anatomical diagnostics of biopsy (surgical) material based on medical and economic analysis, analyzes of the results of internal quality control in medical organizations involved in the implementation of the federal project "Fight against cancer"	Analytical, sociological, statistical, expert evaluation method, mathematical modeling of final results, comparative analysis	Forms No. 62 "Information on resource support and provision of medical care to the population," No. 14-MYeD (compulsory medical insurance) "Information on the work of a medical organization in the compulsory medical insurance system," accounting reporting forms for 2018-2022, negotiable statements for non-financial assets (fixed assets) of the pathological and anatomical department and clinical pathomorphology department GBUZ NSO "GKB No. 1." Forms of federal statistical observation No. 30 "Information on a medical organization," No. 12 "Information on the number of diseases registered in patients living in the service area of a medical organization." 350 questionnaires assessing satisfaction with the quality of lifetime pathological and

		anatomical studies for doctors of clinical specialties. Referrals for a lifetime pathological and anatomical study of the registration form No. 014/y, Protocols of a lifetime pathological and anatomical study of the registration form No. 014-1/y in the amount of 500 units for internal audits, Logs for recording the receipt of biopsy (surgical) material and issuing the results of lifetime pathological and anatomical studies of the registration form No. 014-2/y (in the amount of 3). Medical care quality expert reports for 2019-2022

CHAPTER 1 THEORETICAL FOUNDATIONS OF THE ORGANIZATION OF LIFETIME PATHOLOGICAL AND ANATOMICAL DIAGNOSTICS OF BIOPSY (SURGICAL) MATERIAL

1.1 Analysis of organizational models of lifetime pathological and anatomical diagnosis of biopsy (surgical) material

Conceptual apparatus for lifetime pathological and anatomical diagnosis of biopsy (surgical) material R. U. Khabriev, M. A. Paltsev in the publication "System of voluntary certification of processes for performing pathomorphological (pathological and anatomical) studies and pathological and anatomical services in health care "give the following concept to this type of diagnosis" Biopsy - lifetime pathological and anatomical (pathomorphological, histological (pathohistological), histochemical, immunohistochemical (immunomorphological), molecular biological, electron microscopic, morphometric, etc.) examination of organs and tissues. Biopsies - tissue sections (frozen, paraffin, celloidin, etc.). Unlike biopsy, cytological examination does not study tissue sections, but cytological material - fine-needle punctates, smears, imprint smears or centrifugates [139; 163].

The terms "biopsy," "biopsy material" broadly mean any lifetime diagnostic or surgical material, as well as placentas (afterbirths). In addition, in practice, surgical material is often simultaneously diagnostic if a biopsy study was not carried out before surgery. In essence, lifetime pathological and anatomical studies are complex, combining histological, histochemical, immunomorphological, electron microscopic, cytogenetic methods. All these studies are called pathological-anatomical or pathohistological (synonyms - pathomorphological, morphological, histological). Types of biopsy examination are: 1) diagnostic biopsy - intravital examination of tissues in order to establish a diagnosis (incision, puncture, endoscopic and other biopsies, scrapings, etc.); 2) surgical biopsy (surgical material) - lifetime examination of tissues in order to establish or confirm a diagnosis, if the material was obtained during a surgical operation and other manipulations carried out for therapeutic purposes; 3)

placenta (afterbirth) - equated to surgical material, regardless of the method of obtaining (spontaneous or artificial termination of pregnancy) [162]. Biopsy allows to establish or clarify the clinical diagnosis, determine the initial stage of the disease, the etiology of pathological processes, select antitumor drug therapy, track the dynamics and effectiveness of treatment [38].

By order of the Ministry of Health of Russia dated 24.03.2016 No. 179n "On the rules for conducting pathological and anatomical studies," the term "pathological and anatomical studies" was approved, replacing the term "pathomorphological studies." According to the order of the Ministry of Health of Russia dated 24.03.2016 No. 179n "On the rules for conducting pathological and anatomical studies," the subject of intravital pathological and anatomical research is the study of macro- and microscopic changes in tissue fragments, organs or traces (biopsy and surgical material), which were collected for medical reasons as part of providing the patient with appropriate medical care in accordance with the procedures for providing medical care, based on standards of medical care and taking into account clinical recommendations (treatment protocols) [127]. In-life pathological and anatomical studies are carried out in the provision of primary specialized medical care and specialized medical care: on an outpatient basis and in a 24-hour hospital.

Depending on the labor intensity, lifetime pathological and anatomical studies of biopsy (surgical) material are divided into 5 categories of complexity. Pathological and anatomical studies are carried out in pathological and anatomical departments of medical organizations, the list of which is determined by the Ministry of Health of the constituent entity of the Russian Federation. Depending on the performance, all pathological and anatomical departments are divided into three groups.

A special type of morphological study is cytological research - the study of not histological sections of tissue pieces, but smears, prints, punctates, cell centrifugates. The development of the cytological method of morphological examination is extremely promising, since, in comparison with the histological one, much less material is needed to establish a diagnosis (the safety of taking a biopsy increases) and the response is ready within 15 minutes to several hours (practically, as with urgent intraoperative

biopsies, while the response time of planned biopsies is from 2 to 7 days). The development of the cytological method is constrained by the need in some cases to have information about tissue rather than cellular changes, as well as insufficiently developed diagnostic criteria for a number of pathological processes. As a result, cytological studies provide more than 30% of uninformative, "false positive" or "false negative" responses, which is important for a clinician to consider when planning a morphological diagnostic study method and interpreting the response. In Russia, cytological studies are often carried out not in pathological and anatomical departments, but in clinical diagnostic or cytological laboratories by doctors of a special specialty - cytologists. Cytological studies according to the orders of the Ministry of Health of Russia dated 21.02.2000 No. 64 "On Approval of the Nomenclature of Clinical Laboratory Studies" and dated 18.05.2021 No. 464n "On Approval of the Rules for Laboratory Studies" are methods of clinical laboratory diagnostics of biological material [130]. However, in many countries, cytology is an integral part of clinical pathology (pathological anatomy) and cytological studies are required to be carried out by pathologists.

Organizational models of lifetime pathological and anatomical diagnostics of biopsy (surgical) material.

Currently, two organizational forms of research are most relevant for intravital pathological and anatomical studies of biological material:

local form - research in the pathological and anatomical department of this medical organization at the stages of primary, specialized medical care;

remote form - research in the pathological and anatomical service of another medical organization, in a centralized laboratory [130].

The centralization of medical care in the conduct of lifetime pathological and anatomical studies is planned and carried out on the basis of a comprehensive assessment of the medical feasibility of research, organizational capabilities and economic efficiency. Cost-effectiveness is determined by comparing the costs of conducting studies of biological material in an in-house medical organization and the costs of conducting the same study in a remote (centralized) laboratory, which in the latter case include the costs not only for analytical work of a third-party organization,

but also for transporting biomaterial to the contractor and transferring the results to the customer (pre- and post-analytical stages) [130]. Currently, in order to significantly reduce the cost of conducting lifetime pathological and anatomical studies of biomaterials, the outsourcing model is increasingly used, which means a business technology that provides for the transfer of diagnostic functions to third-party specialized medical organizations along with responsibility for their results [21].

E.V. Kulakova, editor-in-chief of the RAMS Portal, expert of the LPU Economics electronic system, points out the advantages and risks of outsourcing in her article "Transferring the supporting functions of a medical organization to outsourcing." As the main reasons for the use of outsourcing in healthcare, the author notes: optimization of the organization's costs, a higher responsibility of the outsourcer to the medical customer organization compared to the responsibility of full-time employees, the best quality of research performed by a third-party specialized organization, the absence of the need to control processes - it is replaced by control over the results, which takes much less time, freeing up space that allows them to be used for basic medical activities, the desire to concentrate the management resources of the organization on the main activity, which contributes to improving the quality of management. The disadvantages of outsourcing E.V. Kulakova include: a decrease in the speed of making management and other decisions, possible risks of non-fulfillment or improper execution of contracts, an increase in costs associated with the need to monitor the outsourcer's compliance with the requirements of the law and the terms of the contract, the threat of violation of confidentiality (the possibility of leakage of information related to the category "medical secrecy" through employees of a third-party organization), the possibility of forming dependence on an external contractor if it is necessary to introduce additional functions or modernize the functionality of the medical information system [69]. Diagnostic functions in the behavior of intravital pathological and anatomical studies of biological material are outsourced most often due to a shortage of technological equipment and (or) qualified personnel [69].

One of the most important strategic directions for the development of healthcare in the Russian Federation for the long term until 2030 is the creation of a unified state

electronic information system, which will allow, based on the use of information and communication technologies, to timely and fully provide the necessary information: patients and medical workers - to improve the quality and accessibility of medical care; healthcare management professionals - to improve industry efficiency and resource use [1; 4; 62]. In connection with the rapid development of information and communication technologies, a new branch has now formed, denoted by the term "system integration" [5; 25; 26; 27; 34].

According to the definition of A.V. Melnik, information and communication technologies are a set of technologies that ensure the production, processing, storage and transmission of information [62; 65; 66; 68; 89]. The need to develop information and communication technologies is determined by problems in Russian healthcare, which significantly reduce the quality and availability of medical services, the most significant of which are three: personnel shortage in the healthcare system; imbalances in the location of health care facilities, leading to the fact that the bulk of large medical centers, staffed with highly qualified personnel, are located in the capital; a weak material base and insufficient funding of the health care system [1; 43; 49; 134; 137; 152]. Information and communication technologies contribute to solving a number of tasks in the field of early diagnosis of diseases, ensure the timely provision of medical care to patients, the effective use of available resources, reference and information support for making medical decisions, high-quality education and continuing education, collection, storage and access of health workers to databases with medical and management information [19; 42; 43; 54; 57; 59; 92; 97; 140; 141; 143; 151; 161; 162, 172, 173].

To successfully solve the tasks set in the field of informatization, the following measures are currently implemented:

- widespread informatization of medical and diagnostic and managerial processes, which ensures the maintenance of an electronic medical record and access to federal information resources, in order to make timely correct (effective) medical decisions;

- vertical integration of the created medical information systems into a single information space (VIMIS) and ensuring formalized information exchange with regional and federal systems [9; 10; 11; 12; 42; 46; 49; 57; 58; 121].

International Standard ISO/IEC 2382-1: 1993 defines an information system as an information processing system that works in conjunction with organizational resources that provide and distribute information [100]. One of the concepts related to electronic health care is unified medical electronic systems that allow organizing the rational use of health care resources, ensuring the continuity of medical care and communication between specialists of different specialties [171]. A medical information system is defined as a set of information, organizational, software and technical means intended for automation of medical processes and (or) organizations "[58; 59; 61; 94;155; 156; 160; 164]. Another source provides a definition of a medical information system belonging to S. A. Gasparyan - "one of the forms of organization of medical activities that allows medical personnel, with appropriate technological support, to use a set of mathematical and technical means that ensure the collection, storage, processing, analysis and issuance of medical information" [100]. The modern medical information system includes:

1) patient flow management, including registration, formation of referrals, work schedules of specialists, offices, equipment, preliminary registration [62; 63];

2) comprehensive accounting of medical services, including accounting for services provided under compulsory medical insurance, voluntary medical insurance, direct contracts with legal entities and individuals;

3) automated workplaces of doctors and nurses, "electronic medical histories";

4) automated workplaces of administration and "non-medical" personnel with the possibility of accounting for personnel, equipment, medical devices;

5) setting up and administration, including the formation of the International Classification of Diseases, reference books, classifiers, organizational structure;

6) data analysis and reporting module, including reporting required by official health authorities [36; 37; 39; 64; 93; 99; 152; 189].

Many domestic and foreign authors (in particular Johnson K. B.) in their publications note the obstacles accompanying the introduction of a medical information system, the main of which are:

1) situational obstacles - lack of time and financial difficulties, high costs for information technology, software, inconsistency with practical needs;

2) cognitive and physical obstacles (insufficient skills in working with computer programs);

3) obstacles to obligations (confidentiality issues);

4) obstacles in knowledge and relationships (insufficient knowledge about the positive effect of information technology, philosophical resistance to information technology) [6; 7; 11, 64; 70; 71; 124; 125; 126; 132; 133; 134; 172; 187].

The key principles of the unified health information system are:

1) elimination of duplication of information entered into the system, replacement of paper medical and reporting documents with electronic ones, rational use of working time of medical personnel;

2) the introduction of telemedicine technologies for operational communication between medical organizations of various levels, including for advising doctors from remote medical institutions, as well as organizing distance educational courses for continuous training of medical workers on the basis of leading federal medical institutions engaged in research, educational and medical activities [17; 18; 21; 25; 26; 50; 54; 65; 66; 145]. Among the risks in creating a unified information system in the healthcare sector, T. N. Demicheva notes the impossibility of laying fiber-optic cables in certain settlements of the Russian Federation, as well as the difficulty of maintaining the confidentiality of personal data of patients when introducing electronic document management. According to the author, an increase in targeted funding for programs to equip medical organizations with appropriate equipment and the creation of a specialized electronic database accessible to all medical workers with a unified system of interconnection between various health care institutions contributes to increasing the efficiency of the use of information and communication technologies in the field of health [43; 68; 104; 105; 108]. Federal Law No. 242-FZ of 29.07.2017 "On

Amendments to Certain Legislative Acts of the Russian Federation on the Use of Information Technologies in the Field of Health Protection" approves the definition of "telemedicine technologies" and sets out the specifics of providing medical care using telemedicine technologies.

Telemedicine technologies are information technologies that ensure remote interaction of medical workers with each other, with patients and (or) their legal representatives, identification and authentication of these persons, documentation of their actions during consultations, consultations, remote medical monitoring of the patient's health [8; 92;103; 158; 166]. Yu. N. Drescher defines telemedicine as "a set of implemented," embedded "in medical information systems, fundamentally new means and methods of data processing, combined into holistic technological systems that ensure the creation, transmission, storage and display of an information product (data, knowledge) at the lowest cost in order to carry out necessary and sufficient medical and diagnostic measures, as well as training for all those who need them in the right place and at the right time "[27; 44].

The main goal of telemedicine is to bring medical services as close as possible to a person [44], to create conditions under which the help of highly qualified specialists will become more accessible to residents of remote areas [50; 70; 71; 72; 74; 75; 76; 112; 123; 135; 136]. Telemedicine technologies eliminate the information isolation of doctors, creating fundamentally new opportunities for them to communicate with colleagues from large medical centers, training in the process of regular counseling [28; 29; 30; 31]. Medical care using telemedicine technologies is organized and provided in the manner established by the authorized federal executive body, as well as in accordance with the procedures for the provision of medical care and on the basis of standards of medical care [71; 72; 73; 75; 76]. The main areas of telemedicine use are telemedicine consultations, remote examination, diagnostics, and tele-education [28; 29; 44; 105; 114; 167; 172, 173]. The advantages of teleconsultations are: fulfillment of individual requests of specialists; Get answers to your questions quickly. high quality of conclusions, which is ensured by the appropriate level of consultants; possibility of regular communication with professionals within the framework of practical training,

conducting an independent examination in case of a conflict situation with a patient or experts of an insurance company [30; 31; 33; 40; 97; 120]. Remote monitoring is carried out on the basis of data entered into information systems. In order to ensure the protection of personal data and information constituting a medical secret, documentation of information on the provision of medical care to a patient using telemedicine technologies is carried out using an enhanced qualified electronic signature of a medical worker [116; 117; 118; 165; 173].

Currently, in the activities of domestic pathological and anatomical services, there are many problems associated with the exchange of data between the attending physician and the performer of lifetime pathological and anatomical studies of biopsy (surgical) material, the timely transfer of the results of these studies. Information systems developed in this section of diagnostics, as a rule, are narrowly focused. As a result, existing information systems are a complex of disparate automated workplaces, but not a single information environment [35; 36; 37; 52; 94; 178]. Elimination of these problems is possible with the help of modern information and organizational technologies, which allow minimizing the influence of factors that reduce the quality and availability of this type of diagnostics. Automation of manual microscopy is determined on the one hand by technological progress, on the other - by the requirements of specialists. Currently, a number of authors are considering the positive experience of using remote information medical technologies in organizing the work of pathological and anatomical services. A pathological and anatomical study conducted at a distance using image transmission through various communication lines and studying this image on a video monitor has identified a new direction in the development of telemedicine communications, called telepathology.

In the collective monograph "From Telemedicine to Electronic Health Care" (authors V. M. Levanov, O. I. Orlov, I. A. Kamaev, O. V. Perevedentsev, edited by Academician A. I. Grigoriev), the following definition of telepathology (telemorphology) is given - remote morphological study of pathological processes based on video images of histological sections and cytological preparations for staging and clarification diagnosis. Diagnosis or morphological examination of the image on the

computer monitor, obtained using a video camera or a digital camera from a microscope and transmitted over digital communication lines, is carried out. In telepathology, two modes can be used: static (transmission of fixed frames by e-mail) and dynamic (transmission of a video sequence of images with the possibility of discussing the drug by doctors) [111; 159]. The concept of developing a functional automated telepathology network with real-time evaluation of frozen slices and difficult cases was put forward by Ronald Weinstein in the mid-1980s. At the first stage, the idea of "static telepathology" was proposed: the doctor, using a camera mounted on a microscope, photographed and digitally saved images of a section or a series of sections, after which they could be sent by e-mail to another pathologist [183]. Currently, the use of special scanning systems has allowed telepathologists to remotely examine digitized micropreparations in real time (on-line). Thus, a virtual drug is a digital representation of a classical micropreparation that can be evaluated remotely [38; 39; 135; 139; 183].

From the point of view of the structural organization of digital pathomorphology, three directions of development are distinguished:

1) creation and development of specialized centers that carry out a full cycle of intravital pathological and anatomical diagnostics from the receipt of biological material to the receipt of an opinion;

2) retrofitting of the previously created pathological and anatomical service with the restructuring of business processes, training of specialists and the introduction of protocols;

3) creation of federal Reference Centers, to ensure the operation of which it is required to equip regional services in order to obtain digitized data or organize optimal logistics of biological material to perform a full diagnostic cycle [171].

Thus, the obvious advantages of using virtual microscopy and telecommunication technologies in the organization of lifetime pathological and anatomical diagnostics are:

1) remote image analysis and increasing the availability for doctors of medical organizations of consulting assistance of qualified pathologists, regardless of the distance to specialized pathological and anatomical services, organizing a consulting network of specialists;

2) expansion of opportunities for quality control of this type of diagnostics;

3) reducing the waiting period for the study result (consultative response);

4) the possibility of comparing the opinions of leading pathologists and their own experience for more accurate subsequent diagnosis, use as an educational tool;

5) archiving of video images of pathological processes, including rare diseases;

6) the possibility of redesigning processes, since the dynamic mode of video microscopy allows the consultant to scan the entire micro-drug even in the absence of a pathologist in the consulted medical organization [101; 102; 103; 104; 106; 119].

The goal of "digital pathomorphology" is the use of digital technologies in solving problems of pathological anatomy with an emphasis on rapprochement with clinical disciplines. Digital pathomorphology is not only a full-format scanning of glasses, but also the transfer to a digital platform of all processes, from the moment of diagnosis, performing surgical interventions and invasive diagnostic studies, to analyzing digital images and participating in this patient process [138; 171].

The development of telecommunication technologies in general, and in the Russian Federation in particular, requires solving problems of both a pathological, anatomical and organizational nature. The first include: ensuring the technical correspondence (identity) of the video image obtained at a distance, the primary true picture on the histological section and achieving the effectiveness of the histological conclusion for a specific patient, the opportunity for the consultant to independently investigate micro-drugs at a distance using remote access. Organizational problems include: ensuring the quality of histological preparations, which must meet standards and ensure the reliability of medical information, an unbalanced level of responsibility, uncertain document flow, legal support, a low level of professional training of doctors on telepathology, rigidity of thinking, high cost of telemedicine services, technical difficulties (telecommunications networks, software), protection of personal data and information constituting medical secrecy.

1.2 Lifetime pathological and anatomical examination of biopsy (surgical) material as a product of the functioning of the organizational system for conducting pathological and anatomical diagnostics

When conducting a lifetime pathological and anatomical study of biopsy (surgical) material, three stages are distinguished: pre-analytical, analytical and post-analytical. Digital, information, remote technologies determine the possibility of changes in the organization of almost all stages of lifetime pathological and anatomical diagnostics of biopsy (surgical) material.

The pre-analytical stage begins with prescribing lifetime pathological and anatomical studies to the patient in accordance with clinical recommendations, taking into account the standards of medical care in the relevant profiles and taking tissue fragments, organs or traces by specialist doctors for these studies. When establishing a preliminary diagnosis of a malignant neoplasm in accordance with the order of the Ministry of Health of Russia dated 19.02.2021 No. 116n "On approval of the Procedure for providing medical care to the adult population for oncological diseases," taking biological material for cytological research and (or) in-life pathological and anatomical examination of biopsy (surgical) material and referral to the pathological and anatomical department is organized by an oncologist (outpatient oncology care center, primary oncology office or outpatient department of an oncology dispensary or hospital) within one day after the preliminary diagnosis of malignant neoplasm. If it is impossible to take biopsy (operating) material in a medical organization, which includes an outpatient oncological care center (primary oncological office), the patient is sent by an oncologist to an oncological dispensary (oncological hospital) or to a medical organization providing medical care to patients with oncological diseases [129].

Preparation of guidance documents is carried out by a doctor who takes biological material during medical interventions, according to the approved forms of medical records: No. 014/y "Referral for intravital pathological and anatomical examination of biopsy (surgical) material" (order of the Ministry of Health of Russia dated 24.03.2016 No. 179n, Annex No. 2), No. 446/y "Referral for cytological examination of material

obtained during preventive gynecological examination, screening" or form No. 203/y-02 "Referral for cytological diagnostic examination" (order of the Ministry of Health of Russia dated 24.04.2003 No. 174 "On approval of registration forms for cytological studies"). The referral for in-life pathological and anatomical examination (ph 014/y) and cytological examinations (ph Nos. 446/y, 203/y) are filled in in accordance with the unified requirements for the design of referrals for this type of diagnosis [127]. The diagnosis of the sending institution in the directions is formulated clearly using the official nomenclature of diseases, the diagnosis code is additionally indicated according to the MKB-10 [115]. Referrals are signed by the doctor taking biological material with indication of the date of referral (sampling). The presence of electronic document management in a medical organization does not exclude the need to use directions according to approved forms or their analogues obtained when printing from electronic databases. Directions (all accounting forms) are filled in two copies. The first copy of the Direction with a copy of the Protocol of intravital pathological and anatomical (cytological) examination remains in the archive of the pathological and anatomical department/laboratory. The second copy of the Direction with the original Study Protocol shall be transferred to the sending medical organization (subdivision). A record of the date and method of material sampling is entered into the card of an outpatient or inpatient patient patient by the doctor taking the material for research [127]. To conduct a pathological and anatomical study of biopsy (surgical) material, together with biological material, a medical intervention protocol and an extract from medical documentation are sent to the pathological and anatomical bureau (department), containing the results of laboratory, instrumental and other types of diagnostic studies, a clinical diagnosis indicating the diagnosis code in accordance with the MKB-10. The obtained biopsy (surgical) material is fixed by placing in hermetically sealed containers with a fixing liquid - 10% neutral formalin solution. The ratio of volumes of fixing fluid and tissue is important: for the best fixation, the volume of fixing fluid should be at least 20 times higher than the volume of tissue immersed in it. It is forbidden to use fixators that are not coordinated with the pathological and anatomical department. The material is carefully labeled with the patient's full name and medical history number. This data is

applied to the container with the object to be examined. An important condition is the exact correspondence of the data on the capacity label to the information specified in the attached direction. Non-fixed biological material is delivered only immediately after surgery [127]. Modern digital technologies make it possible to record all actions during these procedures in the information system, number transportation containers and assign a corresponding identifier to each container [171].

Unified slides are used to prepare smears for cytological studies. Cell swabs are fixed by drying at room temperature. For marking, the standard recording field on the slide is used.

Storage of biological material placed in the fixing fluid is carried out at room temperature. Additional cooling, especially freezing, of both unfixed and fixed material is not allowed. The shelf life of the material in a pure fixing solution before delivery to the pathological and anatomical department should not exceed two days. If the size of tissue fragments exceeds 10 mm in the largest diameter, such material is delivered to pathological and anatomical department within one day [83].

Delivery of biological material to the pathological and anatomical bureau (department) is carried out by the personnel of the clinical department (medical organization) where it was received. Biological material is transported in special transportation containers. For separate containers are provided for pathological, anatomical and cytological material [115]. Transporting biological material over long distances always carries the risk of deforming it, making the biomaterial unsuitable for further investigation. These risks and possible errors can be eliminated by reducing the distance to the investigator, applying new methods of tissue preservation, or using the possibility of researching the drug in digital format.

In the established routine practice, the stages of taking biological material, its preliminary fixation and transportation, which may affect the quality of the study, are carried out without the participation of a pathologist. Information systems allow you to standardize, record the process of taking biological material by a clinician using photo and video recording as part of a digital protocol of surgery or diagnostic research. Visual information allows the pathologist to assess the method of sampling and the area

from which the biological material is taken. A pathologist can use a biopsy protocol combined not only with a standard organ map, but also with the visual information obtained using other instrumental studies (CT and ultrasound), which contributes to the involvement of the pathologist in the clinical process and a decrease in the number of repeated biopsies [171].

The following procedures of the pre-analytical stage are reception, primary sorting and registration of biological material, carried out by the medical registrar of the pathological and anatomical department. During registration, the biological material is assigned a unique registration number [127]. Information on the receipt of biological material for a lifetime pathological and anatomical study is entered in the medical records form No. 014-2/y "Log of the receipt of biopsy (surgical) material and the issuance of the results of lifetime pathological and anatomical studies" and in paragraphs 1-16 of the Protocol of the lifetime pathological and anatomical study of biopsy (surgical) material (Protocol) of form No. 014-1/y [125]. Simultaneously with the entry in the registration log, a unique registration number is put in the Protocol and on all primary research materials - paraffin blocks (filling cassettes during filling) and micropreparations (slides during microtomy). The registration number on the slide must clearly correspond to the registration number of the block from which this micro-preparation is made. Cytological material is recorded separately from histological material using distinctive additional identifiers. In the case of electronic document management, all data of the discipline forms and the corresponding numbering are entered into the computer database with the obligatory preservation of the journal archive of the studies performed. The registration of the biopsy (surgical) material completes the pre-analytical stage, followed by the analytical stage procedures involving work with the analyte (taken tissue sample). In routine clinical practice, a pathologist and laboratory assistants take part in the process of working with a tissue sample, but there is no possibility of participation of a clinician [171].

V.V. Menshikov in the article "System of national standards for laboratory medicine in Russia: the results of 10 years of development" notes that each stage of diagnostics has its own specific factors that affect the quality of processes. The

effectiveness of the processes of the pre-analytical stage of intravital pathological and anatomical research is influenced by: 1) clinical factors (severity and longevity of the disease);

2) iatrogenic factors (puncture, biopsy, endoscopy, various medical procedures); 3) conditions for the intake, temporary storage and transportation of biological material (material intake procedure, preservatives, preservation containers, primary processing procedures) [90; 91].

Planning of the pre-analytical stage includes: full informing of the medical staff about the features of all studies, listing of all studies, including those that are made available as a matter of urgency, regular updating of standard operating procedures for laboratory technicians and doctors for the collection of biological material, use of scanners for automatic registration of approved forms of Directions for lifetime pathological and anatomical studies of biological material, automation of the system for registration of samples for research, control of the temperature regime and delivery time of samples of biological material, ensuring the complete safety of patients and medical personnel when taking biological material, guarantee to patients of confidentiality of personal data and information constituting medical secrecy. All violations during sample collection, transportation and processing shall be documented [91].

Features of the organization of the analytical stage of intravital pathological and anatomical diagnostics.

The sequential procedures of the analytical step are:

1) macroscopic study of biopsy (surgical) material;

2) excision of biopsy (surgical) material; 3) execution of histological technologies for processing biopsy (surgical) material; 4) microscopic examination of the micropreparation; 5) completion of the Protocol for the in-life pathological and anatomical study of biopsy (surgical) material of registration form No. 014-1/y with the completion of the conclusion [127]. Before starting a macroscopic examination of biological material, the pathologist examines the medical documentation. Macroscopic examination of biopsy (surgical) material is performed pathologist in accordance with the clinical recommendations "Standard technological procedures during pathological

and anatomical studies "approved by the Presidium of the Russian Society of Pathologists dated 25.06.2016 No. 30/1. If necessary, the pathologist receives explanations from the specialist doctor who took the biopsy (surgical) material during medical intervention. Macroscopic examination data shall be entered into the appropriate item of the Protocol of Form No. 014-1/y. Tissue cutting is also carried out by a pathologist, the volume of the cut and the prescribed colors (reactions) are determined by the pathologist based on the tasks of the study, the volume of biopsy (surgical) material, the method of obtaining it, and the clinical diagnosis. Excision of biopsy (surgical) material involves excising pieces of organs and tissues and placing them into fixing solutions. Primary accounting data (number of biopsy (surgical) material study subjects obtained during excision and assigned coloration (reactions) are entered into the Protocol [127]. At this stage, the biological material is subject to timely fixation, before the start of autolysis processes, using the required volume of the fixator. Currently, in a number of pathological and anatomical services, the process of final fixation is recorded, including using photo and video fixation of biological material, and the cut material is assigned tags. If the biological material comes with an existing identifier, the laboratory assistant scans the identifier and gains access to information about the patient and the procedure performed in digital form [171].

Performing histological technologies when processing biopsy (surgical) material taken for pathological and anatomical research is carried out by the nursing staff of the pathological and anatomical department and includes: decalcification (if there are bone fragments in the material); wiring (dewatering and paraffin impregnation); paraffin filling with paraffin blocks; microtomy (making paraffin sections, mounting them on slides and drying); painting (staging of the reaction, determination) of paraffin sections on the slide, conclusion of painted sections under the cover glass or under a special film, drying of micropreparations; sorting of micropreparations [127].

Dewatering and paraffin pouring with the manufacture of paraffin blocks are currently carried out by automated systems - fabric processors. With hardware posting methods, the final material fixing is set to at least 2-3 hours. Wiring programs are selected based on the specific technological conditions of separation, types and volumes

of the test material. In addition to the standard program, additional technical capabilities of modern histological processors, such as vacuum, high pressure, microwave irradiation, are currently used to speed up the wiring of the material. An arbitrary shortening of the wiring time under normal external conditions can lead to a sharp deterioration in the quality of impregnation of the fabric [83]. Only one piece is poured into one paraffin block, only one unique registration number corresponding to the piece number is applied to one block.

The microtome cutting process is currently the least automated and is carried out manually by a laboratory assistant. Automated procedures are painting with painting stations and encasing under a cover glass or film. Currently, special devices - autostainers - are widely used for automatic painting of paraffin sections. A fundamentally important result of the introduction of technologies for automated staining of micropreparations is the unification of staining conditions, which is important for obtaining comparable results, eliminating laboratory errors with a sharp increase in productivity [51; 83]. The painted sections are enclosed under the cover glass using specialized histological mounting media, under a special film - without mounting media. Making mistakes when performing these procedures is most critical for the quality of the study as a whole, since it makes it difficult to further work not only with a microscope - scanner, but also with a conventional light microscope due to the presence of various artifacts [171].

Marking of objects taken for further research is carried out with assignment of a unique registration number to each object. Each histological preparation is marked with a registration number identical to the unique registration number of the corresponding block [142]. In order to exclude violations of technological standards when performing histological technologies for processing biological material in some pathological and anatomical services, as procedures are performed, sample preparation protocols are formed in digital form, and they can be monitored and adjusted. The medical information system allows you to include photo and video recording of clipping processes, display protocols for laboratory assistants during the stages of sample

preparation, form a system for identifying biological material, scanned images, and barcode seals [171].

During cytological studies, fixation and staining of smears of biological material is carried out according to the established method. Currently, the standardized technology for preparing a cytological drug is liquid cytology, which is recognized as the most informative way to obtain biological material and is recommended as the "gold standard" for diagnosing female intraepithelial neoplasias. The advantages of liquid cytology are: improved material quality, long shelf life of the resulting material, the ability to quickly manufacture the drug, the manufacture of a standardized monolayer smear, the use of standardized staining techniques.

Microscopic examination is carried out by a pathologist and is not only a study of micropreparations, but also a comparison of the results obtained with the data of macroscopic examination and the data contained in the extract from medical records. In order to clarify the diagnosis of the disease, taking into account the requirements of standards of medical care and clinical recommendations, at the stage of microscopy, a pathologist may additionally prescribe the following: additional methods for coloring micropreparations - histochemical, immunohistochemical, electron-microscopic, molecular biological, genetic; additional methods of polarization, fluorescence, transmission or scanning electron microscopy [127]. Microscopy data, taking into account the results of the applied additional painting methods, are entered into the Protocol. Cytological examination includes microscopic examination of cell morphology. At the end of the study the pathologist fills out the remaining columns of the Protocol, including the wording of the conclusion, the code of diagnosis (condition) by MKB-10, as well as comments on the conclusion and recommendations, if any [127]. According to the information letter of the Ministry of Health of Russia dated 29.03.2018 No. 13-2/2-106, in order to improve the system of medical care for patients with cancer when diagnosing a malignant neoplasm, the histological wording is filled in the Protocol of the pathological and anatomical study (morphological) diagnosis of malignancy and 6-digit International Classification of Diseases-Oncology-ICD-O code

(4 signs - cell type (histology), 1 digit - the nature of the neoplasm, 1 sign - the degree of malignancy or differentiation of malignant neoplasms [88].

The most significant stage in the use of digital technologies in intravital pathological and anatomical diagnostics is full-format scanning of pathomorphological glasses. For large medical organizations, it is more rational to use high-performance equipment - 200-400 glasses at the same time. A prerequisite is the integration of scanner software into medical information systems with the formation of a standardized data storage protocol. The use of open formats for data digitization (in particular, DICOM) allows you to master fusion technology - combining digitized morphological data with data from radiation imaging methods, which makes it possible to carry out topographic diagnostics of pathological processes [33; 34; 171].

Digital technologies and access to digitized data allow a pathologist should be remotely involved in the analysis and formation of a conclusion on the study of specialists of various profiles, including the possibility of holding meetings of the tumorboard [171].

Clause 15 of the Order of the Ministry of Health of Russia of 19.02.2021 No. 116n "On Approval of the Procedure for Providing Medical Care to the Adult Population for Cancer" in complex clinical cases regulates the participation in the diagnostic process of the pathological and anatomical departments (bureaus) of the fourth group (Reference Centers) through information interaction of oncologists and pathologists. In order to clarify the diagnosis, including the prevalence of the oncological process and the stage of the disease, assess, interpret and describe the results, the oncologist will arrange for sending digital images of pathomorphological studies or biopsy (surgical) material to the Reference Centers for repeated pathomorphological, immunohistochemical, and molecular genetic studies.

The completed Study Protocol shall be signed (including with the use of an electronic digital signature) by a pathologist and a specialist physician performing consultations. The original of the Protocol is sent to the medical organization (department) that sent the biopsy (surgical) material for in-life pathological and anatomical examination (if there is an electronic document flow, the paper medium is

printed from the medical information system), the second copy of the Protocol is stored in the archive of the pathological and anatomical bureau (department) [127].

The result of the cytological examination is a microscopic description and cytological diagnosis, which is formulated using cytological and histological terms in accordance with the ICD, if the material is obtained during a preventive gynecological examination, the cytogram characteristic is additionally attached [130]. An important procedure is to compare the cytological conclusion with pathological and anatomical. In case of neoplasms, it is considered a coincidence to establish a cytological diagnosis according to the main form, even if the degree of tumor differentiation is not indicated or does not coincide. In some cases, an affirmative or presumptive cytological diagnosis can correctly verify the lesion, although lifetime pathological and anatomical examination does not confirm the cytological diagnosis. The terminological correspondence or inconsistency of the established diagnosis with the accepted cytological classifications is taken into account [184]. Currently, when analyzing data, the priority is to automate the description, quantitative counting and formation of conclusions on the studies carried out. The use of artificial intelligent software and hardware tools to analyze images and search for deviations from the norm, diagnose cancer is the direction of the near future in the process of automation of lifetime pathological and anatomical diagnostics, requiring the formation of a separate data set (including based on electronic medical records) for each deviation and training of the neural network [171].

The effectiveness of the processes at the analytical stage is influenced by: the composition and properties of the test sample, equipping the pathological and anatomical department with equipment in accordance with the equipment standard, the properties of various types of equipment and consumables used to process a sample of biological material, the accuracy of compliance by personnel with the sequence, duration, temperature regime of individual analytical procedures provided for by the established research methodology [90]. Planning of the analytical stage of in-life pathological and anatomical research includes: description of work processes for the purchase of medical devices and consumables, as well as their delivery directly to

workplaces; development of standard operating procedures for research; internal control and quality assessment of studies and their documentation [91]. The effectiveness of the processes at the analytical stage of the intravital pathological and anatomical study is determined by the degree of compliance of the histological technology procedures with the standards, objectivity when interpreting the study results in terms of establishing a diagnosis and assessing the therapeutic measures taken [90; 91].

The most significant features of the organization of the post-analytical stage of lifetime pathological and anatomical diagnostics are.

1) Fulfillment of regulatory deadlines for lifetime pathological and anatomical studies of biopsy (surgical) material: for intraoperative biopsy (surgical) material - up to 20 minutes per study subject; for material that does not require decalcification and (or) additional colors (reactions) - not more than 4 working days; for material requiring decalcification and (or) application of additional colors (reactions), preparation of additional paraffin sections - not more than 10 working days; for material requiring additional immunohistochemical study methods up to 5 markers - no more than 7 working days, immunohistochemical study methods more than 5 markers - no more than 15 working days, additional electron microscopic study methods - no more than 7 working days; for material requiring additional molecular biological research methods - not more than 10 working days; additional genetic research methods - no more than 10 working days; for traces - no more than 4 working days [127]. By Order of the Ministry of Health of Russia No. 116n dated 19.02.2021 "On Approval of the Procedure for Providing Medical Care to the Adult Population for Oncological Diseases," it was determined that the term for performing pathological and anatomical studies necessary for histological verification of a malignant neoplasm should not exceed 15 working days from the date of receipt of biopsy (surgical) material at the pathological and anatomical bureau (department) [129]. Scheduled cytological studies of the material are carried out no later than 48 hours from the date of receipt of the material in pathological and anatomical department/laboratory. Digital technologies reduce the time for obtaining conclusions on lifetime pathological and anatomical studies by clinicians, since there is no need for prompt transportation of research protocols to the customer.

Digitized medical data, including in-life pathological and anatomical diagnostics, through remote access simplify the procedure for the patient's participation in the diagnosis and treatment of the disease, which contributes to improving the quality of medical care [171].

2) Taking into account the studies performed.

The number of in-life pathological and anatomical studies and related indicators shall be taken into account based on the number of study cases on the basis of the Protocols. A case is a study of biopsy (surgical) material received from a patient within one visit (treatment, hospitalization) for one disease, including all stages of the study and additional methods (if these methods are prescribed by a pathologist). Accounting for the number of technological operations performed in the pathological and anatomical department by specialists with higher medical education is carried out according to the number of additional methods of painting micropreparations (staging reactions, definitions), which should be understood as a set of measures aimed at conducting a study of one tissue sample by treating it with one color (reaction, definition). Accounting of the number of technological operations performed by an employee with secondary medical education is carried out according to the following criteria: when cutting, wiring, microtomy - by the number of objects (tissue samples poured into one paraffin or frozen block); when coloring micropreparations - by the number of objects treated with one coloring (reaction, determination) [127].

3) Archiving of materials in the pathological and anatomical bureau (department).

In a medical organization conducting lifetime pathological and anatomical studies of biopsy (surgical) material, an archive is formed, which includes the following materials obtained from the results of lifetime pathological and anatomical studies of biopsy (surgical) material: 1) Directions; 2) Protocols; 3) Journals; 4) micropreparations; 5) tissue samples in paraffin blocks; 6) tissue samples in 10% neutral formalin solution [127]. The period of storage in the archive of tissue samples in a 10% solution of neutral formalin in the presence of a tumor or tumor-like process is at least one year from the date of execution of the Protocol, in other cases - at least until the end of execution of the Protocol; directions and Protocols - corresponds to the shelf

life of medical documentation [127]. Cytological reports are kept in the department for 3 years. When using information and computing systems (computer technology), cytological conclusions are entered into the "electronic" medical history. Drugs without pathological changes are not preserved. Glass preparations with pathological changes (with a cytological picture of specific inflammation or oncological diseases) are archived and stored for 20 years with the obligatory creation of conditions that exclude loss of information content [130]. Removal of micropreparations and blocks from the archive is carried out only by agreement with the head of the pathological and anatomical department and is registered in the log of archival materials (there is no special registration form) [83]. The effectiveness of processes at the post-analytical stage of lifetime pathological and anatomical research is determined by the timing of submitting results to clinical units, the accuracy of the archiving procedure for research materials, which allows timely use of the possibility of obtaining a "second opinion" of a pathologist, including remotely [83].

1.3 Assessment of the activity of the pathological and anatomical service and quality management of lifetime pathological and anatomical diagnostics of biopsy (surgical) material

1.3.1 Assessment of the activity of the pathological and anatomical service

P. G. Malkov, G. A. Frank note that a qualified economic analysis of the activities of pathological and anatomical departments can serve as the basis for making management decisions to reduce costs, optimize the production process and increase the clinical effectiveness of research. The initial data for the economic analysis of the activities of the pathological and anatomical department, the authors determine "the characteristics of the structure, staffing, personnel and qualifications of personnel, the characteristics of material and technical support; the number and profile of attached healthcare organizations; characteristics of volumetric indicators of activity (the number of studies of biopsy and surgical material, the number of special methods used for

diagnostics - such as histochemical, bacterioscopic, immunomorphological and other methods); cost characteristics (staff salaries, expenses for the purchase of medical and laboratory equipment, reagents and other consumables, for the maintenance of production premises and ensuring the production process) [81; 82; 146, 147].

The authors pay special attention to such quantitative indicators as:

1) absolute increase in the total number of studies and examined patients - the ratio of the total number of studies performed in the pathological and anatomical department for a certain period to the same indicator for the previous period, expressed in percent;

2) clinician satisfaction index is the ratio of indicators of the need for diagnostic studies of a certain type to the actual volume of studies performed, expressed as a percentage [81; 146]. Indicator of satisfaction of the need for lifetime pathological and anatomical studies of a certain type (Br) - an indicator representing the ratio of the absolute number of studies conducted in a certain pathology (Va) to the total number of patients with this nosology registered according to report form No. 12 (Bd), and expressed in percent [81];

3) indicator of lifetime verification of the diagnosis for individual diseases (V). The indicator of verification of the diagnosis of malignant neoplasm is calculated as the ratio of the absolute number of cases of biopsy studies in which the diagnosis of malignant neoplasm is confirmed (v) to the total number of biopsy studies performed in the same pathology (an), expressed as a percentage [81].

The actual volume of biological material to be treated provides an estimate of the load per unit of active equipment. The Russian Society of Pathologists recommended the norms of load on equipment in the pathological and anatomical department (Table 2)

Table 2 - Recommended Equipment Load Rates

Main types of histological laboratory equipment	Units of measure	Load rating
Station for macroscopic examination and cutting	objects per instrument per year	20 000
Fabric carousel processor	objects per instrument per year	15 000
Fabric Processor Type	objects per instrument per year	60 000
Station for filling and manufacturing of paraffin blocks	objects per instrument per year	20 000
Histology Paint Machine	micropreparations per instrument per year	75 000
Machine for the conclusion of histological preparations under the cover glass	micropreparations per instrument per year	15 000

As an integral characteristic of the economic efficiency of the laboratory, the authors suggest using:

1) cost-effectiveness ratio - the ratio of the average cost of research to the average unit of time;

2) the coefficient of average labor intensity is the ratio of the total amount of time spent on diagnostic studies for a certain period of time (in UET) to the total number of studies performed for a given period of time. Currently, research labor intensity indicators are considered taking into account the complexity categories of biopsy (surgical) material [81; 82].

Depending on the labor intensity, lifetime pathological and anatomical studies of biopsy and surgical material are divided into 5 difficulty categories (Table 3). On average, within one lifetime pathological and anatomical examination is carried out on three objects (tissue samples). The cytological material studied is also divided into five difficulty categories.

Table 3 - Indicators of labor intensity and design load standards for lifetime pathological and anatomical studies of biopsy (surgical) material, taking into account the difficulty category

Service name	Labor input (UET/hour)		Annual load rating	
	doctor	laboratory assistant	doctor	laboratory assistant
Examination of biopsy (surgical) material of difficulty category I	2,00/0,33	3,80/0,63	5 450	2 860
Examination of biopsy (surgical) material of difficulty category II	4,00/0,67	8,80/1,47	2 690	2 220
Examination of biopsy (surgical) material of difficulty category III	6,00/1,00	12,10/2,02	1 800	890
Examination of biopsy (surgical) material of difficulty category IV	10,00/1,67	24,00/4,00	1 080	450
Service name	Labor input (UET/hour)		Annual load rating	
	doctor	laboratory assistant	doctor	laboratory assistant
Examination of biopsy (surgical) material of difficulty category V	15,00/2,50	26,00/4,33	720	420

3) research automation coefficient is the share of studies performed using automated equipment (robotic systems) in the total research volume [81; 82];

4) at present, a document automation coefficient is used to assess the activities of the pathological and anatomical service in the Russian Federation as part of the development of the paperless technology concept [93].

Electronic document management allows you to minimize the cost of creating paper media, speed up the search for the necessary document, organize the simultaneous work of several persons on one document, speed up the process of creating documents (for example, Research Directions) by including fragments from other documents

(examination by a specialist doctor, operation protocol). The developed unified standard of electronic signature ensures identification of the author of the document and protection of the document from changes by unauthorized persons [40]. Direct clinical effects are used as the main criterion for the effectiveness of medical technologies: prompt diagnosis, shorter time for establishing a correct clinical diagnosis, timely and effective treatment with restoration of functions [16; 24; 79; 80; 110; 122]. Some authors (O. P. Maslova, monograph "Evaluation of the effectiveness of medical services based on resource potential") propose to use the medical efficiency coefficient to assess the effectiveness of medical care, which is calculated as the ratio of the number of cases with the achieved result to the total number of cases [84].

1.3.2 Quality management of lifetime pathological and anatomical studies of biopsy and surgical material

A diagnostic process is a system of interrelated diagnostic measures carried out in order to achieve the planned results. Typically, the output of one process forms directly the input of the next. Managing processes in an organization and ensuring their interaction is called a "process approach." Its advantage is continuity of control. Process improvement is achieved by implementing the Deming cycle (PDCA cycle): plan, act, check, act (Figure 1) [67; 144; 180; 181; 182; 184].

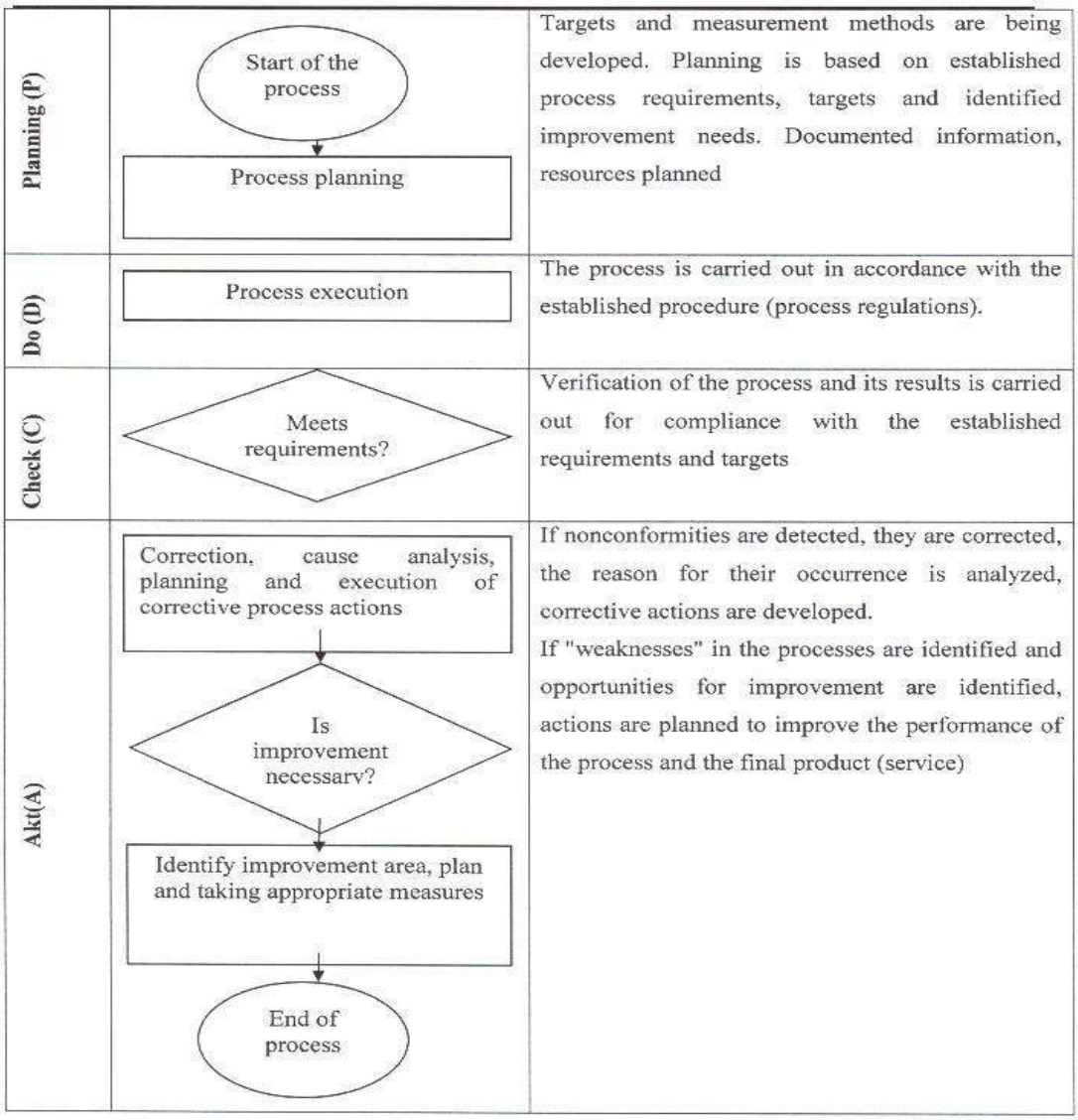


Figure 1 - Application of the Deming cycle to process control

High-quality research involves planning the stages of intravital pathological and anatomical examination of biopsy (surgical) material. O. A. Klimenkova, A. V. Emmanuel in the article "Quality indicators: conditions for benchmarking laboratory services" draw attention to the fact that in laboratory medicine, quality indicators are used to assess the effectiveness of processes. The quality indicator is considered as a

basic tool that allows users to quantify the quality of selected items by comparison with certain criteria. In essence, the quality indicator is a performance criterion that allows you to determine the fact of achieving the target value [56]. Process Quality Management Workflow for Lifetime Steps pathological and anatomical examination is shown in Figure 2 [67].

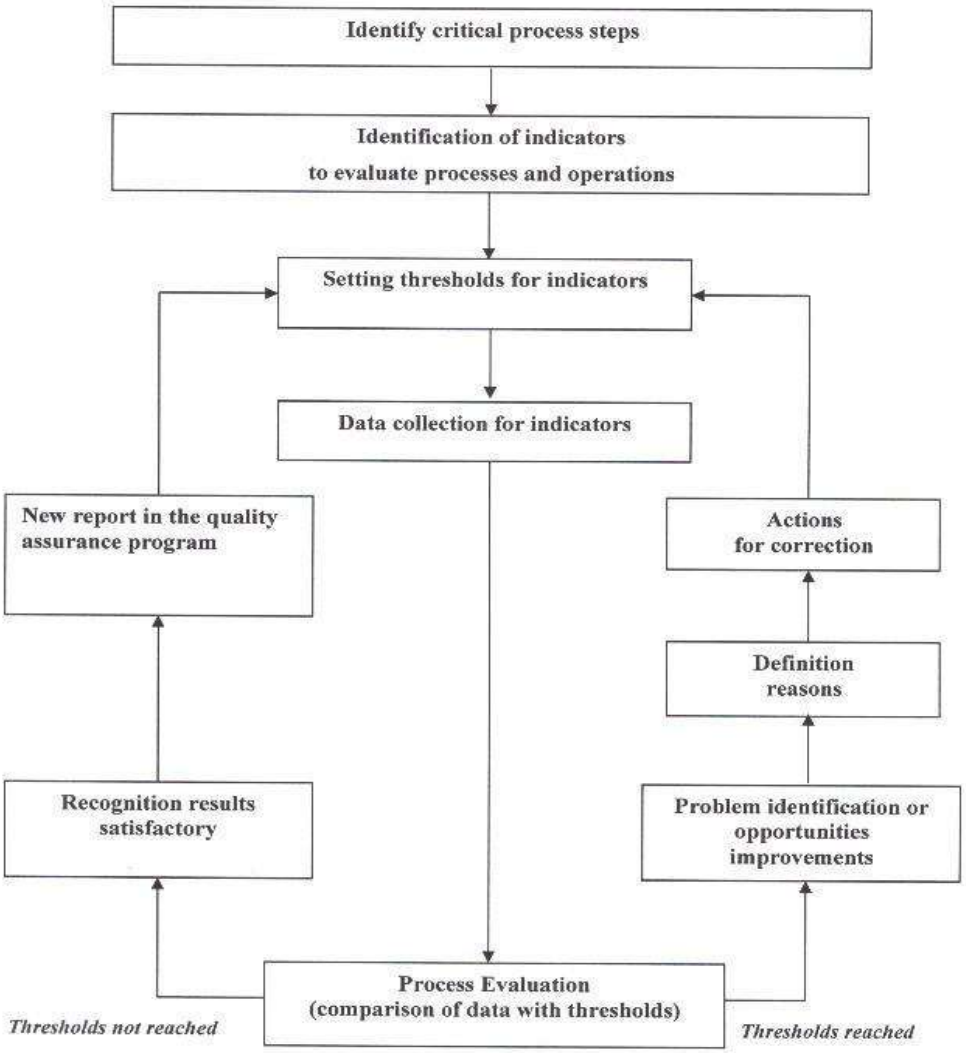


Figure 2 - The sequence of quality management operations during the technological process at the stage of performing the pathological and anatomical study

However, lifetime pathological and anatomical diagnosis of biopsy (surgical) material does not apply to laboratory services. The procedure for conducting studies on clinical laboratory diagnostics and intravital pathological and anatomical diagnostics is determined by various Orders of the Ministry of Health of Russia, which excludes the use of uniform indicators (indicators) to assess the quality of studies. V. L. Kovalenko, V. N. Koksharov, L. V. Kaktursky, O. D. Mishnev, V. Z. Terekhov in the article "Materials for the development of target indicators of the quality of pathological and anatomical studies" quality indicators are considered as numerical indicators expressed in percentages obtained during the assessment of medical care and indirectly reflecting the quality of its main components (structure, process or result). The ranges of quality indicator values set as acceptable are referred to by the authors as target quality indicators. Sources for setting target (threshold) values of quality indicators are clinical guidelines, systematic reviews, results of best practices, expert opinions [86].

The quality of a lifetime pathological and anatomical study of biological material is understood as obtaining a reliable result of a study related to a specific patient, performed at the proper analytical level within the prescribed time frame with the execution of a standard protocol of the conclusion transferred to the customer.

Quality management during intravital pathological and anatomical diagnostics of biological material is based on a process approach. Obtaining a reliable study result depends on the effectiveness of the processes performed at each stage of this type of diagnostics. A system of measures to improve in-life pathological and anatomical diagnostics can be developed based on the establishment of a target achievement index - that is, the ratio of the actual value of the quality indicator in a particular pathological and anatomical institution/unit to the target value of the quality indicator.

A number of authors (V. L. Kovalenko, V. N. Koksharov, L. V. Kaktursky, O. D. Mishnev) propose the following set of target (permissible) quality indicators for pathological and anatomical studies.

For resource support: staffing of pathological and anatomical institutions/units with medical and laboratory personnel - at least 60%; providing the possibility of additional laboratory (bacteriological, virological, toxicological, etc.) studies - in 100%;

providing the possibility of using modern technological methods of morphological research (immunomorphological, electron-microscopic, FISH-method, etc.) - in 100%.

According to intravital pathological and anatomical diagnostics:

- the frequency of uncertain pathological and anatomical diagnoses (due to the failure to provide complete clinical and laboratory data, the non-use of modern methods of morphological diagnostics) - no more than 10%;

- compliance with the terms of the study of biopsy and surgical material: urgent intraoperative biopsies (20 minutes) - at least 90%; small biopsy material (4 days) - at least 90%; other surgical biopsy material that does not require decalcification (6 days) - at least 90%; other surgical biopsy material requiring decalcification (14 days) - at least 90%;

- the frequency of coincidence of diagnoses of urgent intraoperative and subsequent planned pathological and anatomical studies is at least 90%;

- the frequency of changing pathological and anatomical diagnoses during repeated pathological and anatomical studies of biopsy (surgical material - no more than 5% [86].

Quality management of lifetime pathological and anatomical studies is impossible without analyzing consumer satisfaction with the quality of this type of diagnosis. V. L. Kovalenko and V. N. Koksharov in their work "Materials for the development of indicators of consumer satisfaction with the results of pathomorphological works and services" note that in order to analyze satisfaction with the quality of pathomorphological diagnostics, it is imperative to conduct a survey of consumers of pathological and anatomical services [85; 169].

Taking into account the complexity and diversity of activities pathologist indicators (indicators) of consumer satisfaction with the results of his research are complex and include:

1) the possibility of obtaining by the consumer the results of a standard set of morphological studies within the framework of the program of state guarantees of free medical care, excluding the use of personal funds of the patient;

2) the possibility of obtaining a "second opinion" based on consultation, expert

assessment of the materials of the primary pathological and anatomical study of biopsy (surgical) material, including using remote information technologies [85; 169];

3) compliance with the terms of the study and provision to the consumer of standard conclusions determined by regulatory documents for biopsy (operational) material;

4) presentation of the results of pathological and anatomical studies to clinicians using modern information and communication technologies [85; 169];

5) the nature of the final product of pathological and anatomical diagnostics is the ratio of the final and descriptive forms of pathological and anatomical conclusions [85; 169];

6) satisfaction of doctors of clinical specialties with the quality of clinical, pathological and anatomical comparisons, their impact on improving the quality of medical care;

7) defects of pathological and anatomical diagnostics revealed during a certain period within the framework of expert activities of insurance medical organizations and having subjective reasons [85; 169].

The same authors (Kovalenko V.L., Koksharov V.N., Kaktursky L.V., Mishnev O.D., Terekhov V.Z.) propose to carry out a generalized semi-quantitative assessment of satisfaction with quality pathological and anatomical works and services using the modified formula "[86; 169]:

$$ICD = \Sigma Rf + \Sigma Rp + \Sigma Pabs/N$$

where ICI is the integral quality satisfaction factor

pathological and anatomical works and services;

∑ Rf - sum of values of full achievement of the expected result;

∑ Pp - sum of values of cases of partial achievement of the expected result;

∑ Pabs - sum of values of absence of expected result; N is the number of respondents surveyed.

In this case, the complete achievement of the expected result is assigned the value

"+ 1," the partial achievement of the expected result "0," the values of absence of expected result "-1." This formula can be used for each indicator or for their combination. The gradation of the integral satisfaction index can be as follows: high level - from 0.6 to 1.0; average level - from 0.4 to 0.59; low level - from 0 to 0.39 [86; 169].

Based on a real assessment of the current quality system pathological and anatomical studies include analysis of indices of achievement of the goal - ratios between achieved and target indicative indicators of activity.

P. G. Malkov et al proposed a system of indicators to assess compliance with all stages of intravital pathological and anatomical studies and standard technological procedures related to the study and the registration of its results in the patient's medical documentation [113].

The basis for the use of indicators is the assessment of compliance with the clauses of the Rules for Conducting Pathological and Anatomical Studies, approved by Order of the Ministry of Health of Russia dated 24.03.2016 No. 179n "On the Rules for Conducting Pathological and Anatomical Studies," or filling out the corresponding clauses of registration forms No. 014/y (Directions), No. 014-2/y (Journal), No. 0014-1/y (Protocol). The scoring form is 0/1.

Estimated indicators are formed for the following stages of filling out medical documentation:

1) assessment of the registration of the patient's medical record (justification of medical indications for the lifetime pathological and anatomical diagnosis of biopsy (surgical) material, the presence of a description of the medical intervention in which the biopsy (surgical) material was obtained, the original Protocol of the intravital pathological and anatomical study of biopsy (surgical) material in the patient's medical record (maximum score 4);

2) assessment of the Direction filling for in-life pathological and anatomical examination of biopsy (surgical) material according to form No. 014/y (maximum score 20);

3) evaluation of filling in the Log of biopsy (surgical) material receipt and

issuance of the results of lifetime pathological and anatomical studies of biopsy (surgical) material according to form No. 014-2/y (maximum score 11);

4) assessment of the completion of the Protocol of lifetime pathological and anatomical examination of biopsy (surgical) material according to form No. 014-1/y (maximum score 18);

5) assessment of the timing of lifetime pathological and anatomical studies of biopsy (surgical) material (maximum number of points 1);

6) assessment of the presence in the Archive of primary materials of lifetime pathological and anatomical studies of biopsy (surgical) material (micropreparations, tissue samples in paraffin blocks and in 10% formalin solution, a log for issuing primary materials, a log for issuing copies of Protocols, copies of Protocols, advisory revision, acts of writing off primary materials) with a maximum number of points - 7. Target score in all lifetime pathological and anatomical studies - at least 60 points [113].

Quality control of micropreparations in the pathological and anatomical service is carried out at least at three levels - by a laboratory assistant, pathologist and head of the department. In addition, the improvement of the quality of lifetime pathological and anatomical studies is achieved by participating in the program of the federal external quality assessment system (FSVOK). The purpose of external assessment of the quality of studies is to assess the degree of comparability of the results of studies performed in healthcare institutions, as well as the compliance of these results with established standards of analytical accuracy. Regular external quality assessment and routine internal quality control complement but do not replace each other. External quality assessment is aimed primarily at ensuring the uniformity of measurements throughout the country and at identifying systematic errors in laboratory methods, while internal quality control is designed to maintain the stability of research, identify and eliminate unacceptable random and systematic errors. However, neither internal quality control nor participation in the PSVOC allows for an assessment of the pre-analytical stage, and also does not give complete confidence that the research results are correctly interpreted. It is possible to achieve the absence of errors at the pre-analytical and analytical stages only if the employees of the pathological and anatomical department

join forces with specialists from clinical departments [67].

Currently, in complex clinical cases, to clarify the diagnosis, including the prevalence of the oncological process and the stage of the disease, in order to assess, interpret and control the results of lifetime pathological and anatomical research, oncologists organize consultations in federal reference centers using telemedicine technologies. The procedure for referring patients to federal Reference Centers (NMRC) is determined by order of the Ministry of Health of Russia dated 23.12.2020 No. 1363n "On approval of the Procedure for referring insured persons to medical organizations, the functions and powers of the founders in respect of which are exercised by the Government of the Russian Federation or federal executive bodies, for the provision of medical care in accordance with the uniform requirements of the basic program of compulsory medical insurance "and is carried out in the direction of the attending physician of form No. 057/y-4. The current routing scheme for oncological patients provides for the referral of patients and micro-drugs to federal Reference Centers by oncologists from regional oncological dispensaries and outpatient oncological care centers. This order does not exclude the possibility of self-referral of the patient to the federal center in the presence of research results. As part of the information remote interaction of medical workers, digitized images of scanned micropreparations obtained using scanning microscopes are sent to the Reference Centers for consultation. According to the order of the Ministry of Health of Russia dated 16.02.2021 No. 116n "On Approval of the Procedure for Providing Medical Care to the Adult Population for Cancer," a scanning microscope (micro-drug scanner) is included in the standard of equipping medical organizations providing medical care to patients with cancer [129]. The use of telemedicine consultations of scanned micropreparations allows:

1) in the field of resource quality: improve the professional level of personnel, rationally and efficiently use equipment, consumables [185; 186; 188; 189; 190];

2) in the field of quality assurance of processes (technologies): optimize and reduce the time of the diagnostic process, select the optimal treatment tactics, methods, volumes and optimal time for surgical intervention, improve the organization of medical care;

3) in the field of ensuring the quality of results: reduce the duration of treatment in a hospital, increase life expectancy, taking into account the improvement of its quality, increase the availability of medical care and increase its safety [45; 46; 120; 136; 157; 175; 185; 190].

SUMMARY

1. Defects in the manufacture of histological preparations can cause erroneous interpretation of the disease or pathological process, therefore, their prevention is an important component of ensuring the quality of lifetime pathological and anatomical diagnostics.

2. Violations of standard technological procedures at any stage of lifetime pathological and anatomical diagnostics create the practical futility of a qualitative result [186].

3. In order to minimize the impact of the human factor on the results of the work of pathological and anatomical departments (institutions), the introduction of elements of unification and robotization of histological technology is promising [188].

4. The main problems of the activities of the pathological and anatomical departments are associated with personnel shortages and insufficient equipment with technological equipment.

5. The introduction of medical information systems allows integrating the activities of geographically distant from each other specialists and pathologists, ensure the formation of electronic document management and pathological and anatomical archive, increase the speed of information exchange, reduce the burden on personnel.

6. Indicators of the quality of lifetime pathological and anatomical studies are indicators reflecting the quality of the structure, processes and results of intravital pathological and anatomical diagnostics.

7. Telemedicine remote diagnostics, which is an element of the medical information system, is considered as a technology for managing the quality of lifetime pathological and anatomical diagnostics and affects the quality of resources, processes and results.

CHAPTER 2 MATERIAL AND RESEARCH METHODS

The study was conducted in 2015-2022. The object of the study was a system for organizing lifetime pathological and anatomical diagnostics of biopsy (surgical) material in medical organizations of the Novosibirsk Region; the subject of the study is the relationship of the organizational structure with the technological processes of intravital pathological and anatomical diagnostics in medical institutions of the Novosibirsk Region. The follow-up units were Directions for in-life pathological and anatomical examination of biopsy (operating) material of registration form No. 014/y, Protocols for in-life pathological and anatomical examination of biopsy (operating) material of registration form No. 014-1/y, expert opinions based on the results of individual examinations, questionnaires of doctors, survey cards of heads of medical organizations, reports on internal quality control of diagnostic care.

The leading medical organization in which the study began was the State Novosibirsk Regional Clinical Diagnostic Center, which in 2016 was reorganized by joining the City Clinical Hospital No. 1 in Novosibirsk. Research bases - 26 medical organizations at the level of central hospitals in the districts of the Novosibirsk Region, central hospitals in Berdsk, Iskitima, Ob, State Novosibirsk Regional Clinical Hospital, Novosibirsk Regional Clinical Oncological Dispensary, City Gynecological Hospital No. 2, City Clinical Hospital No. 2, City Hospital No. 4, City Clinical Hospital No. 25, 12 polyclinic in Novosibirsk (No. 1 (clinical), 2, 7, 13 (clinical), 17, 18, 20, 22, 24, 29, polyclinic department of the City Clinical Hospital No. 19, consultative and diagnostic polyclinic No. 2), also a medical organization of federal subordination Siberian District Medical Center FMBA of Russia.

The total study scope is shown in Table 1. To solve the tasks, the study was carried out in four stages:

1) study and scientific analysis of modern domestic and foreign sources of literature on the system of organization of lifetime pathological and anatomical diagnostics of biopsy (surgical) material;

2) a comprehensive analysis of the activities of the pathological and anatomical

services of medical organizations in the Novosibirsk Region based on the results of sociological research, statistical indicators, results of multi-criteria expert analysis of decision-making on the selection of criteria for assessing the compliance of research processes with technological standards, calculation of the Kendall concordance coefficient to assess the consistency of expert opinion on the organization of intravital pathological and anatomical diagnostics, as well as the development of an organizational and functional model of the system of intravital pathological and anatomical diagnostics of biopsy (surgical) material;

3) implementation and scientific substantiation of the organizational and functional model of the system of intravital pathological and anatomical diagnostics of biopsy (surgical) material based on the process approach;

4) assessment of the medical and economic efficiency of the organizational and functional model of the lifetime system pathological and anatomical diagnostics of biopsy (surgical) material based on medical and economic analysis, analyzes of the results of internal quality control in medical organizations involved in the implementation of the federal project "Fight against cancer.

2.1 Analytical Study Method

At the first stage, relevance was substantiated, the tasks of scientific research were formed, an analysis of domestic and foreign sources of literature on the issues of the system of organization of lifetime pathological and anatomical diagnosis of biopsy (surgical) material, regulatory framework. An analysis of 176 domestic and 13 foreign literary sources was carried out.

At the second stage, a comprehensive analysis of the main health indicators of the population and health care of the Siberian Federal District for 2013, 2014, 2015, 2016, 2017, 2018, 2019 and 2020, primary materials of the activities of the pathological and anatomical services of medical organizations of the Novosibirsk Region were carried out. Data from analytical reports on the status and main tasks of the development of the pathological and anatomical service of the Russian Federation for 2014, 2015, 2016,

2017, 2018 and 2019 were used for the analysis. (edited by G. A. Frank) for 2020, 2021 and 2022. (edited by G. A. Frank and V. I. Starodubov), on the state of oncological care for the population of Russia in 2015, 2016, 2017 and 2018. (edited by A. D. Kaprin, V. V. Starinsky, G. V. Petrova), 2019, 2020, 2021 and 2022 (edited by A. D. Kaprin, V. V. Starinsky, A. O. Shakhzadova) (P. A. Herzen Moscow Cancer Research Institute), forms of statistical observation No. 30 "Information on the medical organization" for 2014-2022, No. 14 "Information on the activities of units of a medical organization providing medical care in inpatient conditions," No. 12 "Information on the number of diseases registered in patients living in the service area of a medical organization," No. 17 "Information on medical and pharmaceutical workers" for 2014-2022. on the territory of the Novosibirsk region and individual medical organizations. (GBUZ NSO "State Novosibirsk Regional Clinical Diagnostic Center," GBUZ NSO "City Clinical Hospital No. 1," GBUZ NSO "State Novosibirsk Regional Clinical Hospital," GBUZ NSO "Novosibirsk Regional Clinical Oncological Dispensary," GBUZ NSO "Gynecological Hospital No. 2"), annual reports on the results of the activities of the main specialized specialists of the Ministry of Health of the Novosibirsk Region (in oncology, obstetrics-gynecology, pathological anatomy).

Absolute, relative and average values were used, the growth rates of oncological care indicators, the organization of intravital pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk region for 2015-2022.

The indicators of morbidity, detectability and morphological verification of malignant neoplasms in the Novosibirsk region were studied.

To determine the percentage of satisfaction of the need for intravital pathological and anatomical studies of a certain type in the Novosibirsk region, the formula [81] was used:

$$B_r = B_a \times 100 / B_d$$

where B_r is the indicator of satisfaction of the need for lifetime pathological and anatomical studies of a certain type in%;

B_a - the absolute number of studies that were conducted in a certain pathology;

B_d - the total number of patients with this nosology registered according to report form No. 12.

To calculate the indicator of verification of the diagnosis of malignant neoplasm, the following formula was used:

$V = v \times 100 / a_n$

where V - percentage of malignant neoplasm diagnosis verification;

v - absolute number of cases of biopsy studies in which the diagnosis of malignant neoplasm is confirmed;

a_n - total number of biopsy studies performed in the same pathology [80].

An analysis was carried out of the staffing, indicators of staffing with busy rates and individuals, equipment with the main technological equipment of the pathological and anatomical services of medical organizations of the Novosibirsk region. Quantitative indicators of in-life pathological and anatomical diagnosis of biopsy (surgical) material, the structure of cases and study objects by complexity categories were studied over time from 2015 to 2022. The ratio of cases of intravital pathological and anatomical studies of biopsy (surgical) material and the number of patients registered with malignant neoplasms in the oncological dispensary for 2015-2022 is shown. Indicators of the labor intensity of intravital pathological and anatomical studies of biopsy (surgical) material in medical organizations of the Novosibirsk region, depending on the category of complexity of the study, as well as the features of the system for organizing intravital pathological and anatomical diagnostics in the Novosibirsk areas currently.

2.2 Sociological research method

The sociological method is implemented in three stages. The study instrument was a scale consisting of measurement indicators [13; 14].

A survey was conducted of specialist doctors of medical organizations of the Novosibirsk region, who are the main customers of lifetime pathological and anatomical studies: oncologists and obstetricians-gynecologists - using the developed survey card

specialist doctors (Annex A). A survey of medical specialists was conducted before the implementation of the organizational and functional model of intravital pathological and anatomical diagnosis of biopsy (surgical) material and after its introduction.

To study the opinion of the heads of medical organizations of the Novosibirsk region, an additional map of the survey of managers has been developed (Annex B). The survey cards of specialist doctors and heads of medical organizations were prepared taking into account the requirements for compiling sociological survey questionnaires. Each specialist was asked questions that provided several answers.

The maps of the survey of specialist doctors used the scales:

- nominal (specialty, conditions for the provision of medical care: outpatient in a hospital);

- interval (work experience);

- ordinal (assessment of the opinion of doctors - "in full," "partially";

"in accordance with the approved regulatory values," "exceeding the regulatory values"; scope of information in the Study Protocol

"more-less"; "sufficient volume according to clinical guidelines" - "insufficient volume according to clinical guidelines") [131].

Each specialist was asked questions that provided several answers. The survey maps for both groups of respondents provide questions to assess the quality of lifetime

pathological and anatomical diagnostics by the following parameters:

- deficiencies that have the greatest impact on the quality of lifetime pathological and anatomical diagnostics of biological material;

- satisfaction with the quality of completion of the Study Protocols;

- estimation of biological material delivery time;

- evaluation of terms of Research protocols delivery to customers;

- satisfaction from receiving a "second opinion" based on the study results.

The volume of the required number of respondents (sample population) **is** calculated using the formula:

$$n = \frac{pqt^2N}{\Delta^2 N + pqt^2,}$$

where n is the number of samples;

N (814) - the number of the general population;

p (97%) - the studied relative sign, the probability of a positive assessment of the quality of studies;

q - probability of absence of this event (100-p);

t (2) is the confidence factor (at $t \geq 2$ the probability of an error-free forecast is 95% or more ($p < 0.05$);

Δ (2%) - maximum permissible error level [13; 77; 78].

$$n = \frac{97 \times 3 \times 2^2 \times 814}{2^2 \times 814 + 97 \times 3 \times 2^2} = 214$$

In the period before the introduction of the organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material, 350 questionnaires of specialist doctors (43% of the total) were received. Among all respondents there were 248 (70.9%) doctors in the specialty "obstetrics and gynecology," 102 (29.1%) doctors in the specialty "oncology." Of the respondents, 161 doctors (46%) provide medical care in hospitals, 189 doctors (54%) - on an outpatient basis. After the introduction of the organizational and functional model of intravital pathological and anatomical diagnostics, the volume of questionnaires of specialist doctors also amounted to 350 people, of which 160 doctors (45.7%) provide medical care in hospitals, 190 doctors (54.3%) - on an outpatient basis.

2.3 Statistical Method of Processing Results of Opinion Polls

To analyze the obtained data, intensive and extensive indicators and average values were calculated.

To compare the variability of respondents' responses and determine the presence of emissions, an interquartile range equal to the difference between the upper and lower quartiles was used [14].

Statistical processing of variables related to the ordinal scale was carried out using non-parametric tests. Statistical significance and differences in the two distributions by relative indicators that do not obey the normal distribution were estimated using the calculation of Pearson's chi-square test (x2) [15]. For calculation

Pearson's chi-square used the formula:

$$x^2=\sum \frac{(f_0 - f_e)^2}{f_e}$$

where f_0 and f_e are the observed and expected frequencies of the feature.

Using Pearson's chi-squared (x^2) test at a significance level of 0.01, the existence of differences in physician responses was assessed by care setting (inpatient, outpatient) and specialty (oncologists and obstetricians-gynecologists).

The null hypothesis - H0 - is formed as follows: between two samples (doctors of outpatient medical organizations - hospital doctors; oncologists and obstetricians-gynecologists) there is no expected difference. The opposite of the statement that in reality there is a difference between the constellations is an alternative hypothesis - H1.

As a result of the test, the null hypothesis was either accepted or rejected in favor of an alternative one.

When calculating the chi-square (x^2) Pearson test, the following were performed:

1) calculation of theoretical frequency (f_T);

2) the difference between the empirical and theoretical frequency for each category is calculated;

3) the number of degrees of freedom is determined. Corrected for "continuity" (if v = 1);

4) the obtained differences are squared;

5) obtained squares of differences are divided into theoretical frequency;

6) the amount received is $\chi^2_{\text{Эмп.}}$

Differences between the two distributions were assessed as statistically significant if $\chi^2_{\text{Эмп.}}$ reached or exceeded $\chi^2_{0.01}$ (H1) [15].

To assess the degree of satisfaction of doctors of clinical specialties with the quality of filling out the Study Protocols, an indicative indicator was calculated using the formula:

$$ISF = \Sigma P_f + \Sigma P_p + \Sigma P_{Pdoes\ not\ satisfy}/N,$$

where ISF is the integral satisfaction factor with the quality of filling in the Study Protocols;

$\sum P_f$ - sum of case values "fully satisfies";

$\sum P_p$ - sum of case values "partially satisfies";

$\sum P_{does\ not\ satisfy}$ - sum of case values "does not satisfy at al";

N is the number of respondents surveyed.

In this case, the value "fully satisfies" is assigned the value "+ 1," "partially satisfies" - "0," the value dissatisfaction "completely does not satisfy" "-1." Gradation of the indicator by levels was used: high level - from 0.6 to 1.0; average level - from 0.4 to 0.59; low level - from 0 to 0.39 [85; 169].

The survey of the heads of medical organizations of the Novosibirsk region was conducted in order to study their opinion on the list of shortcomings that most affect the quality of lifetime pathological and anatomical diagnosis of biological material, assessment of the fulfillment of the approved delivery dates for biological material and study protocols, satisfaction with the possibility of obtaining a "second opinion" on the study result. Additionally, an opinion assessment is provided for the heads of medical organizations to determine the advantages and disadvantages of using centralization and outsourcing of diagnostic functions. The leaders included chief doctors, deputy chief doctors for medical work and outpatient care of 49 medical organizations. Within the framework of the study, 100 survey cards of heads of medical organizations were obtained. Assessment of statistical significance and identification of differences in the responses of doctors of clinical specialties and heads of medical organizations was also carried out by calculating the chi-square (x^2) Pearson test.

2.4 Expert Method and Multi-Criteria Decision Analysis

As part of the expert analysis method, individual analytical assessments were carried out: the experts used all information on the stages of in-life pathological and anatomical studies of biopsy (surgical) material, assessed the compliance of the procedures at each stage of diagnosis with the approved standard, analyzed the degree of influence of the identified inconsistencies on the study result and issued an opinion in the form of an Expert Assessment Report [16; 22; 79; 169]. The selection of specific experts was carried out from among the heads of the pathological and anatomical departments of medical organizations of the Novosibirsk region based on a statistical analysis of the results of past activities as experts.

Investigated 500 cases of lifetime pathological and anatomical studies before implementation and 500 cases after implementation organizational and functional model of lifetime pathological and anatomical diagnostics in the Novosibirsk region. In order to justify the selection of criteria for assessing the compliance of the procedures with the approved standards, the multi-criteria decision analysis (MCDA) method was used, which included the following stages [95; 96]:

1) analysis of the main problems and weaknesses in organizing the stages of lifetime pathological and anatomical diagnostics of biopsy (surgical) material;

2) determination of significant criteria for a possible step-by-step assessment of compliance of the procedures with the approved technological standards;

3) assessment of the quality of MCDA criteria by experts to identify inconsistencies and analyze the degree of impact of inconsistencies on the study result. The importance of each criterion is expressed by experts in points (0-100). The higher the score, the higher the undesirability of violations of this criterion;

4) determining the weight (significance) of each MCDA criterion in the aggregate, checking their continuity for all categories of personnel when performing the stages of lifetime pathological and anatomical diagnosis of biopsy (surgical) material;

5) aggregation using a decision rule based on evaluation of criteria and weight. Calculation of the total score by multiplying the points of the criteria by their weight, followed by summing up the points for all criteria;

6) inclusion of MCDA criteria to justify management decisions on their use to assess the compliance of procedures with approved technological standards during lifetime pathological and anatomical diagnostics.

The list of criteria for evaluating the implementation of procedures and the characteristics of non-conformities to the standard are given in Tables 4, 5 and 6**.**

Table 4 - List of criteria for evaluating the performance of the pre-analytical stage procedures and characteristics of non-compliance with the approved standards during lifetime pathological and anatomical diagnostics

Name criterion		Characteristics of non-conformities
Pre-analytical stage		
1.	Discipline Formation Standard (Form No. 014/y, approved by Order of the Ministry of Health of Russia dated 24.03.2016 No. 179n)	The Direction does not indicate the macroscopic characteristic of the pathological process or the number of objects
		No diagnosis of underlying disease in Direction
		Additional clinical details are incomplete or missing
		Biological material registration number mismatch in vial direction and labeling
		The information in the Referral is not sufficient to identify the patient
2.	Technological standard for taking, preliminary fixation and labeling of biological material by a clinical specialist doctor	Violations of the technological standard for taking biological material
		Inadequate formalin pre-fixation of biological material
		Non-compliance of volumes of fixing agent and tissue sample during preliminary fixation of biological material
		Pre-fixation of biological material after freezing
		Use of fixators inconsistent with the pathological and anatomical department
		Use of non-standard containers for biological material fixation
		Non-conformity of marking of objects with the information specified in the Direction

		Date and time of goods receipt are NOT indicated in the Logbook of the accounting form No. 014-2/y
		Serial numbers of vials and number of objects are NOT indicated in the Logbook of Accounting Form No. 014-2/y

Table 4 (continued)

Name criterion		Characteristics of non-conformities
Pre-analytical stage		
3.	Standard Delivery Times and Conditions for Transporting Biological Material to the Study Executor	Transportation was carried out within the standard period (24 hours), but without formalin
		Transportation of biological material fixed with formalin was carried out within a period exceeding 24 hours after taking
		The biological material was transported in violation of the temperature interval that provides the diagnostic value of the biomaterial
		Transportation of biological material is carried out in a way that does not provide safety for the courier, society and personnel receiving biomaterial for research
4.	Technological Standard for Material Registration in the Logbook of Receipt of Biopsy (Surgical) Material and Issuance of the Results of In-Life Pathological and Anatomical Studies (Registration Form No. 014-2/y, approved by Order of the Ministry of Health of Russia dated 24.03.2016 No. 179n) in the Pathological and Anatomical Service	The unique registration number is NOT entered in the Journal of the accounting form No. 014-2/y

Table 5. List of Criteria for Evaluation of Analytical Stage Procedures and Characteristics of Noncompliance with Approved Standards during lifetime Pathologic and Anatomical Diagnostics

Name criterion		Characteristics of non-conformities
Analytical stage		
1.	Technological standards for macroscopic study, cutting and final fixation of biological material in the pathological and anatomical service	Mechanical damage to tissue sample, excessive compression of unfixed tissue by tools
		Inadequate or suboptimal formalin fixation
		Ingress of foreign tissue, staples, suture material into the tissue sample
		Non-compliance with the technological standard of thickness of fabric samples, cut area, size, shape of samples during cutting
		Violations of cassette filling volume or selection of cassettes of inappropriate type
		Non-compliance of volumes of fixing agent and tissue sample during final fixation
2.	Technological Standard for Histological Processing of Biological Material (Wiring, Filling, Microtomy of Paraffin Blocks, Drying, Staining, and Manufacturing of Micropreparations)	Violations of the procedure for wiring a tissue sample (excessive dehydration with microvibration along the edge of the tissue)
		Violations of the microtomy procedure (inappropriate temperature of the water bath, insufficient stretching of the tissue on the water bath)
		Staining abnormalities (cytoplasmic stains do not contrast well with nuclear staining)
3.	Microscopic Description Standard in the Protocol of In-Life Pathological and Anatomical Examination of Material of Record Form No. 014-1/y, approved by Order of the Ministry of Health of the Russian Federation No. 179n dated 24.03.2016	Microscopic description is not a justification for the diagnosis, does not contain a qualitative characteristic of the pathological process
		Microscopic description does not fully justify the diagnosis, contains an incomplete qualitative characteristic of the pathological process
		The Protocol does not indicate the assigned colors (reactions, definitions)

Table 5 (continued)

Name criterion		Characteristics of non-conformities
Analytical stage		
4.	Standard for Conclusion in the Protocol of In-Life Pathological and Anatomical Examination of Biopsy (Surgical) Material of the Registration Form No. 014-1/y, approved by Order of the Ministry of Health of Russia dated 24.03.2016 No. 179n	In the conclusion of the Protocol of in-life pathological examination of biopsy (surgical) material, a nosological diagnosis is indicated, in the tumor process, the stages T, N M, the number of studied and affected lymph nodes, the histological type of the tumor, the degree of differentiation G are indicated, but the purity of the boundaries of the surgical incision is NOT indicated
		In the conclusion of the Protocol of in-life pathological examination of biopsy (surgical) material, a nosological diagnosis is indicated, in the tumor process, the histological type of the tumor, the degree of differentiation G, but the stages T, N, M, the number of examined and affected lymph nodes, the purity of the boundaries of the surgical incision are indicated
		In the conclusion in the Protocol of the in-life pathological examination of biopsy (surgical) material, only nosological diagnosis is indicated

Table 6. List of Criteria for Evaluation of Post-Analytical Stage Procedures Execution and Characteristics of Non-Conformities to Approved Process Standards during lifetime pathological and anatomical diagnosis [107]

Name criterion		Characteristics of non-conformities
Post-analytical stage		
1.	Technological Standard for Registration of Study Results in the Journal for Registration of the Receipt of Biopsy (Surgical) Material and Issuance of the Results of In-Life Pathological and Anatomical Studies	The date of issue of the original Study Protocol is not indicated in the Logbook of Receipt of Biopsy (Surgical) Material and Issuance of the Results of In-Life Pathological and Anatomical Studies (Registration Form No. 014-2/y
		There is no receipt from the recipient of the original Protocol in the Logbook of Receipt of Biopsy (Surgical) Material and Issuance of the Results of In-Life Pathological and Anatomical

	(Accounting Form No. 014-2/y)	Studies (Registration Form No. 014-2/y)
2.	Regulatory deadlines for submission of Protocols for in-life pathological and anatomical studies of biopsy (surgical) material of registration form No. 014-1/to the attending physicians	The regulatory deadlines for submission of the Protocol of pathological and anatomical studies of biopsy (surgical) material (registration form No. 014-1/y) were exceeded due to the "additional cutting" of samples due to the assumption of violations of histological technology procedures
		The regulatory deadlines for the submission of the Protocol of pathological and anatomical studies of biopsy (surgical) material (registration form No. 014-1/y) were exceeded due to the untimely provision of additional clinical information
		The regulatory deadlines for submission of the Protocol of pathological and anatomical studies of biopsy (surgical) material (registration form No. 014-1/y) were unreasonably exceeded, which influenced the timeliness of determining treatment tactics

An individual analytical assessment of the implementation of standard procedures for lifetime pathological and anatomical examination of biopsy (surgical) material was completed by issuing a separate Expert Assessment Report (Annex C) indicating the nature of the impact of the identified inconsistencies on the result or the duration of the pathological and anatomical examination. Assessment of the quality of lifetime pathological and anatomical studies was carried out by comparing the performed volumes with the standards and determining the quality level of the lifetime pathological and anatomical studies (QLPS). The parameter (QLPS) was determined according to the formula [60,107]:

$$QILS == \frac{EHT + EMD + ECS + EPSP}{4},$$

where QILS - Quality Indicator for lifetime pathological and anatomical studies;

EHT – evaluation of histological technology;

EMD – evaluation of microscopic description standard implementation in the Study Protocol;

ECS – evaluation of the conclusion standard in the Study Protocol;

EPSP – evaluation of the Study Protocol submission period.

When assessing according to the selected criteria, when identifying inconsistencies with the approved standards and regulations, the experts used an indicative scale:

To assess the scope of execution of each criterion, the experts adopted the following scale of non-conformities (from 0 to 1.0):

- full implementation of the standard (normative), absence of non-conformities - 1.0;

- insignificant deviations from the standard (normative) implementation - 0.90;

- significant deviations from the standard (standard) due to objective reasons - 0.75;

- significant deviations from the standard (standard) in the absence of objective reasons - 0.50;

- gross deviations from the standard (standard), resulting in errors in the diagnosis and treatment of patients with severe consequences - 0.25;

- inadmissible deviations from the standard (normative) - 0 [87; 107].

Insignificant deviations from the standard (standard) - an estimate of 0.90 - include such deviations that did not have a noticeable impact on the study result, the duration of the study, the reliability of the registration of the Study Protocol of accounting form No. 014-1/y and did not entail unreasonable expenditure of resources.

Significant deviations from the standard (standard) due to objective reasons - a score of 0.75 - experts characterized deviations that, although associated with objective reasons, entailed or could entail a decrease in quality in terms of both the timeliness and correctness of the diagnosis, and in the appointment of optimal treatment by the attending physician.

Significant deviations from the implementation of the standard (standard) in the absence of objective reasons - an estimate of 0.50 - were considered by the experts to be deviations that were regarded as violations of the optimal technological standard (standard) and entailed (or could entail) untimely diagnosis or incorrect diagnosis with a

negative impact on the outcome of the disease [107].

Gross deviations from the implementation of the standard (standard) - an estimate of 0.25 - include cases of late execution of standard processes, errors in establishing a diagnosis with possible serious consequences for patients and associated with professional incompetence or improper performance of their duties by medical personnel [60].

An analysis of the results of examinations of the quality of medical care in the amount of 11,809 medical records, 72 Acts of examinations of insurance medical organizations (SIMAZ-MED, SOGAZ-MED, INGOSSTRAKH-M) was carried out. Examinations of the quality of medical care carried out by insurance medical organizations and the territorial fund of compulsory medical insurance of the Novosibirsk Region until 2019 did not include an expert assessment of the quality of the Protocols in lifetime pathological and anatomical studies of biopsy (surgical) material. Since 2019, experts of medical insurance organizations, when monitoring the volume, timing, quality and conditions for the provision of medical care to patients with suspected cancer or with an established diagnosis of cancer, assess the Protocols of pathomorphological studies in accordance with the methodological recommendations of the Federal Fund for Compulsory Health Insurance against 30.08.2018. No. 1086/30/and. In 2019, at the first stage, during external inspections, experts assessed the amount of information in the Protocols of pathomorphological studies in accordance with the specified methodological recommendations, the insufficient amount of information was assessed as a defect in the maintenance of medical records. Since 2020, when conducting external quality reviews of filling in the Protocols of lifetime pathological and anatomical studies, an assessment of the compliance of the Protocol with accounting form No. 014-1/y and the requirements of the current version of clinical recommendations for nosological forms is carried out.

2.5 Expert consensus analysis using non-parametric statistical Kendall concordance coefficient test

To study the strengths and weaknesses of the system for organizing lifetime pathological and anatomical diagnostics, as well as to determine the main directions for its improvement, an expert assessment sheet for the system for organizing lifetime pathological and anatomical diagnostics of biopsy (surgical) material in state medical organizations of the Novosibirsk Region has been developed (Annex D), containing 20 questions with an assessment on a five-point scale of the elements of the system for organizing the diagnostic process. The experts of the system for organizing lifetime pathological and anatomical diagnostics of biopsy (surgical) material identified the chief freelance specialist of the Ministry of Health of the Novosibirsk Region with a degree in pathological anatomy, head of the department of pathological anatomy of Novosibirsk State Medical University, doctor of medical sciences, professor A.P. Nadeev and 2 heads of departments of pathological anatomy - GBUZ NSO "GKB No. 1" and GBUZ NSO "NOCOD."

In order to assess the consistency of expert opinions on the importance (value) of factors in the system of organization of lifetime pathological and anatomical diagnostics of biological material in the Novosibirsk region used non-parametric statistical.

Kendall concordance test coefficient. Factors influencing the organization, quality and timeliness of in-life pathological and anatomical studies of biopsy (surgical) material, evaluated by experts in points from 1 (minimum) to 5 (maximum). Assessment of the importance of factors was made by assigning them a rank number. The factor to which the expert gives the highest rating is assigned rank 1. If an expert recognizes several factors as equivalent, then they are assigned the same rank number. If the expert has related ranks (the same rank numbers), the ranks are reformatted. Based on the reformatting of the expert evaluation ranks, a consolidated rank matrix is formed. To calculate the Kendall concordance coefficient, a formula is used when there are related ranks (the same factor values) in the estimates of one expert [23; 98; 168]:

$$W = \frac{S}{\frac{1}{12} * m^2(n^3 - n) - m * \sum T_i},$$

where S – sum of rank squares;

n = 20 (number of factors to rank);

m = 3 (number of experts);

$$T_i = \frac{1}{12} * \sum (t_i^3 - t_i),$$

where T_i – number of bundles (types of repeating elements) in estimates in expert assessments i,

t_i - number of elements in the l-th bundle for the i-th expert (number of repeating elements) [168].

The Kendall concordance coefficient takes values from 0 to 1: it is 1 with the maximum consistency of expert opinions and is 0 with the maximum inconsistency.

2.6 Organizational and Functional Modeling Method

At the third stage of the study, taking into account the accumulated experience, on the basis of the process approach, an organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region was formed [174]. Within the framework of this stage, local orders were prepared and implemented on the conduct of internal quality and safety control of medical activities, the organization of lifetime pathological and anatomical studies of biopsy (surgical) material, on the introduction of electronic registration forms of Directions (No. 014/y) and Protocols (No. 014-1/y) of lifetime pathological and anatomical studies of biopsy (surgical) material. Approved Internal Quality Control Card for lifetime a pathological and anatomical study of biopsy (surgical) material with a phased assessment of indicators, standard operating procedures for taking biological material, conducting a preparatory and technological block of procedures for the pre-analytical stage of intravital pathological and anatomical research, as well as conducting

a cytological study of biopsy (surgical) material. Letters were prepared and sent to the Ministry of Health of the Novosibirsk Region and the Medical Information and Analytical Center with proposals for the introduction and integration of registration forms during lifetime pathological and anatomical studies of biopsy (surgical) material into the Medical Information System of the Novosibirsk Region.

2.7 Medico-economic analysis of efficiency of introduction of organizational and functional model lifetime pathological and anatomical diagnosis of biopsy (surgical) material in the Novosibirsk Region

As part of the fourth stage of the study, a comparative analysis of the activities of the departments of clinical pathomorphology and pathological anatomy of the GBUZ NSO "GKB No. 1" and the department of pathological anatomy of the GBUZ NSO "NOCOD" was carried out before and after the introduction of the organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) and after its introduction. Actual income and expenses, the dynamics of remuneration of employees for 2019-2022. in these medical organizations. The indicators of fund-making, fund output and fund intensity of the departments of clinical pathomorphology and pathological anatomy of GBUZ NSO "GKB No. 1" for 2019-2022 were studied. Fund-making was defined as the ratio of the average book value of fixed assets to the average number of employees performing lifetime pathological and anatomical diagnostics of biopsy (surgical) material. Fund turnover is defined as the ratio of income to the value of fixed assets of the corresponding branch, fund intensity is defined as the ratio of the value of fixed assets to the income of the branch.

In order to conduct an economic assessment of the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region, a cost-effectiveness analysis was carried out with the calculation of costs per unit of efficiency (compliance of the quality of filling in the Protocols of lifetime pathological and anatomical studies of biopsy (surgical) material with the approved standard). The system of organization of

lifetime pathological and anatomical diagnostics, which is characterized by lower costs per unit of efficiency, was considered more effective from an economic point of view [4, 10].

In carrying out this type of analysis of the system for organizing lifetime pathological and anatomical diagnostics of biological material before the introduction of the organizational and functional model and after its introduction in the territory of the Novosibirsk Region, the following formula was used:

$$CEA = DC + IC / Ef,$$

where CEA – cost ratio per unit of efficiency;

DC – direct costs;

IC – indirect costs;

Ef – effectiveness of treatment.

A "cost minimization" analysis was also carried out, which is a special case of a cost-effectiveness analysis. A comparative assessment of different forms and different conditions of application of one medical technology was carried out [2; 24; 113].

In order to assess the economic efficiency of the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics, the ratio of costs and revenue was studied. The analysis of the economic efficiency of the activities of pathological and anatomical services before and after the introduction of the organizational and functional model of lifetime pathological and anatomical diagnostics was carried out on the example of the Novosibirsk Regional Clinical Oncological Dispensary (GBUZ NSO NOCOD) and the City Clinical Hospital No. 1 (GBUZ NSO GKB No. 1). For the analysis, data from forms No. 14-Med (compulsory medical insurance) "Information on the work of a medical organization in the field of compulsory medical insurance" and No. 62 "Information on resource provision and provision of medical care to the population" for 2019, 2020, 2021 and 2022 were used.

In order to compare the results of the survey of two dependent samples -

specialist doctors before and after the introduction of the organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material, a non-parametric Wilcoxon test was used. The initial step was to subtract each individual "before" value from the "after" value. Hypotheses were formed for indicators, the dynamics of which was regarded as positive with their increase:

H_0 - indicators after the implementation of the organizational and functional model of intravital pathological and anatomical diagnostics exceed the values of indicators before implementation;

H_1 - indicators after the introduction of the organizational and functional model of lifetime pathological and anatomical diagnostics are less than the values of indicators before the introduction.

For indicators, the dynamics of which was assessed as positive with their decrease:

H_0 - indicators after the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics are less than the values of indicators before implementation;

H_1 - indicators after the introduction of the organizational and functional model of lifetime pathological and anatomical diagnostics exceed the values of indicators before the introduction.

Those directions that were atypical were noted. The sum of the ranks of these "atypical" directions constitutes the empirical value of the Wilcoxon test (T):

$$T = \sum_{i=1}^{n} R_t = 0$$

Critical values for Wilcoxon T-test for n = i were found in the table of Appendices. Next, it is investigated whether the empirical value T falls into the zone of significance $T_{эмп} < T_{кр}(0,01)$, and, accordingly, the hypothesis H_0 is accepted or rejected.

To study the medical effectiveness of the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy

(surgical) material, a repeated expert assessment of cases of lifetime pathological and anatomical diagnostics was carried out in the amount of 500 cases. Taking into account that on an ongoing basis, medical insurance organizations began to conduct quality reviews of Protocols for lifetime pathological and anatomical studies in 2019, a comparison of inconsistencies identified during internal control and violations in filling out Study Protocols during external examinations was carried out for 2019-2022.

The dynamics of quality indicators of resources, processes and results during in-life pathological and anatomical studies of biopsy (surgical) material before and after the improvement of the system for organizing in-life pathological and anatomical diagnostics was investigated using the final results model, which was proposed in 2021.

R.I. Ginnyatulina to assess the quality management system of medical care in the city hospital [32]. For each of the three groups, experts have determined a list of the most significant indicators. The target (normative) value of each indicator is estimated in points (from 0 to 1). The actual assessment of those quality indicators whose changes are considered positive when they grow is calculated as the ratio of the actual value of the indicator to the normative value multiplied by the assessment of the normative indicator in points [32].

$$AAI_p = AVI / NVI \times ANI_p,$$

where AAI_p – actual assessment of the indicator in points;

AVI – actual value of the indicator;

NVI – normative value of the indicator;

ANI_p – assessment of the normative indicator in points.

The actual assessment of those quality indicators, the changes of which can be considered as positive when they decrease, is calculated according to the following formula [32].

$$AAI_p = NVI / AVI \times ANI_p$$

The following formula [32] was used to calculate the integral quality index (IQI):

$$IQI = \sum (AVI / NVI \times ANI_p) + \sum (NVI / AVI \times ANI_p)$$

To establish the direction and strength of the relationship between the studied indicators (quality indicators of the results of lifetime pathological and anatomical studies and an integral quality indicator), correlation analysis was used with the calculation of the correlation coefficient (r).

SUMMARY

1. The methods used meet the objectives of the study and ensure optimal results.

2. The use of the analytical method made it possible to study the state of the system of organization of lifetime pathological and anatomical diagnostics in the Russian Federation and on the territory of the Novosibirsk Region.

3. In the course of the sociological method, the opinion of specialist doctors (oncologists and obstetricians-gynecologists) on the quality of filling and the timing of the provision of the Protocols in life was investigated pathological and anatomical diagnosis of biopsy (surgical) material. In order to study the problems of the organization system of the studied section of diagnostics, the survey of specialist doctors was supplemented with a survey of heads of medical organizations.

4. The method of individual expert assessments was applied using the principles of multi-criteria analysis of decision-making: the inclusion of standardized criteria in the structure for assessing the implementation of technological procedures for in-life pathological and anatomical studies of biological material made it possible to determine their priority in terms of the greatest impact on the result, ensure the consistency and reproducibility of the assessment, and also exclude the impact of subjective factors on the study result [83; 95].

5. In order to assess the consistency of expert opinions on the importance (value) of factors in the system of organization of lifetime pathological and anatomical diagnostics of biological material in the Novosibirsk Region and determination of the main directions for its improvement used non-parametric statistical Kendall concordance test coefficient [98, 168].

6. Changes in the quality of resources, processes and results during in-life pathological and anatomical studies of biopsy (surgical) material before and after optimization of the system for organizing in-life pathological and anatomical diagnostics were assessed using the final results model [32].

CHAPTER 3 SOCIAL AND HYGIENIC ASSESSMENT OF THE SYSTEM OF ORGANIZATION OF LIFETIME PATHOLOGICAL AND ANATOMICAL DIAGNOSTICS OF BIOPSY AND SURGICAL MATERIAL IN THE NOVOSIBIRSK REGION

3.1 Incidence, detectability, morphological verification of malignant neoplasms in the Novosibirsk region

The main directions for improving the system of lifetime pathological and anatomical diagnosis of biopsy and surgical material are largely determined by the incidence of malignant neoplasms and the need to achieve the target indicator for detecting oncological pathology at early stages (Tables 7, 8 and 9).

From 2015 to 2018 there is an increase in the primary incidence of malignant neoplasms by 4.4% (from 449.8 to 469.4 per 100 thousand population). Since 2019, there has been a decrease in the primary incidence of malignant neoplasms in the Novosibirsk Region: from 2019 to 2021. by 22.3% (from 413.9 to 321.8 per 100 thousand population).

From 2015 to 2019 there is an increase in the number of patients registered in an oncological institution in the Novosibirsk Region by 9.7%, which is due to an increase in morbidity and detection, as well as an increase in the survival rate of cancer patients. In 2020, in the year of the beginning of the pandemic of the new coronavirus infection COVID-19, the number of patients registered in an oncological institution in the Novosibirsk Region was 2 870,2 per 100 thousand of the population, which is 0.4% less than in 2019 and is due to a decrease in the volume of planned medical care and the detection of cancer. In 2021, this indicator increased by 2020 compared to 0.06% and amounted to 2 872,0 per 100 thousand of the population.

Table 7 - Patient populations with newly diagnosed malignancy

Territories	Number of patients with newly diagnosed malignancy													
	abs. numbers							per 100,000 population						
	2015	2016	2017	2018	2019	2020	2021	2015	2016	2017	2018	2019	2020	2021
Siberian Federal District	72 740	73 571	75 531	68 955	68 883	59 253	61 396	376,7	380,7	390,8	357,5	401,1	346,1	365,6
Novosibirsk region	10 565	11 388	11 400	11 455	11 563	10 307	8 984	384,6	412,3	410,1	410,7	413,9	368,3	321,2

Table 8 - Year-end patient populations with malignancy (total)

Territories	Number of malignant neoplasm patients registered with the oncology institution at the end of of the corresponding year													
	abs. numbers							per 100,000 population						
	2015	2016	2017	2018	2019	2020	2021	2015	2016	2017	2018	2019	2020	2021
Siberian Federal District	423 790	438 134	454 603	438 972	455 367	457 357	454 295	2 194,4	2 267,3	2 352,3	2 547,7	2647,2	2667,4	2662,7
Novosibirsk region	72 079	75 688	78 628	80 224	80 382	80 244	80 187	2 624,1	2 740,1	2 828,8	2 876,6	2 879,9	2870,2	2872,0

Table 9 - Malignancy detectability, disease stages,%

Territories	Malignancies reported (not counted posthumously)								including stage I-II disease							
	2015	2016	2017	2018	2019	2020	2021	2022	2015	2016	2017	2018	2019	2020	2021	2022
Siberian Federal District	78 295	79 753	82 246	76 015	76 352	65 978	68 490	73 237	52,2	53,6	54,4	55,3	56,3	54,3	56,3	57,9
Novosibirsk region	12 051	12 365	12 407	12 623	12 683	11 333	10 021	10 610	52,4	53,6	53,7	55,3	56	53,1	58	59,7

Table 10 - Morphological verification of malignancies,%

Territories	Proportion of patients with a newly diagnosed morphologically confirmed malignancy							
	2015	2016	2017	2018	2019	2020	2021	2022
Siberian Federal District	91,3	93,4	92,9	92,9	94,3	94,7	95,3	95,0
Novosibirsk region	92,2	94,1	93,0	93,1	96,1	95,7	96,3	94,9

From 2018 to 2021 there is an increase in the share of morphological verification of malignant neoplasms in the Novosibirsk Region (from 93.1% to 96.3%), in 2022 there is a slight decrease to 94.9%. The share of morphological verification of malignant neoplasms in the Siberian Federal District as a whole is slightly less than in the Novosibirsk Region (Table 10).

In the period from 2018 to 2022. The maximum increase in the specific gravity of the "launched" IV stage of malignant neoplasms from the number of newly diagnosed cases was noted in the Novosibirsk Region in 2020 - 22.6% (in 2018 - 10.6%, in 2022 - 20.7%). At the same time, during the same period, there is a gradual increase in the proportion of malignant neoplasms detected in stages I and II - from 55.3% in 2018 to 59.7% in 2022, which is explained by the formation and increase in the activities of Ambulatory Oncological Care Centers aimed primarily at early detection of cancer.

Within the framework of the regional program of the Novosibirsk Region "Fight against oncological diseases" in accordance with the order of the Ministry of Health of the Novosibirsk Region dated 28.06.2019 No. 2118 "On the opening of an outpatient oncological care center on the basis of the state budgetary healthcare institution of the Novosibirsk Region "City Clinical Hospital No. 1" in order to reduce the time for diagnosing cancer, improve the quality of medical care on the basis of the GBUZ NSO "City Clinical Hospital No. 1" was opened the first Ambulatory Cancer Care Center in the Novosibirsk Region. The main functions of the Ambulatory Cancer Care Center GBUZ NSO "GKB No. 1" are early diagnosis of oncological diseases, comprehensive diagnostic examination within the framework of the "oncological search," establishing the prevalence of the oncological process and the stage of the disease using methods of

lifetime pathological and anatomical diagnosis of biopsy material. In addition, Ambulatory Cancer Care Center carries out dispensary observation of patients with identified malignant neoplasms, in accordance with the decision of the medical council of the regional oncological dispensary, conducts chemotherapy treatment of malignant neoplasms in a day hospital, monitoring the effectiveness of treatment. In 01.01.2022, the population served by Ambulatory Cancer Care Center GBUZ NSO "GKB No. 1" amounted to 224.8 thousand people. In 2019, 639 patients were admitted to the Ambulatory Cancer Care Center, in 2020 - 3 952 people, in 2021 - 4,749 people. As soon as possible (1-5 days), the diagnosis of malignant neoplasm was confirmed in 2019 in 127 patients, and in 68 patients (54%) in the first and second stages, in 2020 the diagnosis was confirmed in 271 patients, including 170 people (62.7%) - in the first and second stages, in 2021 - in 331 people, of which in 183 people (55.3%) in the first and second stages. Among confirmed malignant neoplasms, 25% are breast neoplasms, 23% are skin, 15% are bronchi and lungs. In 2020, 350 patients were sent to the regional oncological dispensary to determine further treatment tactics, of which 246 with a confirmed diagnosis of malignant neoplasm, 89 with suspected malignant neoplasm, and 15 with benign neoplasms (breast fibroadenomas). For diagnostic purposes, 557 in-life pathological and anatomical studies of biopsy material were performed at the Ambulatory Cancer Care Center in 2019 (493 cytological studies, 57 - histological, 7 - immunohistochemical studies), in 2020 - 2,908 lifetime pathological and anatomical studies (2,160 cytological studies, 626 histological studies, 122 - immunohistochemical), in 2021 - 2,834 studies (2,435 cytological studies, 365 histological, 34 - immunohistochemical). The timing of cytological studies was up to 3 days, histological - up to 5 days, immunohistochemical - up to 7 days.

3.2 Regulatory Documents Regulating Lifetime Pathological and Anatomical Diagnostics of Biopsy (Surgical) Material in the Novosibirsk Region

The organization of in-life pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region is carried out in accordance with the Federal Law of the Russian Federation of 21.12.2011 No. 323-FZ "On the Basics of Health Protection of Citizens in the Russian Federation" (as amended, which entered into force on 0.01.2016), by order of the Ministry of Health of Russia of 24.03.2016 No. 179n "On the Rules for Conducting

pathological and anatomical studies, "by order of the Ministry of Health of the Novosibirsk Region dated 11.05.2022 No. 1460" On the routing of patients over 18 years of age during certain types of diagnostic studies within the framework of the territorial program of compulsory medical insurance. " The regional patient routing order approved the routing scheme, as well as the lists of referring and receiving medical organizations for conducting pathological and anatomical studies of biopsy (surgical) material and molecular genetic studies in order to detect cancer. Cytological studies of biopsy (surgical) material are carried out in accordance with the order of the Ministry of Health of Russia of 18.05.2021 No. 464n "On Approval of the Rules for Laboratory Studies."

3.3 Full-time positions and individuals of pathological and anatomical departments of medical organizations of the Novosibirsk Region

Lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk region is provided by qualified personnel. Table 11 shows that from 2015 to 2019 the staffing of employed pathologists decreased from 90.7% to 80.6%, in 2022 this figure was 86.7%. The number of individuals of pathologists from 2015 to 2019 increased by 7.1% - from 56 to 60 people. In 2022, the number of individuals of pathologists employed in positions of medical personnel pathological and anatomical

departments, amounted to 69 people. The staffing of individuals with full-time positions of pathologists increased from 39.9% in 2015 to 45.1% in 2019 and 46.9% in 2022.

In the period from 2015 to 2017, the number of individuals of the main employees employed in the positions of nurses (histologists) in the pathological and anatomical departments of medical organizations of the Novosibirsk region decreased from 56 to 33 people, in 2019 amounted to 71 people with a subsequent decrease in 2022 to 61 people (by 14.1%).

Table 11 - Positions and individuals providing lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region

Personnel categories	Indicators	Years							
		2015	2016	2017	2018	2019	2020	2021	2022
Doctors	Staff rates	140,25	147	136	128,75	133	144,25	150,25	147,0
	Busy rates	127,25	121,75	112,5	103,5	107,25	120,75	125,75	127,5
	Natural persons	56	55	57	58	60	63	67	69
	Staffing occupied rates, %	90,7	82,8	82,7	80,4	80,6	83,7	83,7	86,7
	Staffing by individuals, %	39,9	37,4	41,9	45,0	45,1	43,7	44,6	46,9
Middle medical staff	Staff rates	It is not possible to estimate the number of allocated positions of nurses of pathological and anatomical departments, since form No. 30 of the federal statistical observation provides for the provision of this information as a whole for medical organizations without breakdown by structural divisions							
	Busy rates								
	Natural persons	56	94	33	70	71	58	59	61

3.4 Equipment of the main technological equipment of the pathological and anatomical departments of medical organizations of the Novosibirsk Region

Table 12 - Equipment of main process equipment pathological and anatomical departments of medical organizations of the Novosibirsk Region

Name	Number of units of equipment								
	2015	2016	2017	2018	2019	2020	2021	2022	
								in total	of which more than 10 years
Stations for macroscopic examination and cutting	4	4	4	3	7	7	6	6	0
Automatic machines for carousel wiring	31	33	30	26	25	27	21	23	8
Machines for processor-type wiring	8	9	9	10	10	10	13	15	1
Stations for filling and manufacturing of paraffin blocks	6	6	5	7	10	12	14	16	4
Sled microtomes	53	55	53	45	47	47	47	45	27
Rotational mechanical microtomes	14	18	18	15	21	18	21	22	10
Rotational motorized microtomes	6	2	2	2	4	7	8	14	1
Ultramicrotomes	1	1	1	1	1	1	1	1	0
Machines for routine painting of micropreparations	8	9	9	11	13	12	18	21	5
Immunohistostainers	4	4	4	5	6	8	5	6	0
Machines for the conclusion of micropreparations under the cover glass	5	5	4	5	5	7	8	9	2

Table 12 (continued)

Name	Number of units of equipment								
	2015	2016	2017	2018	2019	2020	2021	2022	
								in total	of which more than 10 years
Binocular light microscopes	70	72	77	54	79	74	74	83	32
Binocular universal light microscopes	19	25	21	35	34	26	30	28	9
Electronic microscopes	2	1	1	-	2	1	1	1	0
Polarization microscopy equipment	3	3	4	3	1	2	2	2	1
Digital equipment microscopy	5	4	4	3	4	9	10	10	1

Based on the volume of the studied objects and the recommended norms of the load on the device, the provision of the Novosibirsk Region with the main technological equipment during the lifetime pathological and anatomical diagnostics by type of equipment: stations for macroscopic study and cutting - in 2015 - 10.8%, in 2021 - 18.8%; in 2022 - 17.6%; automata for carousel-type wiring in 2015 - 63%, in 2021 and in 2022 - 50%; automatic machines for processor-type wiring - in 2015 - 67%, in 2021 - 118%; in 2022 - 136%; stations for filling into paraffin and making paraffin blocks - in 2015 - 16.2%, in 2021 - 43.8%, in 2022 - 47.1%; rotational microtomes - in 2015 - 37.7%%, in 2021 - 70.7%, in 2022 - 81.8%; coloring machines for histological preparations - in 2015 - 46%, 2021 - 225%; in 2022 - 233%; machines for the conclusion of histological preparations - in 2015 - 10.5%, in 2021 - 19%, in 2022 - 19.6% (Table 12).

The average provision rate for all types of technological equipment during lifetime pathological and anatomical diagnostics in the Novosibirsk Region in 2015 amounted to 29%, in 2021 - 52.4%, in 2022 - 49%. The largest share of obsolete equipment (the share of units with a service life of more than 10 years) in 2022, it was registered in the group of sled microtomes - 60%, mechanical rotational microtomes -

45.5%, automatic machines for carousel wiring - 34.8%, stations for filling into paraffin and making paraffin blocks - 25%, automatic machines for routine colors of histological preparations - 23.8% [146, 147, 148].

Share of obsolete equipment used in 2022 in the pathological and anatomical services of the Novosibirsk region during the lifetime pathological and anatomical diagnosis of biological material amounted to 33.4% in 2022, which is 0.4% higher than the same indicator in 2021 and 0.9% higher than in 2020. in general, in 2022, the pathological and anatomical services of the Novosibirsk region received 27 units of new equipment.

3.5 Quantitative parameters of lifetime pathological and anatomical diagnosis of biopsy (surgical) material in the Novosibirsk Region

Table 13 - Dynamics and quantitative indicators of lifetime pathological and anatomical diagnostics in the Novosibirsk Region (per 100 thousand population)

Indicator name	Years							
	2015	2016	2017	2018	2019	2020	2021	2022
Number of patients who underwent lifetime pathological anatomical check researches	5 524,1	5 425,0	5 489,6	4 929,6	5 322,6	4 049,7	4 130,0	4 467,5
Number of cases lifetime pathological and anatomical studies	5 214,4	7 483,3	7 570,5	7 436,9	6 582,3	5 288,7	5 233,1	6 661,2
Number of patients with lifetime cytology	7 041,6	6 036,3	5 675,8	4 111,1	6 338,0	5 800,2	5 406,3	5 551,6

Table 13 (continued)

Indicator name	Years							
	2015	2016	2017	2018	2019	2020	2021	2022
Number of cases lifetime cytology studies	7 189,4	6 889,2	6 211,4	6 481,8	6 893,0	6 322,2	5 902,9	6 322,5

Table 14 - Number of lifetime pathological, anatomical and cytological diagnostic tests performed in the Novosibirsk Region by difficulty categories

Types of studies	2015	2016	2017	2018	2019	2020	2021	2022
lifetime cytology								
Patients	193 420	166 737	157 762	114 652	177 045	162 300	151 225	155 307
Objects of cytological material, incl. by difficulty category	285 881	254 491	235 087	237 087	272 778	327 846	306 986	321 485
Category I	131 207	94 462	103 903	70 521	100 830	113 973	103 347	110 324
Category II	88 201	74 095	59 257	44 331	58 956	89 334	91 125	75 797
Category III	38 230	40 217	32 438	32 301	35 350	40 371	39 702	42 344
Category IV	17 971	26 773	20 096	50 201	60 139	53 067	45 378	55 675
Category V	10 272	18 944	19 393	39 733	17 503	31 101	27 434	37 345
lifetime pathological and anatomical examinations biopsy and surgical material								
Patients, incl. by difficulty category	151 738 (directions)	149 852	152 586	137 479	148 682	113 318	115 524	124 978

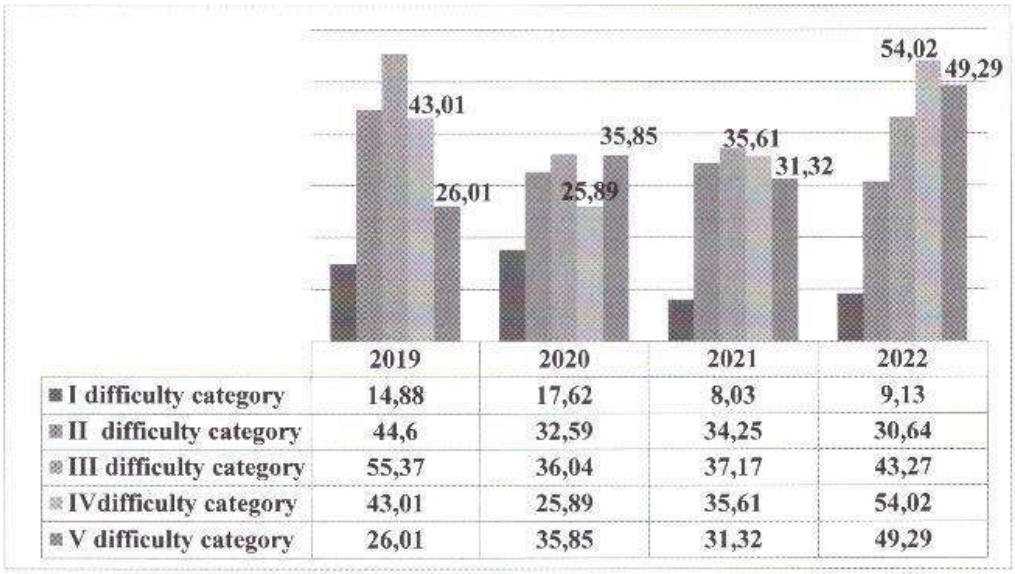
Table 14 (continued)

Types of studies	2015	2016	2017	2018	2019	2020	2021	2022
lifetime pathological and anatomical examinations biopsy and surgical material								
Category I	нет данных по категориям	14 663	11 639	12 149	12 482	8 684	6 558	7 739
Category II		37 611	33 967	31 233	38 047	25 618	25 659	27 054
Category III		37 569	42 406	37 865	39 089	28 841	26 834	27 789
Category IV		37 798	41 020	32 809	35 556	27 640	27 593	31 226
Category V		22 211	23 554	23 423	23 508	22 535	28 880	31 170
Cases, including by difficulty category	143 231	206 706	210 427	742 504	183 869	147 988	146 380	186 348
Category I	12 258	18 055	14 764	44 675	14 876	17 621	8 031	9 133
Category II	34 098	50 221	47 699	161 404	44 600	32 587	34 255	30 638
Category III	55 510	62 822	68 930	229 513	55 373	36 042	37 168	43 275
Category IV	29 377	48 586	51 766	160 951	43 006	25 888	35 608	54 017
Category V	11 988	27 022	27 268	145 961	26 014	35 850	31 318	49 285
Objects, including complexity categories	741 034	741 432	751 177	742 504	752 521	563 311	630 855	689 362

End of Table 14

Types of studies	2015	2016	2017	2018	2019	2020	2021	2022
lifetime pathological and anatomical examinations biopsy and surgical material								
Category I	50 957	47 614	41 209	44675	47220	35 165	22 728	25 325
Category II	160 600	206 201	172 306	161404	187028	121 510	112 770	126 983
Category III	326 046	229 280	244 851	229513	215513	171 919	142 827	138 217
Category IV	138 971	134 843	165 754	160951	159947	123 833	179 201	198 839
Category V	64 460	123 494	127 057	145961	142813	110 884	173 329	199 998
Number of additional colors, reactions, determinations	12 054	59 997	58 979	52 704	17 124	21 276	29 194	78 982

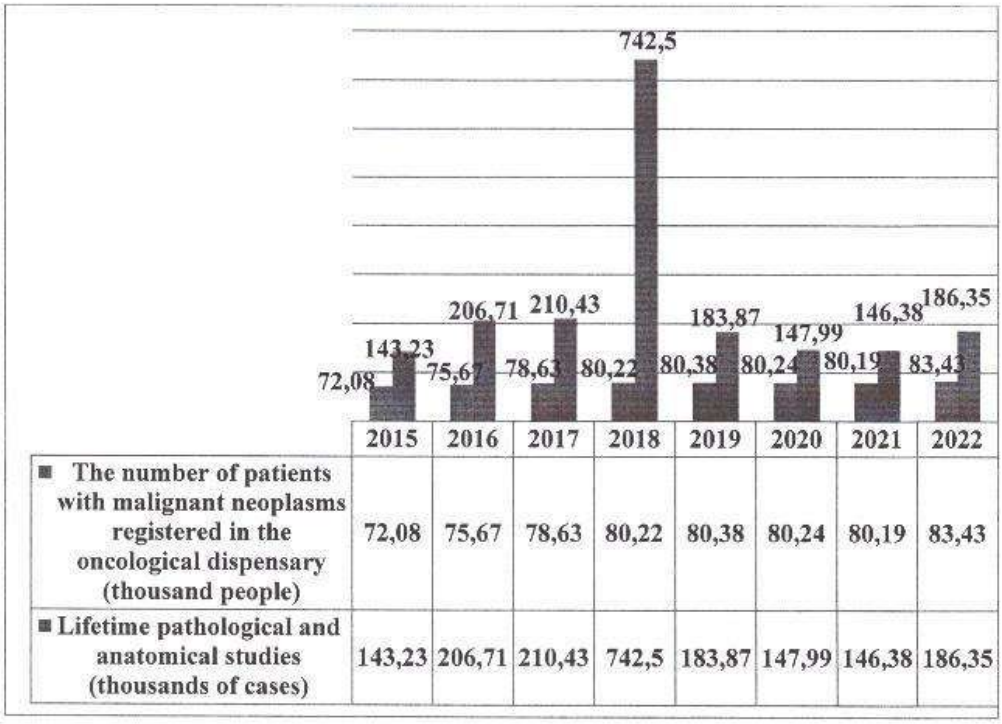
During the study, per 100 thousand population of the Novosibirsk Region, the maximum number of patients who underwent lifetime pathological and anatomical studies was registered in 2015 (5,524.1) and in 2017 (5,489.6), in 2020 compared to 2019, there is a decrease in the number of patients who underwent lifetime pathological and anatomical diagnostics by 23.9% (from 5,322.6 in 2019 to 4,049.7 in 2020), in 2021 relative to 2020 - a slight increase of 2.0% (up to 4,130,0 per 100 thousand population), in 2022 relative to 2021 - a further increase in the number of patients per 8.2% to 4,467,5 per 100 thousand population. The number of cases of lifetime pathological and anatomical diagnosis of biopsy (surgical) material in the Novosibirsk Region per 100 thousand population from 2015 to 2021 varied unevenly: the maximum increase was noted in 2017 7,570.5 per 100 thousand population, the largest decrease - in 2021 to 5,233.1 per 100 thousand population, in 2022 compared to the previous year, there was an increase of 27.3% to 6,661.2 per 100 thousand population (with a target of 10,000 cases per 100 thousand population) (Table 13). In 2023, the number of cases of lifetime pathological and anatomical studies reached 8,446, 1 per 100 thousand of the population.



	2019	2020	2021	2022
I difficulty category	14,88	17,62	8,03	9,13
II difficulty category	44,6	32,59	34,25	30,64
III difficulty category	55,37	36,04	37,17	43,27
IVdifficulty category	43,01	25,89	35,61	54,02
V difficulty category	26,01	35,85	31,32	49,29

Figure 3 - Dynamics of the number of cases of lifetime pathological and anatomical studies by difficulty categories in the Novosibirsk Region, 2019-2022 (in thousands of cases)

In 2022, compared to 2019, there was an increase in the number of cases of intravital pathological and anatomical studies of the IV category of difficulty by 25.6%, the V category of difficulty by 89.5%, and a decrease in the number of cases of studies of the I and II categories of difficulty by 38.6% and 31.3%, respectively [147] (Figure 3). In 2023, the number of cases of V category difficulty studies relative to 2022 increased by 15% and amounted to 56.69 thousand cases [147, 148].



	2015	2016	2017	2018	2019	2020	2021	2022
The number of patients with malignant neoplasms registered in the oncological dispensary (thousand people)	72,08	75,67	78,63	80,22	80,38	80,24	80,19	83,43
Lifetime pathological and anatomical studies (thousands of cases)	143,23	206,71	210,43	742,5	183,87	147,99	146,38	186,35

Figure 4 - Dynamics of lifetime pathological and anatomical studies conducted in the Novosibirsk Region and the number of patients with malignancies registered with the oncological dispensary for 2015-2022

Figure 4 shows that in the period from 2015 to 2022, the number of patients registered in the oncological dispensary with malignant neoplasms increased by 15.7%, while the number of annual cases of lifetime pathological and anatomical studies of biopsy (surgical) material shows a greater increase - by 30.1% [146; 147; 149].

For objects of intravital pathological and anatomical studies of biopsy (surgical) material from 2015 to 2019. there is a slight increase in the number (by 1.6%), in 2020 compared to 2019, the number of objects decreased by 25.1%, from 2021 there is a gradual increase in the number of objects (from 563,311 in 2020 to 630,855 in 2021 and 689,362 in 2022). The decrease in the volume of in-life pathological and anatomical studies of biopsy (surgical) material performed in 2020 and 2021 is associated with a change in the structure of medical care and a reduction in the volume of medical care in

a planned form during the pandemic of the new coronavirus infection (COVID-19).

The decrease in the number of objects of in-life pathological and anatomical studies of biopsy (surgical) material in 2020 and 2021 is accompanied by changes in the structure of objects by categories of complexity of the material. In the structure of lifetime pathological and anatomical studies of biopsy (surgical) material by categories of complexity of objects until 2021, the largest share was of studies of material of the III category of complexity (in 2017 - 32.6%, in 2018 - 30.9%, 2019 - 28.6%, in 2020 - 30.5%). In 2021, there were changes in the structure of the complexity categories of the studied objects, which are preserved in 2022: the largest share belongs to objects of the IV category of complexity (28.4% in 2021 and 28.8% in 2022) and V difficulty categories (27.5% in 2021 and 29% in 2022), objects of the III category of complexity amounted to 22.6% in 2021, 20% in 2022. The absolute number of objects of the V category of complexity of the material increased from 2015 to 2021 by 2.7 times, from 2015 to 2022 - 3.1 times - from 64 460 to 199 998 objects (category V of complexity includes material obtained from patients with immunopathological processes, tumors and tumor-like processes in the absence of histological verification, diseases of the blood system and hematopoietic organs; obtained during puncture biopsies, or other biopsy (surgical) material requiring the use of decalcification and (or) additional methods). In terms of relative figures, the proportion of in-life pathological and anatomical studies of material of category V complexity in 2015 amounted to 8.7%, in 2019 - 19%, in 2020 - 19.7%, in 2022 - 29% (Table 14).

The increase in objects of the V category of complexity is accompanied by an increase in the number of additional colors, reactions and definitions: from 2018 to 2022 - by 49.9% [146; 147; 148].

Uneven changes in the number of cases are also observed in lifetime cytological studies: the lowest level was registered in 2021 (5902.9 cases per 100 thousand of the population), in 2022 compared to the previous year, the number of cases of intravital cytological studies increased by 7.1% and reached 6 322,5 per 100 thousand of the population, but did not reach the dock level (in 2019 – 6 893,0 per 100 thousand of the population). The number of cases of cytological studies of biopsy (surgical) material per

1 patient remains at 1.1. Cytological studies keep priority when examining colpocytological material in smears taken during preventive examinations in healthy people (I category of complexity), as well as material taken in inflammatory and dystrophic processes of the cervix and mammary glands (II category of complexity). The share of cytological studies of material of complexity category I ranges from 25% (in 2014) to 44% (in 2017), 30% (in 2018) and 34.3% (2022), the share of studies of complexity category II decreased from 33% in 2014 to 18.7% in 2018, in 2022 amounted to 23.6%. The number of cytological studies of the IV category of complexity - material for dysplasia, pre-invasive and invasive cancer, pre-neoplastic processes and non-epithelial tumors - increased from 2014 to 2018 almost 3 times, in 2018 the share of studies of the IV category of complexity was 21.2%, in 2019 - 22%, in 2022 - 17.3% in the overall structure of cytological studies. However, in the diagnosis of dysplastic and pre-neoplastic processes, pre-invasive and invasive cancer, the leading role is played by lifetime pathological-anatomical and additional research methods [41].

Minutes of the meeting of the commission on the formation of medical and economic standards of the Ministry of Health of the Novosibirsk Region dated 30.12.2015 No. 30 approved the labor intensity of lifetime pathological and anatomical studies of biopsy (surgical) material presented in Table 15.

Table 15 - Indicators of labor intensity of lifetime pathological and anatomical studies of biopsy (surgical) material, taking into account the difficulty category in the territory of the Novosibirsk Region

Service name	Labor intensity (UET/hour)	
	doctor-pathologist	laboratory assistant т
Llifetime pathological and anatomical examination of biopsy (surgical) material by difficulty categories	—	—
difficulty category I	2,00/0,33	4,30/0,72
difficulty category II	4,00/0,67	4,30/0,72
difficulty category III	6,00/1,00	4,30/0,72

difficulty category IV (without additional colors)	10,00/1,67	4,50/0,75
difficulty category IV (with the use of additional colors)	12,00/2,00	5,30/0,88
difficulty category V (without additional colors)	15,00/2,50	4,50/0,75
difficulty category V (with the use of additional colors)	17,00/2,80	5,30/0,88
Cytological examination of punctates obtained from tumors, pre-tumor, tumor-like formations of various localization of the skin, breast (one drug)	2,00/0,33	2,00/0,33
Diagnostic cytological examination of one preparation of material obtained from scraping from the cervix and cervical canal	2,00/0,33	2,00/0,33
Diagnostic cytology of uterine aspirates	2,50/0,42	2,00/0,33
Cytological examination of one preparation of material obtained during laryngoscopy, bronchoscopy, esophagoscopy, gastroscopy, laparoscopy, colonoscopy and others (imprints from tumor biopsy, scrapings, aspirates, transbronchial punctates)	2,50/0,42	2,00/0,33
Cytological examination of material obtained during surgical interventions and other urgent studies Cytological examination of material obtained during surgical interventions and other urgent studies	5,50/0,92	2,00/0,33

3.6 Organizational Structure of lifetime Pathological and Anatomical Diagnostics of Biopsy (Surgical) Material and Quality Control of lifetime Pathological and Anatomical Studies in the Novosibirsk Region

In order to systematically analyze the organization of lifetime pathological and anatomical diagnostics of biopsy (surgical) material, an analysis of the system structure, that is, the list of subsystems and their interaction, was carried out [156].

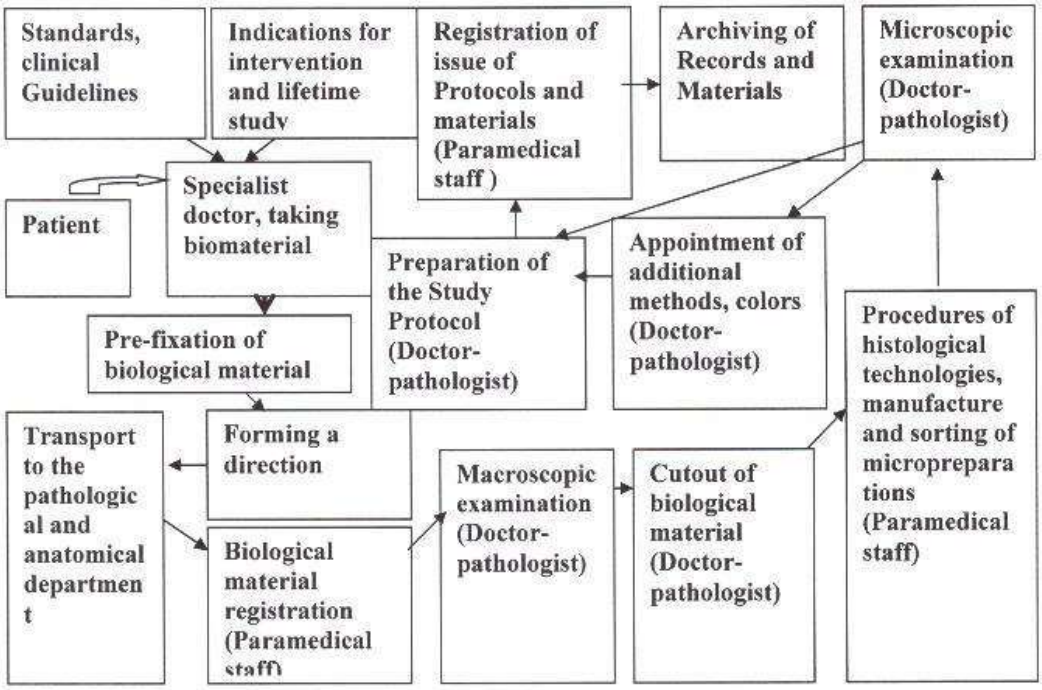


Figure 5 - Organization of the stages of lifetime pathological and anatomical diagnostics before the implementation of the organizational and functional model

Quality control of lifetime pathological and anatomical studies of biopsy (surgical) material is ensured by the following:

- state control carried out by specialists of the Territorial Body of Roszdravnadzor of the Novosibirsk Region;

- departmental control carried out by the chief specialists of the Ministry of Health of the Novosibirsk Region in the specialty "pathological anatomy" and "oncology";

- internal quality control of research at the level of medical organizations;

- examination of the quality of medical care by medical insurance organizations and the Territorial Compulsory Health Insurance Fund.

Internal quality control of lifetime pathological and anatomical studies of biopsy (surgical) material in medical organizations of the Novosibirsk Region is organized in

accordance with the order of the Ministry of Health of Russia dated 10.05.2017 No. 203n "On approval of criteria for assessing the quality of medical care" and the order of the Ministry of Health of Russia dated 31.07.2020 No. 785n "On approval of the Requirements for the organization and conduct of internal quality control and safety of medical activities."

Internal quality control of lifetime pathological and anatomical studies of biopsy (surgical) material in medical organizations of the Novosibirsk Region is carried out at three levels. At the first level, the assessment of the quality of research is carried out by the head pathological and anatomical department (service) in the amount of 100%. At the second level, deputies of the chief physician conduct monthly analysis of at least 20 cases of lifetime pathological and anatomical studies. At the third level, internal control of complex diagnostic cases is carried out by the medical commission of a medical organization. To carry out targeted and thematic internal quality control of studies, methodologists of the quality departments of medical activity or organizational and methodological departments.

Based on the results of internal quality control of studies at levels 1 and 2, the Internal Quality Control Chart for In-Life Pathological and Anatomical Study of Biopsy (operational) material in which the quality of filling out the Study Direction of registration form No. 014/y, the quality of filling in the Log of biopsy (surgical) material and the issuance of the results of lifetime pathological and anatomical studies of the registration form No. 014-/y, the Protocol of in-life pathological and anatomical study of biopsy (surgical) material of the registration form No. 014-1/y and the timing of the studies. During internal control.

At the 1st level, the heads of pathological and anatomical departments additionally assess the compliance of the histological technology with the standard and the procedure for maintaining a histological archive (the availability of an archive of Directions, Protocols, tissue samples, paraffin blocks, micropreparations and a Log of their issuance) [113]. In each control section, scores are evaluated. Identified violations of histological technologies are recorded in the Nonconformity Log and submitted to the Senior Laboratory Assistant for corrective actions in relation to a specific procedure.

Quality control of in-life pathological and anatomical studies of biopsy (operational) material by experts of insurance medical organizations is carried out in accordance with the order of the Ministry of Health of Russia dated 19.03.2021 No. 231n "On approval of the Procedure for monitoring the volume, timing, quality and conditions of medical care for compulsory medical insurance to insured persons, as well as its financial support." In addition, since 2019, experts of insurance medical organizations, when monitoring the volume, timing, quality and conditions for the provision of medical care to patients with suspected cancer or with an established diagnosis of cancer, assess the Protocols of pathomorphological studies in accordance with the methodological recommendations of the Federal Compulsory Health Insurance Fund of 30.08.2018 No. 1086/30/and current clinical recommendations.

The role of the advisory center during lifetime pathological and anatomical studies of biopsy (surgical) material are performed by the Novosibirsk Regional Clinical Oncological Dispensary.

In addition, all pathological and anatomical services of the Novosibirsk Region take part in the program of the federal system of external quality assessment (FSVOK). Pathological and anatomical services receive encrypted samples, which are objects for assessing the degree of comparability of the results of studies performed in pathological and anatomical services, established by the standards of analytical accuracy. In the Novosibirsk City Clinical Hospital No. 1 and the Novosibirsk Regional Clinical Oncological Dispensary, 99% of the results are within the range of reference values.

Negative factors of the system of organization of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region are:

1) territorial remoteness of the specialist doctor of the outpatient medical organization as the customer of the study from the pathologist;

2) violation of the process of preliminary fixation of biopsy (surgical) material and the timing of transportation of the taken biological material to the pathological and anatomical department (from remote areas of the Novosibirsk Region, biological material is delivered to pathological and anatomical department every 10-14 days);

3) the medical information system of the Novosibirsk Region, used by medical

organizations subordinate to the Ministry of Health of the Novosibirsk Region, is represented by automated workplaces of clinical doctors and pathologists who function separately do not form a single information environment and do not provide mutual exchange of diagnostic and medical information between medical organizations;

4) the implementation of histological technologies for processing biological material and the manufacture of micropreparations is characterized by a low level of automation of the main processes, which leads to a decrease in the quality and effectiveness of diagnostic measures;

5) violation of the deadlines for obtaining Protocols of intravital pathological and anatomical studies of biopsy (surgical) material due to insufficient motor transport support leads to an extension of the terms of diagnosis and treatment of patients;

6) the absence of a Reference Center with regulations for the quality control of pathological and anatomical studies on the territory of the Novosibirsk Region makes it difficult to obtain advice and a "second opinion" on research;

7) the shortage of technological equipment limits the conduct of remote consultations of full-format scanned images of micropreparations.

SUMMARY

1. In the period from 2015 to 2022. In the Novosibirsk Region, there is an increase in the number of patients registered in the oncological dispensary, and the number of annual intravital cases pathological and anatomical studies of biopsy (surgical) material. However, the volume of in-life pathological and anatomical diagnostics for the specified period increased by 30.1%, the number of patients registered in the oncological dispensary - by 15.7% [148; 150]. A more pronounced increase in the volume of lifetime pathological and anatomical diagnostics is determined by the demand for morphological verification of pathological processes not only by oncologists, but also by surgeons.

2. Significant positive dynamics in the early detection of malignant neoplasms in the Novosibirsk Region is observed in the period from 2018 to 2022: the proportion of detected malignant neoplasms in Stages I-II increased from 55.3% in 2018 to 59.7% in 2022 (excluding 2020). The share of morphological verification during this period

increased from 93.1% to 94.9%. The achievement of these indicators for the early detection of malignant neoplasms became possible due to the formation of new and increased activities of existing CAOPs.

3. In the period from 2015 to 2019, in medical organizations of the Novosibirsk region, there was a decrease in the percentage of staffing with employed pathologists from 90.7% in 2015 to 80.6% in 2019, followed by an increase to 86.7% in 2022. The number of pathologists for the same period increased by 7,1% (from 56 people in 2015 to 60 people in 2019). In 2022, the number of pathologists reached 69 people. Despite a slight increase in the percentage of staffing of pathologists by individuals (from 39.9% in 2015 to 46.9% in 2022), the deficit in this category of personnel remains at a high level of 78 people. The number of individuals of paramedical personnel (histologists) in the Novosibirsk region in the period from 2015 to 2019 increased from 56 people to 71, followed by a decrease in 2022 to 61 people (by 14%) [146; 148].

4. The availability of basic process equipment remains at a low level (49%), the rate of renewal of process equipment is inferior to the rate of its obsolescence (33.4% in 2022 has a service life of more than 10 years). Light binocular microscopes (83 units) remain the basic microscopic equipment in the Novosibirsk Region, electron microscopy is represented by a single equipment. Despite the gradual increase in the equipment of the pathological and anatomical services of the Novosibirsk region with equipment for digital microscopy (from 4 units in 2019 to 10 units in 2022), a shortage of microscopic equipment remains.

5. In the period from 2018 to 2022, the very structure of intravital pathological and anatomical studies of biopsy (surgical) material by difficulty categories underwent changes: the proportion of cases of studies of the V difficulty category increased from 19.7% in 2018 to 26.4% in 2022. An increase in objects of the V difficulty category is accompanied by an increase in the number of additional colors, reactions and definitions by 49.9%. An increase in category V studies of complexity creates an additional burden on the medical staff of pathological and anatomical services [146; 148].

6. The number of cases of lifetime pathological and anatomical diagnosis of biopsy (surgical) material per 100 thousand population reached the dock-like period and amounted to 6,661,2 cases, but did not reach the target level of 10 000 cases per 100

thousand population.

7. Cytological studies are of particular importance in the study of material obtained during gynecological preventive examinations or in inflammatory, dystrophic processes of the cervix and mammary glands (I and II categories of difficulty). Despite the fact that the number of cytological studies of category IV difficulty increased from 2015 to 2019 years. more than 3 times, the role of cytological studies in the diagnosis of dysplastic and pre-neoplastic processes, pre-invasive and invasive cancer is secondary, and the leading methods are lifetime pathological and anatomical and additional research methods.

8. The persisting personnel shortage, low provision of pathological and anatomical services of the Novosibirsk region with basic technological equipment, combined with a lag in the rate of its renewal from wear and tear, an increase in the structure of lifetime pathological and anatomical studies of cases of category V complexity are risk factors for ensuring the quality of research.

CHAPTER 4 RESULTS OF RESEARCH METHODS OF THE SYSTEM OF ORGANIZATION OF LIFETIME PATHOLOGICAL AND ANATOMICAL DIAGNOSTICS OF BIOLOGICAL MATERIAL IN MEDICAL ORGANIZATIONS OF THE NOVOSIBIRSK REGION

4.1 Analytical Method Analysis

In order to study the indicators of satisfaction of the need for lifetime pathological and anatomical studies of biopsy material, an analysis was carried out of the number of colonoscopies with biopsy for intestinal diseases registered in the Novosibirsk region of intestinal diseases according to report form No. 12.

The scope of diagnostic studies, including those accompanied by taking biological material for lifetime pathological and anatomical examination is determined by clinical recommendations on nosologies and diagnostic feasibility of morphological verification of the pathological process. The data in Table 16 allow us to calculate the indicator of satisfaction of the need for endoscopic intestinal examinations with biopsy in intestinal diseases (by the total number of diseases and by the newly detected pathology recorded in report form No. 12). The number of registered malignant neoplasms of the colon, rectosigmoid, rectum and anal region was considered by the number of registered at the end of the reporting year and first registered in the reporting year.

Table 16 - Incidence in the Novosibirsk Region by intestinal diseases in which lifetime pathological and anatomical studies of biopsy (surgical) material (adult population from 18 years and more) are carried out for 2015-2018

Name of class or individual diseases	International Classification of Diseases Code 10	2015		2016		2017		2018	
		total registered diseases	including for the first time	total registered diseases	including for the first time	total registered diseases	including for the first time	total registered diseases	including for the first time
Malignant neoplasms of the colon, rectosigmoid, rectum and anal region *	C18-C21	6 774	1 224	7 123	1 290	7 526	1 321	8 017	1 350
Non-infectious enteritis and colitis	K50-K52	2 916	566	2 846	514	3 051	521	3064	583
Other bowel diseases	K25-K63	13 833	5 697	16 438	6 863	17 237	6 430	17 276	6 794

Table 16 (continued)

Endoscopic examinations	2015		2016		2017		2018	
	in total	including biopsy	in total	including biopsy	in total	including biopsy	in total	including biopsy
Colonoscopy	21 507	4 807	18 788	4 835	20 391	5 776	21 401	6 744
Rectosigmoidoscopy	н/д	н/д	5 546	634	6 196	758	5 673	681

Indicators of satisfaction of the need for intestinal endoscopic examinations (colonoscopies and rectosigmoidoscopies) with biopsy by total number of diseases:

$$\text{- 2015 } B_r = \frac{B_a}{B_d} \times 100 = \frac{4\ 807}{23\ 523} \times 100 = 20{,}4\ \%,$$

where 4 807 – number of biopsies,

23 523 – total number of bowel diseases;

$$\text{- 2016 } B_r = \frac{5469}{26\ 407} \times 100 = 20{,}7\ \%,$$

where 5 469 – number of biopsies on colonoscopy and rectosigmoidoscopy,

26 407 – total number of bowel diseases;

$$\text{- 2017 } B_r = \frac{6534}{27\ 814} \times 100 = 23{,}5\%,$$

where 6 534 – number of biopsies,

27 814 – total number of bowel diseases;

$$\text{- 2018 } B_r = \frac{7425}{28\ 357} \times 100 = 26{,}2\ \%,$$

where 7 425 – number of biopsies,

28 357 – total number of bowel diseases.

Similarly, the indicators of satisfaction of the need for endoscopic intestinal examinations with a biopsy were calculated according to the newly diagnosed pathology: in 2015 - 64.2%; in 2016 - 63.1%; in 2017 - 79%; in 2018 - 85%.

The analysis shows a steady increase in the indicators of meeting the need for endoscopic examinations with biopsy based on the total number of registered diseases and newly diagnosed intestinal pathology in the Novosibirsk Region over the analyzed

period (from 2015 to 2018).

The indicators of verification of the diagnosis of malignant neoplasm of the colon, rectosigmoid, rectum and anal region during biopsy of biological material were calculated and analyzed.

$$2015 \quad V = v \times 100 / a_n = 1\ 183 \times 100 / 1\ 224 = 96{,}6\ \%,$$

where V – - percentage of malignant neoplasm diagnosis verification;

1 183 (v) – absolute number of biopsy cases in which malignancy diagnosis is confirmed;

1 224 (a_n) – total number of biopsy tests performed for intestinal malignancies.

$$2016\ V = 1\ 250 \times 100 / 1\ 290 = 96{,}9\ \%$$

$$2017\ V = 1\ 279 \times 100 / 1\ 321 = 96{,}8\ \%$$

$$2018\ V = 1\ 319 \times 100 / 1\ 350 = 97{,}7\ \%$$

Over the analyzed period, there is a tendency towards an increase in the indicator of intravital morphological verification of the newly diagnosed malignant neoplasm of the large intestine in the Novosibirsk Region (from 96.6% to 97.7%).

4.2 Analysis of the results of the sociological method of the study of satisfaction with the quality of lifetime pathological and anatomical studies of biopsy (surgical) material

Over the entire period of the study, 350 questionnaires of specialist doctors were received. Of the respondents, 161 doctors (46%) provide medical care in hospitals, 189 doctors (54%) - on an outpatient basis. Among the respondents there were 248 doctors (70.9%) in the specialty "obstetrics and gynecology," of which 80 doctors provide medical care in hospitals and 168 - on an outpatient basis, 102 doctors (29.1%) are in the specialty oncologists, of which 81 people work in hospitals and 21 people on an

outpatient basis. The opinion of specialist doctors on violations that have the greatest impact on the quality of in-life pathological diagnostics of biopsy (surgical) material, satisfaction with the quality of filling out the Study Protocols, the timing of the delivery of biological material and the provision of Study Protocols, satisfaction with obtaining a "second" opinion on the study results was assessed.

Characteristics of the distribution of responses of all specialist physicians (350 people).

From the list of shortcomings that have the greatest impact on the quality of lifetime pathological diagnostics of biopsy (surgical) material, clinicians noted a violation of standard procedures for the collection, fixation and direction of biological material at the pre-analytical stage (26.6 ± 2.4)%, insufficient material and technical equipment of the pathological and anatomical service (26 ± 2.3)% and the lack of an effective logistics system that ensures the timely delivery of biological material and Protocols of studies performed (23.4 ± 2.3)%.

196 doctors (56.0 ± 2.7) % were fully satisfied with the quality of filling out the study protocols, 94 doctors (26.9 ± 2.4) % were partially satisfied, 60 doctors (17.1 ± 2.0) % were completely dissatisfied. In outpatient organizations, 141 specialist doctors (74.6%) positively assessed the quality of filling out the Research Protocols, and 149 doctors (92.5%) among hospital doctors. Of the 290 cases of positive assessment of the quality of the Protocols, the share of respondents providing inpatient medical care was 51.4%, the share of doctors of outpatient organizations was 48.6%, respectively.

When assessing the delivery time of biomaterial from a specialist doctor to a research executor, the proportion of respondents who noted the standard delivery time and the excess of the approved delivery time are equal. At the same time, of the doctors providing medical care in hospitals (n = 161), the proportion of respondents who noted the normative period for the delivery of biological material from the customer to the research executor was 96.3%, of the doctors providing outpatient medical care, the normative period for the delivery of biological material to the research executor was noted by 10.6% of respondents.

When assessing the timing of the provision of research results from 350 specialist

doctors, 267 people (76.3%) noted the standard period, of which 143 people (53.6%) provide medical care in hospitals.

When assessing the possibility of obtaining a "second opinion" through consultation and expert assessment of lifetime materials

pathological and anatomical studies revealed almost equal proportions of respondents who were fully and partially satisfied (48.6% and 51.4%, respectively).

Using Pearson's chi-square test (x^2) with a significance level of 0.01, the existence of differences in two distributions of qualitative signs was assessed depending on the conditions of medical care (inpatient, outpatient) and the specialty of doctors (oncologists and obstetricians-gynecologists).

The null hypothesis - H_0 - is formed as follows: between two samples (doctors of outpatient medical organizations - hospital doctors; oncologists and obstetricians-gynecologists) there is no expected difference. The opposite of the statement that in reality there is a difference between the constellations is an alternative hypothesis - H_1.

As a result of the test, the null hypothesis was either accepted or rejected in favor of an alternative one.

When calculating the chi-square (x^2) Pearson test, the following were performed:

1) calculation of theoretical frequency (f_T);

2) the difference between the empirical and theoretical frequency for each category is calculated;

3) the number of degrees of freedom is determined. Corrected for "continuity" (if v = 1);

4) the obtained differences are squared.

5. The resulting difference squares are divided by the theoretical frequency.

6. The amount received is χ^2_{Emp}

Differences between the two distributions were assessed as significant if the χ^2_{Emp} reached or exceeded the $\chi^2_{0.01}(H_1)$.

Characteristics of the distribution of respondents' responses depending on the conditions of care (inpatient, outpatient). Of the specialists providing inpatient care (n = 161), the proportion oncologists amounted to 50.3%, the share of obstetricians-

gynecologists - 49.7%. Among specialists of outpatient organizations (n = 189), the share of oncologists is 11.1%, obstetricians-gynecologists - 88.9%. The results of the survey of doctors of hospitals and outpatient medical organizations are presented in Table 17.

Table 17 - Characteristics of responses from hospital doctors and doctors of outpatient organizations of the Novosibirsk Region [22]

Indicator	Hospital doctors (n = 161)		Doctors of ambulatory medical organizations (n = 189)		Median (Me)	Interquartile range (IQR)	In total (n = 350)	
	absolute value.	p, %	absolute value	p, %			absolute value	O(p)
Disorders that have the greatest impact on the quality of lifetime pathological diagnostics of biopsy (surgical) material								
Violation of standard procedures for the collection, fixation and direction of biological material at the pre-analytical stage	51	31,7	42	22,2	46,5	9	93	(26,6 ± 2,4) %
Lack of an effective logistics system to ensure timely delivery of biological material and Protocols of performed studies	32	19,9	50	26,5	41	18	82	(23,4 ± 2,3) %
Insufficient material and	44	27,3	47	24,9	45,5	3	91	(26 ± 2,3) %

technical equipment of the pathological and anatomical service								
Personnel shortage in pathological and anatomical services	26	16,1	31	16,4	28,5	5	57	(16,3 ± 2,0) %
Weak quality management system for livetime pathological and anatomical diagnostics	8	5,0	19	10,0	13,5	11	27	(7,7 ± 1,4) %
Satisfaction with the quality of the Study Protocols								
Satisfies, including	149	92,5	141	74,6	145	18	290	(82,9 ± 2,0) %
- satisfies in full	119	73,9	77	40,7	98	42	196	(56,0 ± 2,7) %
- satisfies partially	30	18,6	64	33,9	47	34	94	(26,9 ± 2,4) %
- Not satisfying at all	12	7,5	48	25,4	30	36	60	(17,1 ± 2,0) %
Delivery time of biomaterial from specialist doctor to study executor								
- complies with the normative deadline	155	96,3	20	10,6	87,5	135	175	(50,0 ± 2,0) %
- exceeds the normative deadline	6	3,7	169	89,4	87,5	163	175	(50,0 ± 2,0) %
Assessment of the time lags for producing of Study Protocols								
- the term corresponds to the normative	143	88,8	124	65,6	133,5	19	267	(76,3 ± 2,3) %
- the term exceeds the normative	18	11,2	65	34,4	41,5	47	83	(23,7 ± 2,3) %
Most frequent format of conclusions in Study Protocols								
The study protocol always contains a descriptive	119	73,9	77	40,7	98	42	196	(56,0 ± 2,7) %

description of the pathological process and a nosological diagnosis; in the tumor process, the purity of the resection margin, dimensions, histological structure, the degree of differentiation of the tumor G, the number and nature of the affected lymph nodes pN, stages T, N, M are indicated								
The protocol for the study of biological material contains a nosological diagnosis, but does not contain a descriptive description of the pathological process, the size, histological structure of the tumor are indicated in the tumor	12	7,5	48	25,4	30	36	60	(17,1 ± 2,0) %

process, but the number and nature of the affected lymph nodes, stages T, N, M are not indicated								
The study protocol contains a nosological diagnosis, does not contain a descriptive description of the pathological process, the size, histological structure of the tumor, the number and nature of the affected lymph nodes, stages T, N, M are indicated in the tumor process, but the purity of the resection margin is not indicated	30	18,6	64	33,9	47	34	94	(26,9 ± 2,4) %
Assessment of satisfaction from obtaining a "second opinion" through consultation, expert evaluation of materials from a lifetime pathological and anatomical study								
- satisfies in full	137	85	33	17,5	85	104	170	(48,6 ± 2,7) %
- satisfies partially	24	15	156	82,5	90	132	180	(51,4 ± 2,7) %

Of the disorders that have the greatest impact on the quality of in-life pathological diagnostics of biopsy (surgical) material, hospital doctors more often noted violations of standard procedures for the collection, fixation and direction of biological material at

the pre-analytical stage (31.7 ± 3.7)%), doctors of outpatient medical organizations - the lack of an effective logistics system that ensures the timely delivery of biological material and Protocols of studies performed (26.5 ± 3.2)%) [22].

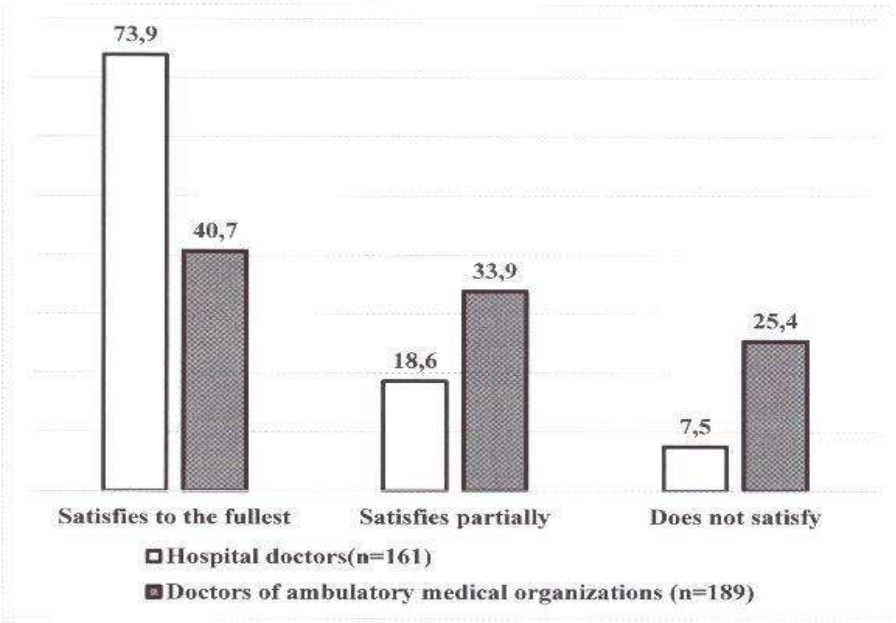


Figure 6 - Satisfaction with the quality of filling out the Study Protocols before the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics in the Novosibirsk Region

Among doctors of outpatient medical organizations (n = 189), the proportion of doctors who are not satisfied with the quality of filling out the Research Protocols is significantly higher than that observed in hospital doctors: (25.4 ± 3.2)%) and (7.5 ± 2.1)%), respectively. Of the doctors of outpatient medical organizations, the proportion of respondents who noted that they were fully satisfied with the quality was (40.7 ± 3.5)%, the proportion of doctors who noted that they were partially satisfied with the quality of filling was (33.9 ± 3.4)%. Among hospital doctors, the share of specialists satisfied with the quality of filling out the Protocols is fully greater than among specialists from outpatient medical organizations, and amounted to (73.9 ± 3.5)%.

Assessing the delivery time of biological material to the investigator, hospital doctors more often noted the fulfillment of regulatory deadlines (96.3 ± 1.5)%), doctors of outpatient medical organizations exceeded the regulatory deadlines (89.4 ± 2.2)%). The share of hospital doctors who noted the fulfillment of the approved deadlines for the provision of Research Protocols is higher than among doctors of outpatient medical organizations: (88.8 ± 2.5)%) and (65.6 ± 3.5)%), respectively. According to the results of the survey, hospital doctors are satisfied with obtaining a "second" opinion in full (85 ± 2.8%), doctors of outpatient medical organizations - partially (82.5 ± 2.8)%) [22].

The differences in the distribution of responses of hospital and outpatient physicians according to the list of deficiencies that most affect the quality of diagnostics, satisfaction with the quality of filling out the Study Protocols, the timing of delivery of biological material, the timing of submission of the Study Protocols and satisfaction with obtaining a "second opinion" based on the results of the studies were assessed using Pearson chi-square criteria (Tables 18, 19, 20, 21 and 22).

Table 18 - Assessment of statistical significance of differences in responses between doctors of hospitals and doctors of outpatient medical organizations of the Novosibirsk Region according to the list of violations that most affect the quality of diagnostics

№	Empirical frequency	Theoretical frequency	$(f_Э - f_Т)$	$(f_Э - f_Т)^2$	$(f_Э - f_Т)^2/f_Т$
1	31,7	26.95	4,75	22,56	0.837
2	22,2	26,95	–4,75	22,56	0,837
3	19,9	23,2	–3,3	10,89	0,469
4	26,5	23,2	3,3	10,89	0,469
5	27,3	26,1	1,2	1,44	0,055
6	24,9	26,1	–1,2	1,44	0,055
7	16,1	16,25	–0,15	0,02	0,001
8	16,4	16,25	0,15	0,02	0,001
9	5,0	7,5	–2,5	6,25	0,833
10	10,0	7,5	2,5	6,25	0,833

Sums	200	200	—	—	4,39

Result: χ^2_{Emp} = 4.39. The critical value of χ^2 at v = 4 at p < 0.01 is 13.277, at p < 0.05 it is 9.488. The differences between the distributions of responses of hospital doctors and doctors of outpatient medical organizations according to the list of violations that most affect the quality of diagnostics are statistically insignificant, since χ^2_{Emp} is less than the critical value (hypothesis H_0).

Table 19 - Assessment of statistical significance of satisfaction with the quality of filling out the Study Protocols with hospital doctors and doctors of outpatient medical organizations of the Novosibirsk Region

№	Empirical frequency	Theoretical frequency	$(f_Э - f_T)$	$(f_Э - f_T)^2$	$(f_Э - f_T)^2/f_T$
1	73,9	57,3	16,6	275,56	4,809
2	40,7	57,3	–16,6	275,56	4,809
3	18,6	26,25	–7,65	58,52	2,229
4	33,9	26,25	7,65	58,52	2,229
5	7,5	16□45	–8,95	80,1	4,869
6	25,4	16,45	8,95	80,1	4,869
Sums	200	200	—	—	23,814

Result: χ^2_{Emp}= 23.814. The critical value of χ^2 at v = 2 at p < 0.01 is 9.21. The differences between the distribution of responses of hospital doctors and doctors of outpatient medical organizations on the issue of satisfaction with the quality of filling out the study protocols are statistically significant, since the χ^2_{Emp} exceeds the $\chi^2_{0.01}$. (hypothesis H_1).

Table 20 - Assessment of statistical significance of differences in the responses of doctors of hospitals and doctors of outpatient medical organizations of the Novosibirsk Region by the timing of delivery of biological material

№	Empirical frequency	Theoretical frequency	$(f_Э - f_T)$	$\|(f_Э - f_T)\|$-0.5	$(\|(f_Э - f_T)\|-0.5)^2$	$(\|(f_Э - f_T)\|-0.5)^2/f_T$
1	96,3	53,45	42.85	42.35	1793.52	33.555
2	10,6	53,45	–42.85	42.35	1793.52	33.555
3	3,7	46,55	–42.85	42.35	1793.52	38.529

4	89,4	46,55	42.85	42.35	1793.52	38.529
Sums	200	200	—	—	—	144,168

Result: χ^2_{Emp} = 144,168. The critical value of χ^2 at v = 1 at p < 0.01 is 6.635. The differences between the distribution of responses of hospital doctors and doctors of outpatient medical organizations in terms of the delivery time of biological material are statistically significant, since the χ^2_{Emp} exceeds the $\chi^2_{0.01}$. (hypothesis H_1).

Table 21 - Assessment of the statistical significance of differences in the responses of doctors of hospitals and doctors of outpatient medical organizations of the Novosibirsk Region by the timing of the provision of Research Protocols

№	Empirical frequency	Theoretical frequency	$(f_Э - f_Т)$	$\|(f_Э - f_Т)\|-0.5$	$(\|(f_Э - f_Т)\|-0.5)^2$	$(\|(f_Э - f_Т)\|-0.5)^2/f_Т$
1	88,8	76,95	11.85	11.35	128.82	1.674
2	65,1	76,95	–11.85	11.35	128.82	1.674
3	11,2	23,05	–11.85	11.35	128.82	5.589
4	34,9	23,05	11.85	11.35	128.82	5.589
Sums	200	200	—	—	—	14,526

Result: χ^2_{Emp} = 14.526. The critical value of χ^2 at v = 1 at p < 0.01 is 6.635. The differences between the distributions of responses of hospital doctors and doctors of outpatient medical organizations by the delivery time of the Study Protocols are statistically significant, since the χ^2_{Emp} exceeds the $\chi^2_{0.01}$ (hypothesis H_1).

Table 22 - Assessment of the statistical significance of differences in the responses of doctors of hospitals and doctors of outpatient medical organizations of the Novosibirsk Region on the issue of satisfaction from receiving a "second opinion"

№	Empirical frequency	Theoretical frequency	$(f_Э - f_Т)$	$\|(f_Э - f_Т)\|-0.5$	$(\|(f_Э - f_Т)\|-0.5)^2$	$(\|(f_Э - f_Т)\|-0.5)^2/f_Т$
1	85	51,25	33,75	33,25	1 105,56	21,572
2	17,5	51,25	–33,75	33,25	1 105,56	21,572
3	15	48,75	–33,75	33,25	1 105,56	22,678
4	82,5	48,75	33,75	33,25	1 105,56	22,678

Sums	200	200	—	—	—	88,5

Result: χ^2_{Emp} = 88.5. The critical value of χ^2 at v = 1 at p < 0.01 is 6.635. The differences between the distribution of responses of hospital doctors and doctors of outpatient medical organizations on the issue of satisfaction from receiving a "second opinion" based on the research results are statistically significant, since the χ^2_{Emp} exceeds $\chi^2_{0.01}$. (hypothesis H_1).

Thus, by calculating Pearson's chi-square test (x2) at a significance level of 0.01, the statistical significance of the differences in the assessment of the studied qualitative signs by doctors providing medical care in hospitals and using the diagnostic capabilities of their own medical organizations and doctors of outpatient medical organizations who send biological material for research to third-party organizations. The differences in the responses of hospital doctors and doctors of outpatient medical organizations according to the list of violations that most affect the quality of diagnostics are statistically insignificant [22].

Additionally, the dependence of the assessment of qualitative signs on the specialty of doctors (oncologists, obstetricians-gynecologists) was investigated.

Distribution of responses by physician specialty. The results of the comparison of the responses obtained in the survey of oncologists and obstetricians-gynecologists are presented in Table 23.

Table 23 - Characteristics of responses of oncologists and obstetricians-gynecologists of the Novosibirsk Region

Indicator	Doctors oncologists (n = 102)		Obstetricians-gynecologists (n = 248)		Median (Me)	Interquartile range (IQR)	In total (n = 350)	
	absolute value .	p, %	absolute value	p, %			absolute value	Ó(p)
Satisfaction with the quality of the Study Protocols								
Satisfies, including	89	87,3	201	81,1	145	112	290	(82,9 ± 2,0) %
- satisfies in full	77	75,5	119	48	98	42	196	(56,0 ± 2,7) %

- satisfies partially	12	11,8	82	33,1	47	70	94	(26,9 ± 2,4) %
- Not satisfying at all	13	12,7	47	18,9	30	34	60	(17,1 ± 2,0) %
Delivery time of biomaterial from specialist doctor to study executor								
- complies with the normative deadline	80	78,4	95	38,3	87,5	15	175	(50,0 ± 2,0) %
- exceeds the normative deadline	22	21,6	153	61,7	87,5	131	175	(50,0 ± 2,0) %
Assessment of the time lags for producing of Study Protocols								
- the term corresponds to the normative	73	71,6	194	78,2	133,5	121	267	(76,3 ± 2,3) %
- the term exceeds the normative	29	28,4	54	21,8	41,5	25	83	(23,7 ± 2,3) %
Most frequent format of conclusions in Study Protocols								
The study protocol always contains a descriptive description of the pathological process and a nosological diagnosis; in the tumor process, the purity of the resection margin, dimensions, histological structure, the degree of differentiation of the tumor G, the number and nature of the affected	77	75,5	119	48	98	42	196	(56,0 ± 2,7) %

lymph nodes pN, stages T, N, M are indicated								
The protocol for the study of biological material contains a nosological diagnosis, but does not contain a descriptive description of the pathological process, the size, histological structure of the tumor are indicated in the tumor process, but the number and nature of the affected lymph nodes, stages T, N, M are not indicated	13	12,7	47	18,9	30	34	60	(17,1 ± 2,0) %
The study protocol contains a nosological diagnosis, does not contain a descriptive description of the pathological process, the size, histological structure of the	12	11,8	82	33,1	47	70	94	(26,9 ± 2,4) %

tumor, the number and nature of the affected lymph nodes, stages T, N, M are indicated in the tumor process, but the purity of the resection margin is not indicated								
Assessment of satisfaction from obtaining a "second opinion" through consultation, expert evaluation of materials from a lifetime pathological and anatomical study								
- satisfies in full	67	59,8	103	41,5	85	36	170	(48,6 ± 2,7) %
- satisfies partially	35	40,2	145	58,5	90	110	180	(51,4 ± 2,7) %

Of the oncologists (n = 102), the share of specialists providing inpatient medical care was 79.4% (81 doctors), the share of specialists providing outpatient medical care was 20.6%, respectively. Of the obstetrician-gynecologists (n = 248), the proportion of specialists providing inpatient medical care was 32.3% (80 doctors), outpatient - 67.7% (168 doctors).

Among oncologists (n = 102), the proportion of doctors who were not satisfied with the quality of filling out the study protocols was 12.7% (13 people, of which 12 doctors provide medical care on an outpatient basis), among obstetricians-gynecologists (n = 248), the proportion of specialists who were not satisfied with the quality of filling out the protocols was 19% (47 people, of which 36 doctors provide medical care on an outpatient basis). Of the oncologists who are satisfied with the quality of filling out the Protocols (89 doctors), the proportion of respondents who noted that they were fully satisfied with the quality was 86.5%, the proportion who noted that they were partially satisfied with the quality was 13.5%. Of the obstetrician-gynecologists who positively assessed the quality of filling out the Research Protocols (201 people), the proportion of specialists satisfied with the quality of filling out the Protocols is fully less (59.2%) than among oncologists, which is explained by the fact that the sample of oncologists is 80% represented by hospital doctors who use the diagnostic capabilities of their own

pathological and anatomical services and more actively interact with pathologists when forming the conclusion of the study.

The statistical significance of differences in satisfaction with the quality of the Study Protocols, the timing of delivery of biological material and the provision of the Study Protocols, and the degree of satisfaction from obtaining a "second opinion" based on the results of studies by oncologists and obstetricians-gynecologists were also assessed using Pearson's chi-square test (Tables 24, 25, 26 and 27).

Table 24 - Assessment of statistical significance of satisfaction with the quality of filling out the Study Protocols by oncologists and obstetricians-gynecologists of the Novosibirsk Region

№	Empirical frequency	Theoretical frequency	$(f_Э - f_T)$	$(f_Э - f_T)^2$	$(f_Э - f_T)^2/f_T$
1	75,5	61,75	13,75	189,06	3,062
2	48	61,75	–13,75	189,06	3,062
3	11,8	22,45	–10,65	113,42	5,052
4	33,1	22,45	10,65	113,42	5,052
5	12,7	15,8	–3,1	9,61	0,608
6	18,9	15,8	3,1	9,61	0,608
Sums	200	200	—	—	17,444

Result: $\chi^2_{Emp} = 17.444$. The critical value of χ^2 at $v = 2$ at $p < 0.01$ is 9.21. The differences between the distribution of responses of oncologists and obstetricians-gynecologists on the issue of satisfaction with the quality of filling out the study protocols are also statistically significant, since the χ^2_{Emp} exceeds $\chi^2_{0.01}$ (hypothesis H_1). This is explained, first of all, by the conditions for the formation of the sample: the sample of oncologists is represented by more than 79% by doctors providing medical care in hospitals, in the sample of obstetricians-gynecologists 67,7% are specialists from outpatient medical organizations.

Table 25 - Assessment of the statistical significance of differences in the responses of oncologists and obstetricians-gynecologists of the Novosibirsk Region by the timing of delivery of biological material

№	Empirical frequency	Theoretical frequency	$(f_Э - f_Т)$	$\|(f_Э - f_Т)\|-0.5$	$(\|(f_Э - f_Т)\|-0.5)^2$	$(\|(f_Э - f_Т)\|-0.5)^2/f_Т$
1	78,4	58,35	20,05	19,55	382,2	6,55
2	38,3	58,35	–20,05	19,55	382,2	6,55
3	21,6	41,65	–20,05	19,55	382,2	9,176
4	61,7	41,65	20,05	19,55	382,2	9,176
Sums	200	200	—	—	—	31,452

Result: $\chi^2_{Emp} = 31.452$. The critical value of χ^2 at $v = 2$ at $p < 0.01$ is 6.635. The differences between the distributions of responses of oncologists and obstetricians-gynecologists in terms of delivery of biological material to the investigator are statistically significant, since the χ^2_{Emp} exceeds $\chi^2_{0.01}$ (hypothesis H_1).

Table 26 - Assessment of the statistical significance of differences in the responses of oncologists and obstetricians-gynecologists of the Novosibirsk Region by the timing of the submission of the Study Protocols

№	Empirical frequency	Theoretical frequency	$(f_Э - f_Т)$	$\|(f_Э - f_Т)\|-0,5$	$(\|(f_Э - f_Т)\|-0,5)^2$	$(\|(f_Э - f_Т)\|-0,5)^2/f_Т$
1	71,6	74,9	–3,3	2,8	7,84	0,105
2	78,2	74,9	3,3	2,8	7,84	0,105
3	28,4	25,1	3,3	2,8	7,84	0,312
4	21,8	25,1	–3,3	2,8	7,84	0,312
Sums	200	200	—	—	—	0,834

Result: $\chi^2_{Emp} = 0.834$. The critical value of χ^2 at $v = 2$ at the level of $p < 0.01$ is 6.635, at the level of $p < 0.05$ is 3.841. The differences between the distributions of responses of oncologists and obstetricians-gynecologists in terms of the provision of the Study Protocols are statistically insignificant, since the χ^2_{Emp} is less than the critical value (hypothesis H_0).

Table 27 - Assessment of the statistical significance of differences in the responses of oncologists and obstetricians-gynecologists of the Novosibirsk Region on the issue of satisfaction from receiving a "second opinion"

№	Empirical frequency	Theoretical frequency	$(f_э - f_т)$	$\|(f_э - f_т)\|-0.5$	$(\|(f_э - f_т)\|-0.5)^2$	$(\|(f_э - f_т)\|-0.5)^2/f_т$
1	59,8	50,65	9,15	8,65	74,82	1,477
2	41,5	50,65	–9,15	8,65	74,82	1,477
3	40,2	49,35	–9,15	8,65	74,82	1,516
4	58,5	49,35	9,15	8,65	74,82	1,516
Sums	200	200	—	—	—	5,986

Result: $\chi^2_{Emp} = 5.986$. The critical value of χ^2 at v = 2 at the level of $p < 0.01$ is 6.635, at the level of $p < 0.05$ is 3.841. The differences between the distribution of responses of oncologists and obstetricians-gynecologists on the issue of satisfaction from receiving a "second opinion" according to the research results are statistically significant, since the χ^2_{Emp} exceeds $\chi^2_{0.05}$ (hypothesis H_1).

When analyzing the dependence of differences in the assessment of qualitative signs by oncologists and obstetricians-gynecologists, the presence of statistical significance of differences was revealed, with the exception of assessing the timing of the submission of the study protocols. The presence of differences is determined by the specifics of sample formation: in the sample of oncologists, the largest share belongs to hospital doctors, in the sample of obstetricians-gynecologists - to doctors of outpatient medical organizations [22]. The provision of research protocols in the opinion of both oncologists and obstetricians-gynecologists is more often carried out within the time period approved by the regulatory document.

In order to assess the fulfillment of the approved deadlines for the delivery of biological material to the research executor and research protocols to customers, a survey of the heads of medical organizations of the Novosibirsk region was conducted. The leaders included chief doctors and their deputies of medical organizations providing medical care to the population in outpatient and inpatient conditions. As part of the study, 100 survey cards of heads of medical organizations were obtained. Comparative characteristics of the responses of specialist doctors and heads of medical organizations

of the Novosibirsk region are presented in Table 28.

Table 28 - Comparative characteristics of responses from specialist doctors and heads of medical organizations of the Novosibirsk Region

Indicator	Clinicians (n = 350)		Heads of medical organizations (n = 100)		Median (Me)	Interquartile range (IQR)	In total (n = 450)	
	absolute value	p, %	absolute value	p, %			absolute value	Ó(p)
Disorders that have the greatest impact on the quality of lifetime pathological and anatomical diagnostics of biopsy (surgical) material								
Violation of standard procedures for the collection, fixation and direction of biological material at the pre-analytical stage	93	26,6	14	14	53,5	79	107	(23,8 ± 2,0) %
Lack of an effective logistics system to ensure timely delivery of biological material and Protocols of performed studies	82	23,4	5	5	43,5	77	87	(19,3 ± 1,9) %
Insufficient material and technical equipment of the pathological and anatomical service	91	26	34	34	62,5	57	125	(27,8 ± 2,1) %

Personnel shortages in pathological and anatomical services	57	16,3	23	23	40	34	80	(17,8 ± 1,8) %
Weak quality management system for lifetime pathological and anatomical diagnostics	27	7,7	24	24	25,5	3	51	(11,3 ± 1,5) %
Satisfaction with the quality of the Study Protocols								
Satisfies, including	290	82,9	95	95	192,5	195	385	(85,6 ± 1,7) %
- satisfies in full	196	56	56	56	126	140	252	(56,0 ± 2,3) %
- satisfies partially	94	26,9	39	39	66,5	55	133	(29,6 ± 2,2) %
- Not satisfying at all	60	17,1	5	5	32,5	55	65	(14,4 ± 1,7) %
Delivery time of biomaterial from specialist doctor to study executor								
- complies with the normative deadline	164	46,9	55	55	109,5	109	219	(48,7 ± 2,4) %
- exceeds the normative deadline	186	53,1	45	45	111,5	141	231	(51,3 ± 2,4) %
Assessment of the time lags for producing of Study Protocols								
- the term corresponds to the normative	267	76,3	79	79	173,0	188	346	(76,9 ± 2,0) %
- the term exceeds the normative	83	23,7	21	21	52,0	60	104	(23,1 ± 2,0) %
Assessment of satisfaction from obtaining a "second opinion" through consultation, expert evaluation of materials from a lifetime pathological and anatomical study								
- satisfies in full	164	46,9	85	85	124,5	79	249	(55,3 ± 2,3) %
- satisfies partially	186	53,1	15	15	100,5	171	201	(44,7 ± 2,3) %

From the list of violations that have the greatest impact on the quality of lifetime pathological and anatomical diagnostics of biopsy (surgical) material, the heads of

medical organizations noted insufficient material and technical equipment of the pathological and anatomical service (34 ± 4,7) %), a weak quality management system for intravital pathological and anatomical diagnostics (24 ± 4,3) %), personnel deficit in pathological and anatomical services (23 ± 4,2) %).

Among doctors - heads of medical organizations (n = 100), the proportion of respondents who are not satisfied with the quality of filling out the Research Protocols is less than that of doctors of clinical specialties (5% and 17,1%, respectively). Of the medical leaders of medical organizations who gave a positive assessment of the quality of filling out the Protocols (95 people), 59% were fully satisfied with the quality, 41% were partially satisfied. Of the doctors of clinical specialties who positively assessed the quality of filling out the Study Protocols (290 people), the share of specialists who were fully satisfied with the quality of filling out the Protocols was more than among the heads of medical organizations, and amounted to 67,6% [22].

The statistical significance of the differences in the responses of doctors of clinical specialties and doctors - heads of medical organizations according to the list of shortcomings that most affect the quality of lifetime pathological diagnostics of biopsy (surgical) material, satisfaction with the quality of filling out the study protocols was assessed using Pearson's chi-square test (Tables 29, 30, 31 and 32).

Table 29 - Assessment of the statistical significance of differences in the responses of doctors of clinical specialties and heads of medical organizations of the Novosibirsk Region according to the list of disorders that most affect the quality of lifetime pathological and anatomical diagnostics

№	Empirical frequency	Theoretical frequency	$(f_Э - f_Т)$	$(f_Э - f_Т)^2$	$(f_Э - f_Т)^2/f_Т$
1	26,6	20,3	6,3	39,69	1,955
2	14	20,3	–6,3	39,69	1,955
3	23,4	14,2	9,2	84,64	5,961
4	5	14,2	–9,2	84,64	5,961
5	26	30	–4	16	0,533

6	34	30	4	16	0,533
7	16,3	19,65	–3,35	11,22	0,571
8	23	19,65	3,35	11,22	0,571
9	7,7	15,85	–8,15	66,42	4,191
10	24	15,85	8,15	66,42	4,191
Sums	200	200	—	—	26,422

Result: $\chi^2_{Emp} = 26.422$. The critical value of χ^2 at $v = 4$ at $p < 0.01$ is 13.277. The differences between the distribution of responses of specialist doctors and heads of medical organizations according to the list of disorders most affecting the quality of intravital pathological and anatomical diagnostics are statistically significant, since the χ^2_{Emp} exceeds $\chi^2_{0.01}$ (hypothesis H_1).

Heads of medical organizations are not direct customers of research, therefore, the opinion of the heads of medical organizations on the quality of filling out research protocols is more or less subjective. At the same time, the results of the assessment of satisfaction with the quality of filling in the Protocols of lifetime pathological and anatomical studies by specialists of the Novosibirsk Region made it possible to calculate the integral coefficient of satisfaction with the quality of the Protocols using a formula based on the study of the sum of the cases when the expected research results were "fully achieved," "partially achieved" and "not achieved" [22, 85; 168]. In this case, cases with the assessment of the study result "fully achieved" were assigned the value "+ 1," "partially achieved" - "0," cases with the assessment "not achieved" - "-1."

$$ICS = \Sigma R_f + \Sigma R_p + \Sigma R_{not\ achiev} / N,$$

$$(+1) \times 196 + 0 \times 94 + (–1) \times 60 / (196 + 94 + 60) = 196 + 0 + (–60) / 350 = 0,389$$

According to a survey of doctors of clinical specialties in the Novosibirsk Region, the integral satisfaction coefficient with the quality of filling in the Protocols of lifetime pathological and anatomical studies is 0.389, which corresponds to a low level of quality. [86; 169].

Table 30 - Assessment of statistical significance of differences in the responses of doctors of clinical specialties and heads of medical organizations of the Novosibirsk Region by the time of delivery of biological material

№	Empirical frequency	Theoretical frequency	$(f_Э - f_T)$	$\lvert(f_Э - f_T)\rvert - 0.5$	$(\lvert(f_Э - f_T)\rvert - 0.5)^2$	$(\lvert(f_Э - f_T)\rvert - 0.5)^2/f_T$
1	46,9	50,95	–4,05	3,55	12,6	0,247
2	55	50,95	4,05	3,55	12,6	0,247
3	53,1	49,05	4,05	3,55	12,6	0,257
4	45	49,05	–4,05	3,55	12,6	0,257
Sums	200	200	—	—	—	1,008

Result: $\chi^2_{Emp} = 1.008$. The critical value of χ^2 at $v = 2$ at the level of $p < 0.01$ is 6.635, at the level of $p < 0.05$ is 3.841. The differences between the distributions of responses of clinicians and heads of medical organizations in terms of delivery of biological material to the investigator are statistically insignificant, since the χ^2_{Emp} is less than the critical value (hypothesis H_0).

Table 31 - Assessment of the statistical significance of differences in the responses of doctors of clinical specialties and heads of medical organizations of the Novosibirsk Region by the timing of the submission of the Study Protocols

№	Empirical frequency	Theoretical frequency	$(f_Э - f_T)$	$\lvert(f_Э - f_T)\rvert - 0.5$	$(\lvert(f_Э - f_T)\rvert - 0.5)^2$	$(\lvert(f_Э - f_T)\rvert - 0.5)^2/f_T$
1	76,3	77,65	–1,35	0,85000000000001	0,72	0,009
2	79	77,65	1,35	0,84999999999999	0,72	0,009
3	23,7	22,35	1,35	0,85	0,72	0,032
4	21	22,35	–1,35	0,85	0,72	0,032
Sums	200	200	—	—	—	0,082

Result: $\chi^2_{Emp} = 0.082$. The critical value of χ^2 at $v = 2$ at the level of $p < 0.01$ is 6.635, at the level of $p < 0.05$ is 3.841. The differences between the distributions of responses of doctors of clinical specialties and heads of medical organizations in terms of the submission of the Study Protocols are also statistically insignificant, since the χ^2_{Emp} is less than the critical value (hypothesis H_0).

Table 32 - Assessment of statistical significance of differences in the responses of doctors of clinical specialties and heads of medical organizations of the Novosibirsk Region on the issue of satisfaction from receiving a "second opinion"

№	Empirical frequency	Theoretical frequency	$(f_Э - f_Т)$	$\|(f_Э - f_Т)\|-0.5$	$(\|(f_Э - f_Т)\|-0.5)^2$	$(\|(f_Э - f_Т)\|-0.5)^2/f_Т$
1	46,9	65,95	–19.05	18.55	344.1	5.218
2	85	65,95	19.05	18.55	344.1	5.218
3	53,1	34,05	19.05	18.55	344.1	10.106
4	15	34,05	–19.05	18.55	344.1	10.106
Sums	200	200	—	—	—	30,648

Result: $\chi^2_{Emp} = 30.648$. The critical value of χ^2 at $v = 2$ at $p < 0.01$ is 6.635. The differences between the distribution of responses of specialist doctors and heads of medical organizations on the issue of satisfaction from receiving a "second opinion" are statistically significant, since the χ^2_{Emp} exceeds $\chi^2_{0.01}$ (hypothesis H_1).

Calculation of Pearson chi-square criterion at significance level equal to 0.01 proves absence of statistical significance of differences in estimation of biological material delivery time to the contractor and time of study protocols submission by specialist doctors and heads of medical organizations of Novosibirsk Region. The differences in the responses of doctors of clinical specialties and heads of medical organizations for disorders that most affect the quality of lifetime pathological and anatomical diagnostics are statistically significant: heads of medical organizations more often noted insufficient material and technical equipment of pathological and anatomical services (34%) and a weak diagnostic quality management system (24%), doctors of clinical specialties - violations at the pre-analytical stage of procedures for collecting, fixing and directing biological material (26.6%) and insufficient material and technical equipment of pathological and anatomical services (26%) [22].

Among the advantages of using centralization and outsourcing, the heads of medical organizations more often noted the stabilization and reduction of the costs of their own medical organization for intravital pathological and anatomical diagnostics

(49 ± 5,0) %, the best quality of research performed by a third-party specialized organization (41 ± 5,0) %, ensuring continuous trouble-free work of personnel (10 ± 3,0) %. Of the disadvantages of using centralization and outsourcing, the heads of medical organizations more often noted the possible risks of non-fulfillment or improper execution of contracts (31 ± 4,6) %, a decrease in the speed of making management decisions, the formation of dependence on a third-party organization if it is necessary to modernize the medical information system (59 ± 4,9) %, a threat to confidentiality (10 ± 3,0) %.

4.3 Analysis of the Results of the Expert Analysis Method

The applied method of individual analytical assessments included assessment of the compliance of procedures with technological standards at each stage of diagnostics, analysis of the degree of impact of detected non-conformities on the study result and preparation of an expert opinion [22; 169].

500 cases of lifetime pathological and anatomical studies of biopsy (surgical) material were investigated. The Multi-Criteria Decision Analysis (MCDA) method was used to justify the acceptance of criteria to assess compliance of procedures with process standards. The comparison of criteria made it possible to determine the most preferable and unacceptable criteria for assessing compliance and analyzing the degree of impact of a potential discrepancy on the result or the duration of the lifetime pathological and anatomical study.

Each criterion when conducting a multicriteria analysis of making a decision on its use to assess the compliance of procedures with technological standards during lifetime pathological and anatomical diagnostics was evaluated by five experts from 0 to 100 points. After determining the score for each criterion, this score is multiplied by the weight of the criterion to obtain the final score (the result of the criterion assessment). The total result is calculated as the sum of the final points for each criterion [95]. Tables 33, 34 and 35 present the criteria for evaluating the performance

of procedures at the pre-analytical, analytical and post-analytical stages of lifetime pathological and anatomical diagnostics of biopsy (surgical) material.

Table 33 - Evaluation matrix of criteria for performing procedures and inconsistencies of the pre-analytical stage during lifetime pathological and anatomical diagnostics of biopsy (surgical) material

Name criterion		Characteristics of non-conformities	Criterion score in points (S)	Criterion weight (W)	Result (S*W)
Pre-analytical stage					
1.	Discipline Formation Standard (Form No. 014/y, approved by Order of the Ministry of Health of Russia dated 24.03.2016 No. 179n)	The Direction does not indicate the macroscopic characteristic of the pathological process or the number of objects	96	0,297	28,512
		No diagnosis of underlying disease in Direction	94	0,291	27,354
		Additional clinical details are incomplete or missing	78	0,241	18,798
		Biological material registration number mismatch in vial direction and labeling	32	0,098	3,136
		The information in the Referral is not sufficient to identify the patient	24	0,073	1,752
	Result			1,000	79,552
2.	Technological standard for taking, pre-fixing and labelling biological material by a clinician	Violations of the technological standard for taking biological material	96	0,187	17,952
		Inadequate formalin pre-fixation of biological material	96	0,187	17,952
		Non-compliance of	81	0,157	12,717

		volumes of fixing agent and tissue sample during preliminary fixation of biological material			
		Pre-fixation of biological material after freezing	86	0,167	14,362
		Use of fixators inconsistent with the pathological and anatomical department	81	0,159	12,879
		Use of non-standard containers for biological material fixation	42	0,081	3,402
		Non-conformity of marking of objects with the information specified in the Direction	32	0,062	1,984
	Result			1,000	81,248
3.	Standard Delivery Times and Conditions for Transporting Biological Material to the Contractor	Transportation was carried out within the standard period (24 hours), but without formalin	96	0,256	24,576
		Transportation of biological material fixed with formalin was carried out within a period exceeding 24 hours after taking	93	0,247	22,971
		The biological material was transported in violation of the temperature interval providing diagnostic	94	0,246	23,124

		value of the biological material			
		Transportation of biological material is carried out in a way that does not provide safety for the courier, society and personnel receiving biomaterial for research	94	0,251	23,594
	Result			1,000	94,265
4.	Technological Standard for Material Registration in the Logbook of Receipt of Biopsy (Surgical) Material and Issuance of the Results of lifetime Pathological and Anatomical Studies (Registration Form No. 014-2/u approved by Order of the Ministry of Health of Russia dated 24.03.2016 No. 179n) in the Pathological and Anatomical Service	The unique registration number is NOT entered in the Journal of the accounting form No. 014-2/y	96	0,344	33,024
		Date and time of goods receipt are NOT indicated in the Logbook of the accounting form No. 014-2/y	89	0,319	28,391
		Serial numbers of vials and number of objects are NOT indicated in the Logbook of Accounting Form No. 014-2/y	94	0,337	31,678
	Result			1,000	93,093

Table 34 - Evaluation matrix of criteria for performing procedures and inconsistencies of the analytical stage during lifetime pathological and anatomical diagnostics of biopsy (surgical) material

	Name criterion	Characteristics of non-conformities	Criterion score in points (S)	Criterion weight (W)	Result (S*W)
Analytical stage					
1.	Technological standards for macroscopic study, cutting and final fixation of biological material in the pathological and anatomical service	Mechanical damage to tissue sample, excessive compression of unfixed tissue by tools	96	0,188	18,048
		Inadequate or suboptimal formalin fixation	98	0,191	18,718
		Ingress of foreign tissue, staples, suture material into the tissue sample	84	0,164	13,776
		Non-compliance with the technological standard of thickness of fabric samples, cut area, size, shape of samples during cutting	89	0,173	15,397
		Violations of cassette filling volume or selection of cassettes of inappropriate type	55	0,107	5,885
		Non-compliance of volumes of fixing agent and tissue sample during final fixation	90	0,177	15,930
	Result			1,000	87,754
2.	Technological Standard for Histological Processing of Biological Material	Violations of the procedure for wiring a tissue sample (excessive dehydration with microvibration along the edge of the tissue)	96	0,326	31,296

	(Wiring, Filling, Microtomy of Paraffin Blocks, Drying, Staining, and Manufacturing of Micropreparations)	Violations of the microtomy procedure (inappropriate temperature of the water bath, insufficient stretching of the tissue on the water bath)	98	0,334	32,732
		Staining abnormalities (cytoplasmic stains do not contrast well with nuclear staining)	100	0,340	34,000
	Result			1,000	98,028
3	Microscopic Description Standard in the Protocol for In-Life Pathological and Anatomical Examination of Biopsy (Surgical) Material, Registration Form No. 014 -1/y, approved by Order of the Ministry of Health of the Russian Federation No. 179n dated 24.03.2016	Microscopic description is not a justification for the diagnosis, does not contain a qualitative characteristic of the pathological process	96	0,389	37,344
		Microscopic description does not fully justify the diagnosis, contains an incomplete qualitative characteristic of the pathological process	96	0,390	37,440
		The Protocol does not indicate the assigned colors (reactions, definitions)	55	0,221	12,155
	Result			1,000	86,939
4.	Standard of Conclusion in the Protocol of In-Life Pathological and Anatomical Examination of Biopsy (Surgical) Material of Record Form No. 014 -1/y,	In the conclusion of the Protocol of in-life pathological examination of biopsy (surgical) material, a nosological diagnosis is indicated, in the tumor process, the stages T, N M, the number of studied and affected lymph nodes, the histological	94	0,321	30,174

	approved by Order of the Ministry of Health of the Russian Federation No. 179n dated 24.03.2016	type of the tumor, the degree of differentiation G are indicated, but the purity of the boundaries of the surgical incision is NOT indicated			
		n the conclusion of the Protocol of in-life pathological examination of biopsy (surgical) material, a nosological diagnosis is indicated, in the tumor process, the histological type of the tumor, the degree of differentiation G, but the stages T, N, M, the number of examined and affected lymph nodes, the purity of the boundaries of the surgical incision are indicated	98	0,336	32,928
		In the conclusion in the Protocol of the in-life pathological examination of biopsy (surgical) material, only nosological diagnosis is indicated	100	0,343	34,300
	Result			1,000	97,402

Table 35. Evaluation Matrix of Criteria for Performing Procedures and Inconsistencies of the postanalytic stage during lifetime pathological and anatomical diagnostics of Biopsy (Surgical) Material

	Name criterion	Characteristics of non-conformities	Criterion score in points (S)	Criterion weight (W)	Result (S*W)
Postanalytic stage					
1.	Technological Standard for Registration of Study Results in the Journal for Registration of the Receipt of Biopsy (Surgical) Material and Issuance of the Results of In-Life Pathological and Anatomical Studies (Accounting Form No. 014 -2/y)	The date of issue of the original Study Protocol is not indicated in the Logbook of Receipt of Biopsy (Surgical) Material and Issuance of the Results of In-Life Pathological and Anatomical Studies (Registration Form No. 014-2/y)	42	0,525	22,050
		There is no receipt from the recipient of the original Protocol in the Logbook of Receipt of Biopsy (Surgical) Material and Issuance of the Results of In-Life Pathological and Anatomical Studies (Registration Form No. 014-2/y)	38	0,475	18,050
	Result			1,0	40,10
2.	Regulatory deadlines for submission of Protocols for in-life pathological and anatomical studies of biopsy (surgical) material of registration form	The regulatory deadlines for submission of the Protocol of pathological and anatomical studies of biopsy (surgical) material (registration form No. 014-1/y) were exceeded due to the "additional cutting" of samples due to the assumption of violations of histological	96	0,329	31,584

	No. 014 -1/to the attending physicians	technology procedures			
		The regulatory deadlines for the submission of the Protocol of pathological and anatomical studies of biopsy (surgical) material (registration form No. 014-1/y) were exceeded due to the untimely provision of additional clinical information	96	0,329	31,584
		The regulatory deadlines for submission of the Protocol of pathological and anatomical studies of biopsy (surgical) material (registration form No. 014-1/y) were unreasonably exceeded, which influenced the timeliness of determining treatment tactics	100	0,342	34,200
	Result			1,0	97,368

The obtained data made it possible to determine the threshold values of the criteria and form priorities when assessing the compliance of the procedures with technological standards during lifetime pathological and anatomical diagnosis of biopsy (surgical) material (Table 36).

Table 36 - Prioritization of criteria for assessment of compliance of procedures with approved standards during lifetime pathological and anatomical diagnostics of biopsy (surgical) material

Priority of applied criterion	Total criteria score	Decision to apply the criterion
High priority	36 points and above	Criterion recommended for use
Medium priority	16-35 points	The criterion can be applied when justifying the impact on the result or the duration of the study
Low priority	15 points or less	Criterion not recommended

An individual analytical assessment of the implementation of standard procedures was carried out by experts in stages in the amount of 500 cases of lifetime pathological and anatomical studies of biopsy (surgical) material by random sampling.

Criteria scoring less than 15 points (insufficient information to identify the patient; non-conformity of the registration number in the Direction and vial labeling; inconsistency of volumes of fixing agent and tissue sample during preliminary fixation of biological material; the use of fixators inconsistent with the pathological and anatomical department, the use of non-standard containers for fixing biological material; violations of the cassette filling volume, ingress of foreign tissue into the tissue sample during cutting) were not used by experts to assess the compliance of the procedures with the approved standards.

In 115 cases (23.0%), additional clinical information in the Direction was provided in an incomplete volume when assessing the implementation of the standard for forming the Direction of accounting form No. 014/y. The provision of incomplete clinical information led to an increase in the duration of the study and the formation of the Protocol [107].

When assessing the fulfillment of the regulatory deadlines and conditions for the transportation of biological material, it was established that in 375 cases (75%) the transportation of biopsy (surgical) material was carried out in excess of the approved period (over 24 hours), but the material was delivered in formalin solution, and exceeding the period did not affect the result or the term of the study [107].

During the assessment of compliance with the registration standard in the Logbook of Biopsy (Surgical) Material Receipt and Issuance of the Results of In-Life Pathological and Anatomical Studies of the Registration Form No. 014-2/y in the Pathological and Anatomical Department, there were no inconsistencies affecting the result or the duration of the study.

During the assessment of the execution of cutting, final fixation, wiring, filling, microtomy of paraffin blocks, drying and staining of drugs in 44 cases (8.8%), inconsistencies were revealed, of which in 35 cases inadequate final fixation with

formalin was revealed, in 9 cases - violations of the staining procedure with uneven staining of the section, when cytoplasmic stains contrast poorly with nuclear staining. In 43 cases, the detected histotechnology violations affected the study duration (up to 7 working days in 14 cases, up to 12 working days in 29 cases): the result was obtained with an excess of the deadline, since the "wet archive" was subjected to additional cutting, followed by repetition of technological procedures (in cases with inadequate fixation) or the colored drug was returned before the "dewaxing" stage (in cases of uneven staining). The indicated deviations from histological technologies according to the scale of inconsistencies (0-1.0) were evaluated as 0.50.

When assessing the implementation of the microscopic description standard in the Protocol of intravital pathological and anatomical examination of biopsy (surgical) material of registration form No. 014-1/y, 25 cases of inconsistencies were identified when the microscopic description is the justification for the diagnosis, but contains an incomplete qualitative characteristic of the pathological process. Despite the fact that they did not have a significant impact on the result or the duration of the study, the experts rated these inconsistencies according to the scale of inconsistencies as 0.90.

When assessing the compliance with the conclusion standard, 102 inconsistencies (20.4%) were identified in the Protocol of lifetime pathological and anatomical examination of Biopsy (Surgical) Material of the Registration Form No. 014-1/y, when the nosological diagnosis, size, histological type of the tumor, degree of differentiation G were indicated, but the number of studied and affected lymph nodes, stage pN, and the state of the resection edges were not indicated (with a scale of 0.75).

When assessing the fulfillment of the regulatory deadlines for the implementation and submission of Protocols for lifetime pathological and anatomical studies of biopsy. (operating) material of accounting form No. 014-1/the attending physicians revealed that in 115 cases. (23%) exceeds the approved deadlines (with a deadline of up to 12 working days for those studies that did not require decalcification or the use of additional colors and immunohistochemical methods), which is justified by the untimely provision of additional clinical information to the pathologist (deviations from the approved regulatory deadlines are estimated on a scale as 0.75)

When assessing the fulfillment of the regulatory deadlines for the implementation and submission of Protocols for lifetime pathological and anatomical studies of biopsy (operating) material of accounting form No. 014-1/the attending physicians revealed that in 115 cases (23%) exceeds the approved deadlines (with a deadline of up to 12 working days for those studies that did not require decalcification or the use of additional colors and immunohistochemical methods), which is justified by the untimely provision of additional clinical information to the pathologist (deviations from the approved regulatory deadlines are estimated on a scale as 0.75).

During the analysis of violations of the deadlines for the submission of Study Protocols, the following structure was determined:

1) studies that did not require decalcification or the use of additional colors and immunohistochemical methods:

1.1 to 7 working days - 73 cases,

1.2 to 10 days - 13 cases;

2) studies that required the use of additional colors - up to 12 working days - 29 cases.

Thus, during internal quality control of 500 cases of in-life pathological and anatomical diagnostics of biopsy (surgical) material, 286 inconsistencies of performance were revealed according to the criteria selected for the study.

To determine the quality level of lifetime pathological and anatomical examination of biopsy (surgical) material, which is the arithmetic mean of the assessments made on the scale of inconsistencies, the formula [60] was used:

$$QILS == \frac{EHT + EMD + ECS + EPSP}{4},$$

where QILS - Quality Indicator for lifetime pathological and anatomical studies

EHT – evaluation of histological technology;

EMD – evaluation of microscopic description standard implementation in the Study Protocol;

ECS – evaluation of the conclusion standard in the Study Protocol;

EPSP – evaluation of the Study Protocol submission period

The results of determining of the Quality Indicator for lifetime pathological and anatomical studies are given in Annex D. It was revealed that in 183 cases (36.6%) the indicator of the quality of lifetime pathological and anatomical examination of biopsy (surgical) material is less than 1,000 (Table 37).

Table 37 - Quality indicators of the studies performed during lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region

№	QILS	Number of cases	Total points
1.	0,725	3	2,175
2.	0,750	13	9,75
3.	0,788	2	1,576
4.	0,813	25	20,325
5.	0,850	5	4,24
6.	0,875	17	14,875
7.	0,913	13	11,869
8.	0,938	103	96,614
9.	0,975	2	1,95
10.	1,000	317	317,00
TOTAL		500	480,384

The smallest quality indicator -0,725 was registered in three cases in which the execution of the histological technology for processing biological material had a score of 0,50, the execution of the microscopic description standard of the micropreparation – 0,90, the execution of the conclusion standard in the Protocol – 0,75, the execution of the Protocol submission period – 0,75.

The mean value of the quality indicator of lifetime studies is 0,961.

Thus, multi-criteria analysis made it possible to determine the most significant criteria for achieving the planned result by selecting from a specific set of criteria for a phased assessment of compliance of procedures with technological standards, ensuring consistency and reproducibility of the decision-making process.

Examinations of the quality of medical care carried out by insurance medical organizations and the territorial fund of compulsory medical insurance of the Novosibirsk Region until 2019 did not include an expert assessment of the quality of the Protocols in lifetime pathological and anatomical studies of biopsy (surgical) material. Since 2019, experts of insurance medical organizations, when monitoring the volume, timing, quality and conditions for the provision of medical care to patients with suspected cancer or with an established diagnosis of cancer, assess the Protocols of pathomorphological studies in accordance with the methodological recommendations of the Federal Compulsory Health Insurance Fund of 30.08.2018 No. 1086/30/and. In 2019, at the first stage, during external inspections, experts assessed the amount of information in the Protocols of pathomorphological studies in accordance with the specified methodological recommendations, the insufficient amount of information was assessed as a defect in the maintenance of medical records. In 2019, during the quality control of medical care by experts of insurance medical organizations in the profiles "oncology" and "surgery" in the amount of 3,073 cases (1,865 and 1,208 cases, respectively), 102 violations of the quality of filling in the Protocols of intravital pathological and anatomical studies of biopsy (operational) material of registration form No. 014-1/y or their absence in the medical records of patients. The volume of the financial claim amounted to 584.70 thousand rubles. Despite the same absolute number of violations of the study protocols identified during internal control and external examinations, the number of non-conformities per 100 cases of control during internal control was 20.4, during external examinations - 3.32, which indicates the quality of internal audits.

In order to study the strengths and weaknesses of the system for organizing lifetime pathological and anatomical diagnostics of biological material in the Novosibirsk Region, the degree of importance of various factors in ensuring the quality and timeliness of lifetime an analysis of the consistency of expert opinions on the list of issues of the Expert Assessment Sheets of the system for organizing lifetime pathological and anatomical diagnostics of biopsy (surgical) material of state medical organizations of the Novosibirsk Region was carried out. Kendall's concordance

coefficient was taken as a measure of consistency of expert opinions on the importance (value) of several factors in the system of organizing lifetime pathological and anatomical diagnostics of biological material in the Novosibirsk Region. In calculating the Kendall concordance coefficient, 7 stages were identified:

Stage 1. Creation of an expert commission. Number of factors n = 20, Number of experts m = 3

Stage 2. Collection of opinions of experts in lifetime pathological and anatomical diagnosis of biopsy (surgical) material in state medical organizations of the Novosibirsk Region through a survey. Factors affecting the organization, quality and timeliness of in-life pathological and anatomical studies of biopsy (surgical) material were evaluated by experts in points from 1 (minimum) to 5 (maximum). Assessment of the importance of factors was made by assigning them a rank number. The factor to which the expert gives the highest rating is assigned rank 1. If an expert recognizes several factors as equivalent, then they are assigned the same rank number. Since each of the three experts had related ranks (same rank numbers), the ranks were reformatted (Table 38).

Stage 3. Compilation of a consolidated rank matrix.

Based on reformatting the rating of factors of the system of organization of lifetime pathological and anatomical diagnostics of biopsy (surgical) material, a consolidated rank matrix was compiled (Table 39).

Table 38- Results of experts evaluation of factors influencing the organization, quality and timeliness of lifetime pathological and anatomical studies of biopsy (surgical) material

Factors	Experts					
	1		2		3	
	points	rank	points	rank	points	rank
Rating on a 5-point scale: the level of professional knowledge of personnel in the pathological and anatomical services of state medical organizations	3	12,5	3	14,5	3	15
Rating on a 5-point scale: the level of technical equipment in the pathological and anatomical services of state medical organizations	1	19,5	2	17,5	2	17
Rating on a 5-point scale: the degree of influence of standardization of technological processes on the quality of research during lifetime pathological and anatomical diagnostics in the pathological and anatomical services of state medical organizations of the Novosibirsk Region	2	17	1	19,5	2	17
Rating on a 5-point scale: the possibility of free research during lifetime pathological and anatomical diagnostics in the pathological and anatomical services of state medical organizations of the Novosibirsk Region	2	17	3	14,5	4	9,5
Rating on a 5-point scale: the degree of influence of the complexity of technological processes on the quality of lifetime pathological and anatomical research in the pathological and anatomical services of state medical organizations of the Novosibirsk Region	3	12,5	4	7,5	4	9,5

Table 38 (continued)

Factors	Experts					
	1		2		3	
	points	rank	points	rank	points	rank
Rating on a 5-point scale: the degree of influence of the use of a medical information system on the optimization of document flow in the pathological and anatomical services of state medical organizations of the Novosibirsk Region	5	1,5	4	7,5	4	9,5
Rating on a 5-point scale: the degree of influence of the use of equipment with a high degree of wear on the quality of the processes of lifetime pathological and anatomical studies in the pathological and anatomical services of state medical organizations of the Novosibirsk Region	4	6	4	7,5	4	9,5
Rating on a 5-point scale: the significance of remote advice from Reference Centers to improve the quality of lifetime pathological and anatomical studies of biopsy (surgical) material	4	6	4	7,5	5	2,5
Rating on a 5-point scale: the level of availability of lifetime pathological and anatomical diagnostics in the Novosibirsk Region	4	6	4	7,5	5	2,5
Rating on a 5-point scale: the quality of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region	3	12,5	4	7,5	4	9,5
Rating on a 5-point scale: systems for archiving research materials in the pathological and anatomical services of state medical organizations of the Novosibirsk Region	4	6	4	7,5	4	9,5

Table 38 (continued)

Factors	Experts					
	1		2		3	
	points	rank	points	rank	points	rank
Rating on a 5-point scale: the degree of influence of the quality of lifetime pathological and anatomical diagnostics on the speed of determining treatment tactics	4	6	5	1,5	5	2,5
Rating on a 5-point scale: the level of participation of personnel of pathological and anatomical services in making management decisions in state medical organizations of the Novosibirsk Region	3	12,5	3	14,5	2	17
Rating on a 5-point scale: the level of participation of personnel of pathological and anatomical services in making management decisions in state medical organizations of the Novosibirsk Region	1	19,5	2	17,5	1	19,5
Rating on a 5-point scale: the degree of influence of the lack of incentives to increase the productivity of the staff of pathological and anatomical services on the quality and timeliness of lifetime pathological and anatomical diagnostics of biological material	4	6	4	7,5	4	9,5
Evaluation on a 5-point scale: the degree of impact of the introduction of a medical information system on the quality of processes and the timeliness of lifetime pathological and anatomical studies of biological material in the pathological and anatomical services of state medical organizations of the Novosibirsk Region	4	6	4	7,5	4	9,5

End of Table 38

Factors	Experts					
	1		2		3	
	points	rank	points	rank	points	rank
Rating on a 5-point scale: the degree of influence of automation of technological procedures on the quality of processes and the timeliness of lifetime pathological and anatomical studies of biological material in the pathological and anatomical services of state medical organizations of the Novosibirsk Region	5	1,5	5	1,5	5	2,5
Rating on a 5-point scale: the degree of influence of logistics functions when sending biological material on the quality of lifetime pathological and anatomical studies in the Novosibirsk Region	3	12,5	4	7,5	4	9,5
Rating on a 5-point scale: the quality of registration of Protocols for studies of lifetime pathological and anatomical diagnostics in the Novosibirsk Region	3	12,5	3	14,5	4	9,5
Rating on a 5-point scale: the degree of influence of the lack of an effective logistics system on the timeliness of obtaining the results of lifetime pathological and anatomical studies of biopsy (surgical) material	2	17	1	19,5	1	19,5

After reformatting, the rank matrix was as follows.

Table 39 - Rank matrix based on the results of experts' assessment of factors affecting the organization, quality and timeliness of lifetime pathological and anatomical studies of biopsy (surgical) material

Experts	1	2	3
1	12,5	14,5	15
2	19,5	17,5	17
3	17	19,5	17

4	17	14,5	9,5
5	12,5	7,5	9,5
6	1,5	7,5	9,5
7	6	7,5	9,5
8	6	7,5	2,5
9	6	7,5	2,5
10	12,5	7,5	9,5
11	6	7,5	9,5
12	6	1,5	2,5
13	12,5	14,5	17
14	19,5	17,5	19,5
15	6	7,5	9,5
16	6	7,5	9,5
17	1,5	1,5	2,5
18	12,5	7,5	9,5
19	12,5	14,5	9,5
20	17	19,5	19,5

Rank matrix

Factors / Experts	1	2	3	Rank sum	d	d^2
x_1	12,5	14,5	15	42	10,5	110,25
x_2	19,5	17,5	17	54	22,5	506,25
x_3	17	19,5	17	53,5	22	484
x_4	17	14,5	9,5	41	9,5	90,25
x_5	12,5	7,5	9,5	29,5	–2	4
x_6	1,5	7,5	9,5	18,5	–13	169
x_7	6	7,5	9,5	23	–8,5	72,25
x_8	6	7,5	2,5	16	–15,5	240,25
x_9	6	7,5	2,5	16	–15,5	240,25
x_{10}	12,5	7,5	9,5	29,5	–2	4
x_{11}	6	7,5	9,5	23	–8,5	72,25
x_{12}	6	1,5	2,5	10	–21,5	462,25
x_{13}	12,5	14,5	17	44	12,5	156,25
x_{14}	19,5	17,5	19,5	56,5	25	625

x_{15}	6	7,5	9,5	23	–8,5	72,25
x_{16}	6	7,5	9,5	23	–8,5	72,25
x_{17}	1,5	1,5	2,5	5,5	–26	676
x_{18}	12,5	7,5	9,5	29,5	–2	4
x_{19}	12,5	14,5	9,5	36,5	5	25
x_{20}	17	19,5	19,5	56	24,5	600,25
∑	210	210	210	630	—	4 686

where

$$d = \sum x_{ij} - \frac{\sum\sum x_{ij}}{n} = \sum x_{ij} - 31.5$$

Check that the matrix has been created correctly based on the checksum calculation:

$$\sum x_{ij} = \frac{(1+n)n}{2} = \frac{(1+20)20}{2} = 210$$

The sums of the columns of the matrix are equal to each other and the checksum (the matrix is composed correctly).

Stage 4. Analysis of the significance of the studied factors is presented in Table 40.

Table 40 - Distribution of factors by significance according to the results of expert evaluation

Factors	Rank sum
x_{17}	5,5
x_{12}	10
x_8	16
x_9	16
x_6	18,5
x_7	23

x_{11}	23
x_{15}	23
x_{16}	23
x_5	29,5
x_{10}	29,5
x_{18}	29,5
x_{19}	36,5
x_4	41
x_1	42
x_{13}	44
x_3	53,5
x_2	54
x_{20}	56
x_{14}	56,5

Stage 5. Assessment of the average consistency of opinions of all experts.

We used the concordance coefficient for the case when there are identical values of factors in the estimates of one expert:

$$W = \frac{S}{\frac{1}{12} * m^2(n^3 - n) - m * \sum T_i},$$

where S = 4686, n = 20, m = 3

$$T_i = \frac{1}{12} * \sum (t_i^3 - t_i)$$

where T_i – the number of bundles (types of repeating elements) in the assessments of the i-th expert;

t_l – number of elements in the l-th bundle for the i-th expert (number of repeating elements).

$T_1 = [(6^3 - 6) + (2^3 - 2) + (3^3 - 3) + (2^3 - 2) + (7^3 - 7)] / 12 = 48,5$

$T_2 = [(4^3 - 4) + (2^3 - 2) + (2^3 - 2) + (10^3 - 10) + (2^3 - 2)] / 12 = 89$

$T_3 = [(3^3 - 3) + (10^3 - 10) + (4^3 - 4) + (2^3 - 2)] / 12 = 90$

$\sum T_i = 48,5 + 89 + 90 = 227,5$

$$W = \frac{4686}{\frac{1}{12} * 3^2(20^3 - 20) - 3 * 227.5} = 0.88$$

W = 0.88 indicates that there is a high degree of agreement between expert opinions.

Stage 6. Estimation of the significance of the concordance coefficient.

For this purpose, Pearson's matching criterion is calculated:

$$X^2 = \frac{S}{\frac{1}{12} * mn(n+1) + \frac{1}{n-1} * \sum T_i}$$

$$X^2 = \frac{4686}{\frac{1}{12} * 3 * 20(20+1) + \frac{1}{20-1} * 227.5} = 50.37$$

The calculated χ^2 was compared with the table value for the number of degrees of freedom K = n - 1 = 20 - 1 = 19 and at a given significance level $\alpha = 0.05$

Since the estimated χ^2 is 50.37 ≥ tabular (30.14353), then W = 0.88 is not a random value, and therefore the results obtained make sense and can be used in further studies.

Stage 7. Preparation of the expert committee decision.

Based on the sum of the ranks, the weighting indicators of the factors considered were calculated. The polling matrix is transformed into a transformed rank matrix using the formula:

$$s_{ij} = x_{max} - x_{ij}$$

where $x_{max} = 19,5$

Table 41 - Matrix of transformed ranks and factors weight indicators according to the results of expert assessment

№ п.п./ Experts	1	2	3	∑	Weight λ
1	7	5	4,5	16	0,03056
2	0	2	2,5	4,5	0,00833
3	2,5	0	2,5	5	0,00926
4	2,5	5	10	17,5	0,03241
5	7	12	10	29	0,0537
6	18	12	10	40	0,07407
7	13,5	12	10	35,5	0,06574
8	13,5	12	17	42,5	0,0787
9	13,5	12	17	42,5	0,0787
10	7	12	10	29	0,0537
11	13,5	12	10	35,5	0,06574
12	13,5	18	17	48,5	0,08981
13	7	5	2,5	14,5	0,02685
14	0	2	0	2	0,0037
15	13,5	12	10	35,5	0,06574
16	13,5	12	10	35,5	0,06574
17	18	18	17	53	0,09815
18	7	12	10	29	0,0537
19	7	5	10	22	0,04074
20	2,5	0	0	2,5	0,00463
Total	—	—	—	540	1

The analysis showed the greatest importance in the system of organization of intravital pathological and anatomical studies of biopsy (surgical) material of four factors: the degree of automation of technological procedures for intravital pathological and anatomical studies, the impact of the quality of intravital pathological and anatomical diagnostics on the speed of determining therapeutic tactics, the importance of remote advice from Reference Centers to improve the quality of research, the impact of using a medical information system on optimizing document flow in the pathological

and anatomical services of state medical organizations of the Novosibirsk Region (Table 41).

SUMMARY

1. The analysis of the demand for endoscopic studies with biopsy in intestinal diseases in the Novosibirsk Region revealed a steady increase in indicators both in the total number of registered diseases (from 2.4% in 2015 to 26.2% in 2018) and in the newly diagnosed intestinal pathology (from 64.2% in 2015 to 85% in 2018).

2. From the list of disorders most affecting the quality of intravital pathological and anatomical diagnosis of biopsy (surgical) material, clinical doctors more often noted violations of the standards for taking, fixing and directing biological material at the pre-analytical stage (26.6 ± 2.4)%), insufficient material and technical equipment of the pathological and anatomical service (26 ± 2.3) %) and the lack of an effective logistics system (23.4 ± 2.3)%), heads of medical organizations more often noted insufficient material and technical equipment of the pathological and anatomical service (34 ± 4.7)%), weak quality management system for intravital pathological and anatomical diagnostics (24 ± 4.3)%), personnel deficit in pathological and anatomical services (23 ± 4.2)%).

3. The dependence of the assessment of the quality of filling in the Study Protocols on the conditions for the provision of medical care was revealed: the share of hospital doctors who are fully satisfied with the quality of filling in the Study Protocols is more (73.9 ± 3.5)%) than among doctors of outpatient medical organizations (40.7 ± 3.5)%). The share of specialists who are completely unsatisfied with the quality of filling out the Research Protocols is much less among hospital doctors (7.5 ± 2.1)%) than among doctors of outpatient medical organizations (25.4 ± 3.2)%).

4. According to a survey of doctors of clinical specialties in the Novosibirsk Region, the integral satisfaction coefficient with the quality of filling in the Protocols of lifetime pathological and anatomical studies of biptic (surgical) material was 0.389, which corresponds to a low level of quality. First of all, the insufficient scope of the description in the conclusions of the morphological verification of malignant neoplasms does not satisfy.

5. The multi-criteria decision-making analysis made it possible to determine priority criteria for assessing compliance with the technological standards of those procedures that most affect the duration and result of lifetime pathological and anatomical examination of biological material. The most significant criteria are: fulfillment of the histological technology for processing biological material, the standard of microscopic description and the standard of conclusion in the Protocol of intravital pathological and anatomical examination of biopsy (surgical) material of the registration form No. 014-1/y, fulfillment of the regulatory deadlines for providing the attending physician with the Protocol of intravital pathological and anatomical examination of biopsy (surgical) material.

6. Within the framework of individual expert analysis, the performance of each of the four criteria was assessed on a scale from 0 to 1.0, depending on the degree of deviation of the procedure from the standard (standard). For each case of expert assessment, an average indicator of the quality level of the study was calculated.

7. Of the 286 cases of violations identified during internal quality control of in-life pathological and anatomical studies of biopsy (surgical) material, 40.2% were violations of the approved study deadlines and the provision of Protocols for in-life pathological and anatomical studies of biopsy (surgical) material to the attending physicians, 35.7% were non-compliance with the standard for filling out the conclusion of the Study Protocol. The percentage of violations of the technological standards for laboratory processing of biological material, staining of micropreparations and microscopic description in the Study Protocol was 24.1%. Violations of histological technologies of final fixation and staining of tissue samples led to violations of the terms of the study. The mean quality of the in-life pathological and anatomical examination was 0.961 points.

8. During external examinations of the quality of medical care, violations of the filling in the Protocols of intravital pathological and anatomical studies of biopsy (surgical) material were detected in 102 cases (3.3% of the examination volume in the profiles "oncology" and "surgery"). In absolute terms, this corresponds to the number of non-compliances with the standard for filling out the conclusion in the Protocols, which

was revealed during internal control.

9. The calculated Kendall concordance ratio (W = 0.88) showed a high degree of agreement of expert opinions on the importance of various factors in the organization system, the quality and timeliness of intravital pathological and anatomical studies of biopsy (surgical). The most significant factors are recognized: the degree of automation of technological procedures of intravital pathological and anatomical studies (λ = 0.09815), the impact of the quality of intravital pathological and anatomical diagnostics on the speed of determining treatment tactics (λ = 0.08981), the importance of remote advice from reference centers to improve the quality of research (λ = 0.0787), the impact of using a medical information system on the optimization of document flow in the pathological and anatomical services of state medical organizations Novosibirsk Region (λ = 0.07407). These factors made it possible to determine the main directions of improving the system for organizing lifetime pathological and anatomical diagnostics of biological material in state medical organizations of the Novosibirsk Region.

CHAPTER 5 ORGANIZATIONAL AND FUNCTIONAL MODEL OF LIFETIME PATHOLOGICAL AND ANATOMICAL DIAGNOSTICS OF BIOPSY (SURGICAL) MATERIAL IN THE NOVOSIBIRSK REGION

5.1 Analysis of factors leading to a decrease in the effectiveness of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in medical organizations of the Novosibirsk Region

Analysis of factors leading to a decrease in the effectiveness of intravital pathological and anatomical diagnostics made it possible to distinguish the following groups:

1) a group of resource and logistic factors: lack of transport for the timely delivery of biological material to the investigator, a shortage of medical personnel and the necessary equipment for the implementation of histological technologies for processing biopsy (surgical) material;

2) group of information and communication factors - absence or failures of MIS (LIS) functioning, untimely receipt of information;

3) a group of technological factors - violations of the standard for taking biological material, histological technologies for processing biological material;

4) a group of analytical factors - violations of the filling standard of the Study Protocol [169].

The study of these factors was the basis for the formation of an organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region, combining the introduction of MIS, automatic laboratory complexes (robotics) and remote examination and consultation by a pathologist of video images (scans) of all areas of the micropreparation [169; 170; 171].

5.2 Main directions for improving the organization of lifetime pathological and anatomical diagnostics of biopsy (surgical) material

The study of the causal relationships of the decrease in the effectiveness of lifetime pathological and anatomical diagnostics of biopsy (surgical) material made it possible to speak about the need to change the system of organization of lifetime pathological and anatomical diagnostics in medical organizations of the Novosibirsk Region and to form an organizational and functional model of this type of diagnostics. The formation of the organizational and functional model began with the preparation and approval of local regulatory documents defining the Procedure for conducting in-life pathological and anatomical studies of biopsy (surgical) material in a medical organization, the organization and procedure for conducting internal quality control and safety of medical activities, a formalized map of internal quality control of lifetime pathological and anatomical studies of biopsy (surgical) material. Standard operating procedures for carrying out individual stages of the diagnostic process were formed and approved**.**

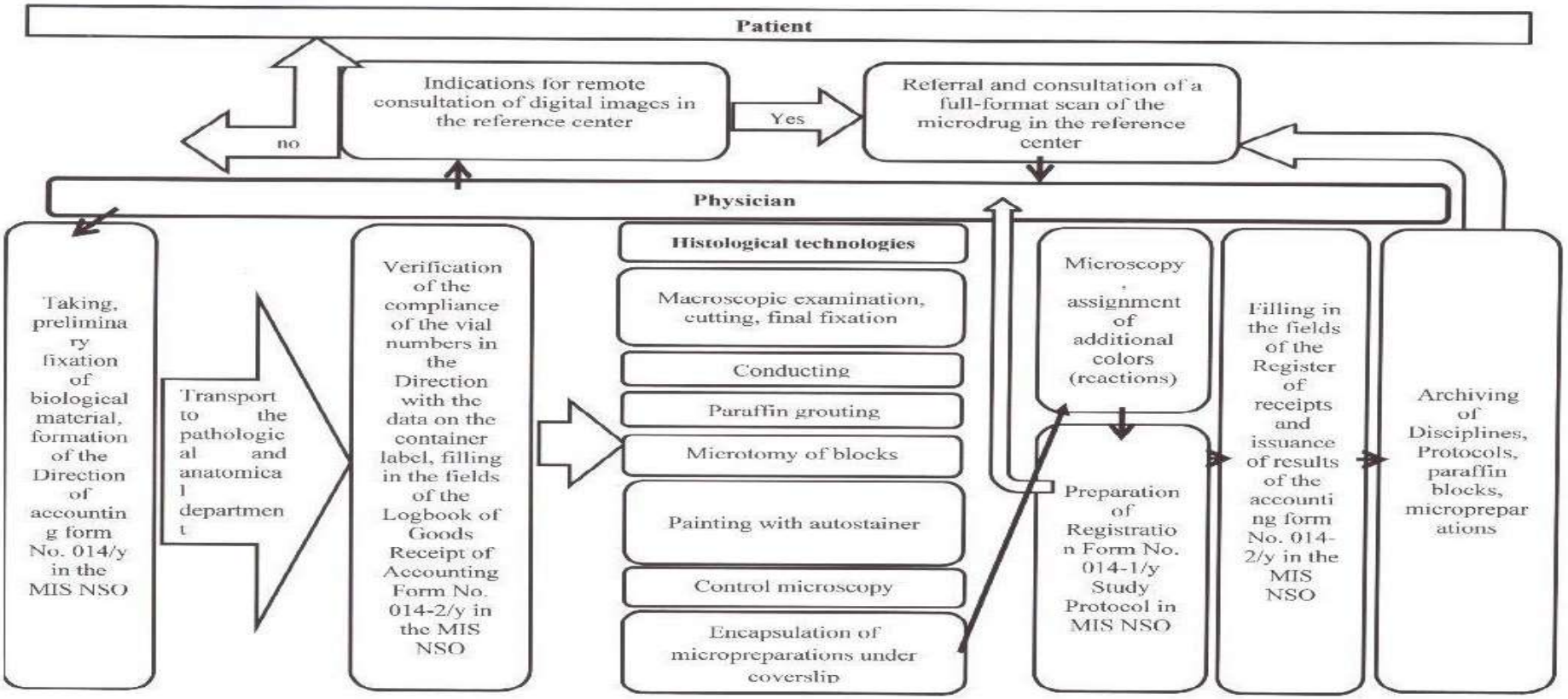


Figure 7 - Organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region

The organizational and functional model of transformation of the system of lifetime pathological and anatomical diagnostics of biopsy (surgical) material, formed on the basis of the process approach, has been introduced into the practical diagnostic work of the Department of Pathological Anatomy and the Department of Clinical Pathomorphology of the outpatient link of the GBUZ NSO "City Clinical Hospital No. 1," as well as the Department of Pathological Anatomy of the GBUZ NSO "Novosibirsk Regional Clinical Oncological dispensary."

The Medical Information System of the Novosibirsk Region (hereinafter referred to as the MIS NSO) has been identified as a tool for using information and communication technologies. At the same time, the GBUZ NSO "City Clinical Hospital No. 1" used the successful experience of introducing a medical information system into the activities of the pathological and anatomical department of the FGBUZ "Siberian District Medical Center" of the FMBA of Russia in Novosibirsk. As part of the study, technical specifications were prepared to use the capabilities of the MIS NSO. In 2020, in connection with the implementation of the forms of accounting documentation on lifetime pathological and anatomical diagnostics, the MIS NSO approved the standard operating procedure for the use of additional functionality of the MIS NSO by oncologists in the formation of Directions for research, pathologists in the formation of Protocols for lifetime pathological and anatomical studies of biopsy (surgical) material in the hospital and in outpatient conditions [53]. The algorithm for filling out the Directions, Research Protocols and the Journal for Registering the Receipt of Biopsy (Operational) Material and Issuing Results in the Medical Information System, developed jointly with the Informatization Center of the Medical Information and Analytical Center, was approved by the Ministry of Health of the Novosibirsk Region 24.03.2020 in the form of methodological recommendations. The effectiveness of the developed information mechanisms was studied. In addition, the engineering and technical personnel of the Informatization Center of the Medical Information and Analytical Center developed and implemented a mechanism for transferring structured electronic medical documents from the MIS NSO to the integrated electronic medical record of the patient, which combines information about the patient's health coming

from various medical organizations in the Novosibirsk Region. A User Guide has been formed for the transfer of structured electronic medical documents (discharge reports and instrumental research protocols, including those accompanied by the procedure for taking biopsy material) from the MIS NSO to the integrated electronic medical record. In order to maximize the reliability and reproducibility of the information stored in the Integrated Electronic Medical Archive, structured electronic medical documents are subject to format-logical control upon admission to the integrated electronic medical record. If errors are detected, the corresponding record is saved in the integrated electronic medical record, but is made unavailable for viewing by new users, and a new version of the record is added during the adjustment. Users who have previously accessed a closed record can continue to access it with instructions on deleting or replacing a new one, as well as the reason for deleting [53].

Calculation of accounting units (cases) was implemented on the basis of executed Protocols and complexity categories of the test material.

Mechanisms have been developed to integrate the information specified by the specialist doctor during the initial examination, the diagnostic study with the taking of biological material, in the protocol of the operation and allowing the formation of Directions for a lifetime pathological and anatomical study of biopsy (surgical) material (form No. 014/y), for a cytological diagnostic study (form No. 203/y-02) in automatic mode [52, 53].

When forming a Referral for cytological examination of material obtained during preventive gynecological examination, screening (form No. 446/y), a summary table is created, into which the gynecological history of each patient is automatically entered, which frees up the time of the gynecologist to fill out the referral on paper. The medical information system provides electronic interaction between a cytologist and a gynecologist who carries out a preventive medical examination. In this case, the answer the cytologist is available in real time on average 24-28 hours after the delivery of the material to the laboratory [52. 53].

In electronic form, not only Directions, but also Research Protocols are saved (form No. 014-1/y, reverse sides of forms No. 203/y-02 and No. 446/y).

An electronic version of the Journal of Registration of the Receipt of Biopsy (Surgical) Material and the Issuance of the Results of lifetime pathological and anatomical studies of Form No. 014-2/y was introduced, which freed laboratory technicians from the need to rewrite the necessary information, minimized personnel costs for this type of work (saving up to 50%) [52, 53].

When conducting in-life pathological and anatomical studies of biopsy (surgical) material, the MIS NSO allows integrating three registration forms: Direction, Protocol and Log of the receipt of biopsy (surgical) material and the issuance of the results of in-life pathological and anatomical studies [52]. Before performing a macroscopic examination of biopsy (surgical) material, a pathologist receives all information in a unified form, without additional time spent filling out the form by a clinician. All subsequent stages of lifetime pathological and anatomical examination (macroscopic description, complexity category of biopsy (surgical) material, date and time of excision, number of objects taken into wiring, assigned colors, microscopic description, conclusion and code according to International Classification of Diseases-10 are recorded by the pathologist in the mock-up of the electronic protocol. It should be noted that the MIS of the NSO allows to additionally record a digital image of the drug of interest obtained by means of its full-format scanning to the Protocol of lifetime pathological and anatomical examination of biopsy (surgical) material or cytological examination formed according to the standard. The presence of digital images of drugs makes it possible to revise them and obtain a "second" opinion, as well as assess the dynamics of pathological processes [52, 53].

Automation of procedures is an important tool to minimize the influence of the human factor on the execution of histological technologies for processing biopsy (surgical) material. The greatest importance of automation was revealed during staining of sections on slides, which is achieved by unification of staining conditions and allows eliminating subjective reasons for errors. The least automated technology remains paraffin block microtomy. The execution of each histological procedure is evaluated in terms of compliance with the conditions of the technology, if violations are detected (conditions for final fixation of the material, change of reagents during wiring, the

presence of artifacts during microtomy and staining), the information is recorded in the Nonconformity Log and transferred to the Senior Laboratory Assistant for appropriate correction of the procedure with a possible redesign of processes. One of the conditions for ensuring the quality of the micropreparation is control microscopy performed by a laboratory assistant. The possibility of remote consultation of digitized full-format scans of micropreparations in federal reference centers almost completely excluded significant errors in the formation of research protocols. In 2020, the Reference Centers consulted 120 cases of lifetime pathological and anatomical studies of biopsy (surgical) material, in 2021 - 85 cases, in 2022 - 137 cases. The consultations were carried out in accordance with the order of the Ministry of Health of Russia dated 23.12.2020 No. 1363n "On approval of the Procedure for sending insured persons to medical organizations, the functions and powers of the founders in respect of which are carried out by the Government of the Russian Federation or federal executive bodies, to provide medical care in accordance with the uniform requirements of the basic compulsory health insurance program."

5.3 Scientific substantiation and assessment of the effectiveness of the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region

The effectiveness of the use of the organizational and functional model of lifetime pathological and anatomical diagnostics of biological material was assessed with continuous monitoring in the following areas: economic efficiency - the ratio of costs to results, based on the rational use of available resources, increased labor productivity and a decrease in the cost of diagnostic services; medical efficiency - the degree of achievement of the planned result in terms of timely and complete diagnostics.

In order to assess the cost-effectiveness, a comparative study of the ratio of the costs of conducting lifetime pathological diagnostics of biopsy (surgical) material and income from sales using different forms and different conditions for using the same medical technology was carried out [2]. The assessment of medical efficacy is based on

a study of the compliance of the implementation of histological technologies with standards, as well as registration of registration forms during lifetime pathological and anatomical studies in accordance with the requirements of the order of the Ministry of Health of Russia dated 24.03.2016 No. 179n "On the rules for conducting pathological and anatomical studies" and clinical recommendations for a specific nosological form.

Table 42 - Assessment of the economic efficiency of the Department of Clinical Pathomorphology of the Outpatient Department of GBUZ NSO "GKB No. 1" before and after the introduction of the organizational and functional model of lifetime pathological and anatomical diagnostics

Indicator	Unit of measure	Period			Deviation 2022 by 2019
		2019	2020	2022	
Number of cases of lifetime pathological and anatomical studies of biopsy (surgical) material	cases	12 483	13 245	14 004	+1 521
Number of objects of lifetime pathological and anatomical studies of biopsy (surgical) material	objects	56 174	46 565	46 830	–9 344
Number of objects per 1 case of lifetime pathological and anatomical studies of biopsy (surgical) material	objects	4,5	3,52	3,34	–1,16
Number of conventional labor units per year	Conventional units of labor	736 473,00	636 367,40	576 455,40	–160 017,60

Table 42 (continued)

Indicator	Unit of measure	Period			Deviation 2022 by 2019
		2019	2020	2022	
Number of conventional labor units per 1 case	Conventional units of labor	59,00	48,05	41,16	–17,84
Fund-making (Department of Clinical Pathomorphology)	Thousand rubles/person	1 954,96	2 105,6	2 156,1	+201,14
Endowment (Department of Clinical Pathomorphology)	—	1,0	1,1	1,9	+0,9
Fund intensity (Department of Clinical Pathomorphology)	—	1,0	0,9	0,5	–0,5
Income of the Clinical Pathomorphology Department s	thousand rubles.	31 279,36	36 600,29	64 510,88	+33 231,52
Costs of the Clinical Pathomorphology department	thousand rubles.	36 170,25	35 730,21	41 926,66	+5 756,41
Absolute cost-effectiveness of the clinical pathomorphology department	thousand rubles	–4 890,89	–870,08	+22 584,22	+27 475,11

Table 42 (continued)

Indicator	Unit of measure	Period			Deviation 2022 by 2019
		2019	2020	2022	
Relative cost-effectiveness of clinical pathomorphology department	%	86,5	102,4	153,9	+67,4
Average actual cost of 1 case	rubles	2 897,56	2 697,64	2 993,91	+ 96,35
Average actual cost of in-life pathological and anatomical diagnostics services per 1 conventional unit of labor	rubles	49,11	56,15	72,73	+23,62
Number of outpatient visits	visits	144 297	122 496	131 896	–12 401
Number of cases of lifetime pathological and anatomical examinations per 1 visit	cases	0,09	0,11	0,11	–0,02

End of Table 42

Indicator	Unit of measure	Period			Deviation 2022 by 2019
		2019	2020	2022	
Number of subjects of in-life pathological and anatomical examinations per 1 visit	objects	0,39	0,38	0,36	–0,03
Average actual cost of lifetime pathological and anatomical diagnostics services per 1 visit	rubles	250,67	291,68	317,88	+67,21
Income from outpatient care	thousand rubles	217 962,50	257 752,30	335 405,00	+117 442,50
Outpatient costs	thousand rubles	282 868,80	309 901,40	342 688,30	+59 819,50
Absolute cost-effectiveness in outpatient care	thousand rubles	–64 906,30	–52 149,10	–7 283,30	+57 623,00

According to Table 42, the number of cases of intravital pathological and anatomical studies of biopsy (surgical) material in the Department of Clinical Pathomorphology of the outpatient link in 2022 compared to 2019 increased by 12.2%. The number of subjects per 1 case of intravital pathological and anatomical examination of biopsy (surgical) material in the Department of Clinical Pathomorphology decreased by 25.8% over the compared period. There is a decrease in the labor intensity of 1 case of lifetime pathological and anatomical examination by 30.2% (from 59 conventional labor units in 2019 to 41.16 conventional labor units in 2022). The stock-making rate of personnel per 1 employee in the department of clinical pathomorphology in 2020 compared to 2019 increased by 7.7% (from 1,954.96 to 2,105.6 thousand rubles), in 2022 compared to 2020 - by 2.4%. This is due to the acquisition of an autostainer in 2019 as part of the material and technical re-equipment program of the structural unit.

The fund output of the Department of Clinical Pathomorphology for the period from 2019 to 2022 increased by 90%, the fund intensity decreased by 50%. It can be seen from the table that in the department of clinical pathomorphology of the outpatient link in 2022, relative to 2019, there is an increase in both income and expenses. Income growth is determined by an increase in tariffs for the provision of diagnostic services for intravital pathological and anatomical diagnostics on an outpatient basis, depending on the category of complexity of the material approved by the Tariff Agreement in the compulsory medical insurance system of the Novosibirsk Region. Revenues from the sale of services in 2022 compared to 2019 increased 2 times - from 31,279,36 thousand rubles to 64,510,88 thousand rubles, expenses for the same period increased by 15.9%. The predominant increase in the revenue side determined the absolute economic efficiency of the clinical pathomorphology department, which amounted to 2022 thousand rubles in 22,584,22 (2019 thousand rubles in 4,890,89), the relative efficiency in 2022 was 153.9%. The average actual cost of 1 case of intravital pathological and anatomical examination of biopsy (surgical) material for the period from 2019 to 2022 increased by 3.3%. When providing medical care on an outpatient basis, the number of visits from 2019 to 2022 increased by 8.6%. The average actual cost of services for intravital pathological and anatomical diagnostics per 1 visit increased by 26.8% over the analyzed period.

The analysis of the structure of actual expenses in the clinical pathomorphology department for the period from 2019 to 2022 shows the largest increase in the cost code "Remuneration and accruals for the remuneration of the main personnel" (by 24.4%), the cost of the code "Reagents, disposable tools, soft equipment involved in the process of providing medical services" increased by 10.5% during the analyzed period (Table 44).

The cost of cases of lifenime pathological and anatomical diagnosis of biopsy (surgical) material performed in a hospital in the pathological anatomy department of the GBUZ NSO "GKB No. 1" is included in the cost of completed cases of treatment in a round-the-clock hospital for specific clinical and statistical groups. To determine the cost of intravital pathological and anatomical diagnostics in the department of

pathological anatomy, the standards of financial costs for conducting one pathological and anatomical study in order to detect cancer, approved by the Decrees of the Government of the Novosibirsk Region "On the territorial program of state guarantees of free medical care to citizens in the Novosibirsk Region" (in 2019 - 620.32 rubles, in 2020 - 655.61 rubles, in 2022 - 2,304,28 rubles). Assessment of the economic efficiency of the Department of Pathological Anatomy (in terms of lifetime pathological and anatomical diagnostics) GBUZ NSO "GKB No. 1" before and after implementation organizational and functional model of lifetime pathological and anatomical diagnostics is presented in Table 43.

Table 43 - Assessment of the economic efficiency of the pathological anatomy department (in terms of lifetime pathological and anatomical diagnostics) GBUZ NSO "GKB No. 1" before and after implementation organizational and functional model of lifetime pathological and anatomical diagnostics

Indicator	Unit of measure	Period			Deviation 2022 by 2019
		2019	2020	2022	
Number of cases of intravital pathological and anatomical studies of biopsy (surgical) material	cases	15 258	16 188	13 556	–1 702
Number of objects of lifetime pathological and anatomical studies of biopsy (surgical) material	objects	85 212	71 500	106 738	+21 526
Number of objects per 1 case of lifetime pathological and anatomical studies of biopsy (surgical) material	objects	5,6	4,42	7,87	+2,27

Table 43 (continued)

Indicator	Unit of measure	Period			Deviation 2022 by 2019
		2019	2020	2022	
Fund-making (Department of Pathological Anatomy)	Thousand rubles/person	537,92	526,30	673,41	+135,49
Endowment (Department of Pathological Anatomy)	—	0,5	0,6	1,4	+0,9
Fund intensity (Department of Pathological Anatomy)	—	1,8	1,6	0,7	–1,1
Income of the Department of Pathological Anatomy (in terms of intravital diagnostics)	thousand rubles	9 464,84	10 613,01	31 236,82	+ 21 771,98
Costs of the Department of Pathological Anatomy (in terms of intravital diagnosis)	thousand rubles	19 764,62	18 512,65	19 814,83	+50,21
Absolute cost-effectiveness (Department of Pathological Anatomy)	thousand rubles	–10 299,78	–7 899,64	+11 421,99	+21 721,77

Table 43 (continued)

Indicator	Unit of measure	Period			Deviation 2022 by 2019
		2019	2020	2022	
Relative cost effectiveness (Department of Pathological Anatomy)	%	47,9	57,3	157,6	+109,70
Average actual cost of 1 case of intravital pathological and anatomical diagnosis (Department of Pathological Anatomy)	rubles	1 295,4	1 143,60	1 461,70	+166,30
Number of beds in hospital	units	1 402	1 402	1 402	0
Number of beds in surgical and oncology services	units	821	752	795	–26
Number of hospital admissions	cases	48 467	43 923	47 008	–1 459
Number of hospital admissions in surgical and oncology services	cases	31 148	26 923	33 382	+2 234

Table 43 (continued)

Indicator	Unit of measure	Period			Deviation 2022 by 2019
		2019	2020	2022	
Number of surgeries	surgeries	20 759	19 546	22 229	+1 470
Bed load per year	cases	34,6	31,3	33,5	–1,1
Bed load in services with surgical activity	cases	37,9	35,8	42,0	+4,1
Number of cases of lifetime pathological and anatomical examinations per 1 case of hospitalization in hospital	cases	0,315	0,369	0,288	–0,027
Number of cases of intravital pathological and anatomical examinations per 1 case of hospitalization in departments with surgical activity (surgical and oncological service)	cases	0,490	0,601	0,406	–0,084

Table 43 (continued)

Indicator	Unit of measure	Period			Deviation 2022 by 2019
		2019	2020	2022	
Number of cases of lifetime pathological and anatomical examinations per 1 surgery	cases	0,74	0,82	0,61	–0,13
Number of objects of lifetime pathological and anatomical studies per 1 case of hospitalization in departments with surgical activity (surgical and oncological services)	objects	2,74	2,66	3,20	+0,46
Number of objects of lifetime pathologic and anatomical Studies per 1 Surgery	objects	4,10	3,65	4,80	+0,70

Table 43 (continued)

Indicator	Unit of measure	Period			Deviation 2022 by 2019
		2019	2020	2022	
Average actual cost of - lifetime pathological and anatomical diagnostics services for 1 case of hospitalization in hospital	rubles	407,80	421,48	421,52	+13,72
Average actual cost of lifetime pathological and anatomical diagnostics services per 1 case of hospitalization in departments with surgical activity (surgical and oncological)	rubles	634,54	687,61	593,58	–40,96
Average actual cost of lifetime pathological and anatomical diagnostics services per 1 surgical intervention	rubles	952,10	947,13	891,40	–60,7
Indicator	Unit of measure	Period			Deviation 2022 by 2019
		2019	2020	2022	
Income hospital	thousand rubles	1 961 662,60	1 933 142,20	2 515 537,50	+553 874,90
Costs for hospital	thousand rubles	1 885 933,80	2 355 014,3	3 172 076,90	+1 286 143,1
Absolute economic efficiency by hospital	thousand rubles	+75 728,80	–421 872,10	–656 539,40	–732 268,20

In the department of pathological anatomy, in which lifetime pathological and anatomical studies of biopsy (operating) material in the areas of doctors of surgical and

oncological services of a round-the-clock hospital, in 2022 against the background of a decrease in the number of research cases (compared to 2019 by 11.2%), the number of study subjects increased by 1 case from 5.6 to 7.87 (by 25, 3%), which is determined by the diagnostic feasibility of the volume of sample cutting and an increase in the number of objects of the test material of the difficulty category V (from 2019 to 2022 - from 5,283 to 8,540 or 161.7%). The indicator of the stock-making capacity of personnel per 1 employee of the department of pathological anatomy in 2022 compared to 2019 increased by 25.2% (from 537.92 thousand rubles to 673.41 thousand rubles), which is explained by the equipment of the department with microscopic equipment and tools. The fund output of the Department of Pathological Anatomy for the period from 2019 to 2022 increased by 2.8 times (from 0.5 to 1.4), the fund intensity for the same period decreased by 2.6 times (from 1.8 to 0.7). In the department of pathological anatomy of GBUZ NSO "GKB No. 1" there was also an increase in both income and expenses. However, if revenues from the sale of services in 2022 increased by 3.3 times compared to 2019 (from 9,464,84 thousand rubles to 31,236,82 thousand rubles), then expenses for the same period are 0.3% (from 19,764,62 thousand rubles to 19,814,83 thousand rubles). The absolute cost-effectiveness of the Department of Pathological Anatomy in 2022 was 11,421,99 thousand rubles, which corresponds to the 157.6%. The average actual cost of 1 case of lifetime pathological and anatomical diagnosis in the pathological anatomy department of the GBUZ NSO "GKB No. 1" for the period from 2019 to 2022 increased by 12.8%. The number of beds of a round-the-clock hospital with surgical activity (surgical and oncological services) for the period from 2019 to 2022 decreased by 3.2%. The number of cases of hospitalization in the departments of surgical and oncological services increased by 7.2%, the number of operations - by 7.1%. The increase in operational activity was accompanied by an increase in the number of objects of lifetime pathological and anatomical diagnostics of biopsy (surgical) material per 1 operation for the period from 2019 to 2022 (by 17.1%). At the same time, the average actual cost of lifetime pathological and anatomical diagnostics services in departments with surgical activity (surgical and oncological service)

decreased per 1 case of hospitalization by 6.5%, per 1 operation - by 6.4%, which is a positive trend in the process of using available resources.

In the structure of expenses of the Department of Pathological Anatomy for the period from 2019 to 2022, there is an increase in the expense code "Remuneration and accruals for the remuneration of basic personnel" by 32.9% and a significant decrease in expenses under the code "Reagents, disposable instruments, soft equipment involved in the process of providing medical services" by 83% (see Table 44). For the round-the-clock hospital GBUZ NSO "GKB No. 1" as a whole for the period from 2019 to 2022, there is an increase in income by 28.2%, expenses - by 68.2%, which determines the negative economic balance between the two components.

Table 44 - Actual expenses for provision of medical services for lifetime pathological and anatomical diagnostics of biopsy (surgical) material at GBUZ NSO GKB No. 1 (in thousand rubles)

№ п/п	List of expenses	Outpatient Clinical Pathomorphology Unit				Department of pathological anatomy of the hospital (in terms of lifetime diagnosis of biopsy (surgical) material)			
		2019	2020	2021	2022	2019	2020	2021	2022
1.	Direct costs, incl.								
1.1.	Remuneration and accruals for the remuneration of the main personnel	12 884,92	14 677,23	14 254,64	16 027,86	11 119,07	13 691,82	13 687,32	14 782,26
1.2.	Reagents, disposable tools, soft equipment involved in the process of providing medical services	18 773,99	16 052,70	3 900,14	20 749,17	5 279,15	858,03	1 084,03	887,95
1.3.	Depreciation of equipment directly used in the provision of medical services	80,12	91,73	79,56	58,69	н/д	н/д	н/д	н/д

Table 44 (continued)

№ п/п	List of expenses	Outpatient Clinical Pathomorphology Unit				Department of pathological anatomy of the hospital (in terms of lifetime diagnosis of biopsy (surgical) material)			
		2019	2020	2021	2022	2019	2020	2021	2022
2.	Indirect costs, incl.								
2.1.	Remuneration and accruals for general hospital personnel	2 667,77	3 109,70	2 990,83	3 327,21	2 298,91	2 900,92	2 871,80	3 068,64
2.2.	Communication services, utilities, works and maintenance services	730,29	765,68	783,10	730,56	1 067,49	1 061,87	1 102,07	1 075,98
2.3.	Other consumables and soft stock not involved in the medical service process	н/д	н/д	н/д	н/д	н/д	н/д	н/д	н/д
2.4.	Depreciation of buildings and structures not related to the provision of medical services	1 033,16	1 033,16	1 033,16	1 033,16	н/д	н/д	н/д	н/д
	TOTAL, thousand rubles	36 170,25	35 730,21	23 041,43	41 926,66	19 764,62	18 512,65	18 745,21	19 814,83

When forming Table 45 "Assessment of the economic efficiency of the activity of the pathological and anatomical service of the Novosibirsk Regional Clinical Oncological Dispensary (GBUZ NSO "NOCOD") before and after the introduction of the organizational and functional model of intravital pathological and anatomical diagnostics, "these forms No. 14-Med were used (Compulsory medical insurance) "Information on the work of a medical organization in the field of CHI" and No. 62 "Information on resource provision and provision of medical care to the population" GBUZ NSO "NOCOD" for 2020, 2021, 2022 year. 2022 deviations are calculated with respect to 2021 year, since in the reporting forms for 2020 there is no information on the revenue part and expenses during lifetime pathological and anatomical studies of biopsy (surgical) material.

Table 45 - Economic Performance Evaluation Before and after the introduction of the organizational and functional model of lifetime pathological and anatomical diagnostics, the pathological and anatomical service of GBUZ NSO "NOCOD"

Indicator	Unit of measure	Period				Deviation 2022 by 2019
		2019	2020	2021	2022	
Ambulatory care						
Number of outpatient (ambulatory) visits	visits	89 168	63 823	67 582	44 227	–23 355
Number of cases of lifetime pathological and anatomical studies of biopsy (surgical) material during outpatient care	cases	1 780	1 527	1 641	2 162	+ 521

Income from the provision of lifetime pathological and anatomical studies of biopsy (surgical) material on an outpatient basis	thousand rubles	3 026,00	2 639,70	3 965,59	13 284,97	+9 319,38
Costs of providing lifetime pathological and anatomical studies of biopsy (surgical) material on an outpatient basis	thousand rubles	н/д	н/д	4 679,73	12 986, 93	+8 307,20
Absolute cost-effectiveness when conducting lifetime pathological and anatomical studies of biopsy (surgical) material on an outpatient basis	thousand rubles	н/д	н/д	–714,14	+298,04	+1 012,18
Income from outpatient care in general	thousand rubles	52 944,11	35 845,16	71 117,89	79 524,36	+8 406,47
Outpatient care costs overall	thousand rubles	55 394,87	64 021, 67	56 324,20	45 838,12	–10 486,08
Absolute cost-effectiveness	thousand rubles	–2 450,76	-28 176,52	+14 793,62	+33 686,24	–2 079,61

Number of cases of lifetime pathological and anatomical examinations per 1 visit	cases	0,022	0,024	0,024	0,05	+0,026
Average actual cost of lifetime pathological and anatomical diagnostics services per 1 visit	rubles	н/д	н/д	69,25	293,64	+224,39
round-the-clock hospital						
Number of beds in hospital	units	288	282	307	301	–6
Number of hospital admissions	cases	9 843	9 733	9 925	11 934	+2 009
Number of hospital admissions in surgical services	cases	2 966	2 747	2 870	3 333	+463
The number of cases of lifetime pathological and anatomical studies of biopsy (surgical) material during the provision of specialized medical care in a round-the-clock	cases	13 054	10 691	11 413	14 917	+3 504

hospital						
Income from the provision of services of lifetime pathological and anatomical studies of biopsy (surgical) material in a round-the-clock hospital	thousand rubles	8 097,66	7 009,13	27 580,31	30 070, 85	+2 490,54
Costs of pathological and anatomical examination of biopsy (surgical) material in a round-the-clock hospital	thousand rubles	н/д	н/д	32 547,14	11 217,57	–21 329,56
Absolute cost-effectiveness when conducting lifetime pathological and anatomical studies of biopsy (surgical) material in a round-the-clock hospital		н/д	н/д	–4 966,83	+18 853,28	–18 839,02
Income hospital	thousand rubles	712 185,72	608 277,39	734 001,45	829 481, 83	+95 480,39

Costs for hospital	thousand rubles	607 915,10	830 764,67	838 240,67	851 845,80	+13 605,13
Absolute economic efficiency by hospital	thousand rubles	+104 270,62	–222 487,28	–104 239,22	–22 363,96	+81875,26
Bed load per year	cases	34,18	34,51	37,18	23,42	–13,76
Number of cases of lifetime pathological and anatomical examinations per 1 case of hospitalization	cases	1,33	1,10	1,15	1,25	+0,1
Number of cases of lifetime pathological and anatomical examinations per 1 case of hospitalization with surgical treatment	cases	4,40	3,89	3,98	4,48	+0,5
Number of objects of lifetime pathological and anatomical studies per 1 case of hospitalization with surgical treatment	objects	5,0	5,3	5,3	6,9	+1,6
Average actual cost of lifetime	rubles .	н/д	н/д	3 279,31	939,97	–2 339,34

pathological and anatomical diagnostics services per 1 case of hospitalization						
Average actual cost of lifetime pathological and anatomical diagnostics services per 1 case of hospitalization with surgical treatment	rubles	н/д	н/д	11 348,47	2 926,58	–8 421,89
TOTAL (ambulatory (outpatient) care + hospital)						
Income from the provision of services of lifetime pathological and anatomical studies of biopsy (surgical) material	thous and rubles	11 123,66	9 648,83	31 545,90	43 355,82	+11 809,92
Costs of lifetime pathological and anatomical examination of biopsy (surgical) material	thous and rubles	н/д	н/д	37 226,87	24 204,50	–13 022,37
Absolute cost-effectiveness during lifetime pathological and		н/д	н/д	–5 680,97	+19 151,32	–1 212,45

anatomical studies of biopsy (surgical) material						
Income by medical organization	thousand rubles	765 129,83	644 122,55	805 119,34	908 006,19	+103 886,85
Costs per medical institution	thousand rubles	663 309,97	894 786,34	894 564,87	897 683,92	+3 119,05
Absolute cost-effectiveness by medical organization	thousand rubles	+101 819,86	–250 663,79	–89 445,60	+11 322,27	+100 767,80
Relative cost effectiveness	%	115,4	72	90,0	101,15	+11,15

Table 46 - Actual expenses for the provision of medical services in GBUZ NSO "NOCOD" (in thousand rubles)

№ п/п	List of expenses	Ambulatory (outpatient) medical care				Inpatient medical care (24-hour hospital)			
		2019	2020	2021	2022	2019	2020	2021	2022
1.	Remuneration and accruals for remuneration payments	16 492,32	53 368,07	47 704,61	38 396,20	138 867,62	237 573,72	275 932,22	303 611,79
2.	Increase in the cost of fixed assets (medical equipment, medical instruments, other fixed assets)	154,67	41,46	369,46	549,07	1 692,06	970,37	4 897,32	4 173,86
3.	Increase in the cost of inventories and rights to use assets (medicines and dressings, medical supplies, food, reagents and chemicals, soft stock, fuels and lubricants)	35 417,54	8 816,14	3 339,09	3 978,19	432 467,36	559 637,90	522 440,83	524 902,93

4.	Payment for works and services (including communication services, transportation services, utilities, maintenance of property, rent for the use of property)	3 135,71	1 582,26	3 140,12	2 286,13	32 407,36	29 906,89	32 650,74	17 382,59
5.	Other expenses	194,63	213,74	1 770,92	628,53	2 480,70	2 675,78	2 319,55	1 774,63
	TOTAL	55 394,87	64 021,67	56 324,20	45 838,12	607 915,10	830 764,66	838 240,66	851 845,80

When providing outpatient care in GBUZ NSO "NOCOD" in 2022 compared with 2019, the number of cases of intravital pathological and anatomical studies of biopsy (surgical) material increased by 21.5%. Revenues in 2022 compared to 2019 from the implementation of an increased number of cases, combined with an increase in the financial standard per unit of the volume of these services, increased by more than 4 times. Despite the increase in the cost of providing these services in 2022 compared to 2021, the absolute economic efficiency in 2022 amounted to 298.04 thousand rubles. In general, when providing medical care in GBUZ NSO "NOCOD" on an outpatient basis, there is a decrease in costs and an increase in income (in 2019, relative economic efficiency was 95.6%, in 2021 - 126.3%%, in 2022 - 173.5%).

In the 24-hour hospital in 2022, compared to 2019, the number of cases of hospitalization with surgical treatment increased by 12.4%, the number of cases of intravital pathological and anatomical studies of biopsy (surgical) material increased by 14.3%, the number of objects per 1 case of hospitalization with surgical treatment increased from 5.0 in 2019 to 6.9 in 2022 (by 38%). In 2022, compared to 2021, revenues from the sale of intravital pathological and anatomical diagnostics increased by 9.0%, the costs of this type of diagnostics decreased by 65.5%, which made it possible to achieve absolute economic efficiency in 2022 - 18,853,28 thousand rubles. (Table 45).

In general, when providing outpatient care and specialized medical care in the round-the-clock hospital of the GBUZ NSO NOCOD, revenues from the sale of lifetime pathological and anatomical studies of biopsy (surgical) material in 2022 are 1.8 times higher than the costs of this type of diagnostics, the absolute economic efficiency of this type of diagnostics amounted to 19 151.32 thousand rubles (179.1%) (see Table 45).

It should also be noted that in 2022-2023, as part of the implementation of clinical recommendations, biopsy (surgical) material oncologists of GBUZ NSO "GKB No. 1" and GBUZ NSO "NOCOD" was sent for molecular genetic studies of mutations in genes to medical organizations of private health care, which have approved planned volumes and amount of financial support within the framework of the basic program of compulsory medical insurance with payment for medical services at tariffs for

diagnostic services within the framework of mutual settlements between medical organizations. So, as of 2023, 390 molecular genetic studies of biopsy (surgical) material in the amount of 10.5 million rubles were carried out in the direction of oncologists at the GBUZ NSO "GKB No. 1."

When analyzing the actual expenses of GBUZ NSO NOCOD for the provision of medical care on an outpatient basis and in a round-the-clock hospital for the period from 2019 to 2022, draws attention to the largest increase in labor costs and accruals for labor payments (on an outpatient basis - 2 times from 16,492,32 thousand rubles to 38,396,20 thousand rubles, in a round-the-clock hospital - 2.2 times from 138,867,62 thousand rubles to 303,611,79 thousand rubles) and according to the expense code "Increase in the value of fixed assets" (on an outpatient basis - an increase of 3.5 times from 154.67 thousand rubles to 549.07 thousand rubles, in a round-the-clock hospital - 2.5 times from 1,692,06 thousand rubles to 4,173,86 thousand rubles) (Table 46). The increase in expenses under the code "Increase in the value of fixed assets" is explained by the equipment of a medical organization with new types of equipment, including a robotic system for histological and immunohistochemical diagnostics of biopsy (operating) material.

In order to study the change in satisfaction with the quality of filling in the Protocols of in-life pathological and anatomical studies of biopsy (surgical) material, the opinion of doctors of clinical specialties (n = 350) was re-examined using the developed questionnaire. Of the respondents, 160 doctors (45.7%) provide medical care in hospitals, 190 doctors (54.3%) - on an outpatient basis.

Compared to 2019, the share of respondents fully satisfied with the quality of filling out the Protocols increased by 36.6% (from 56% in 2019 to 92.6% in 2022; for the Wilcoxon $T_{emp}<T_{cr}(0,01)$, the indicators after the implementation of the organizational and functional model of pathological and anatomical diagnostics exceed those before implementation. The share of respondents partially satisfied with the quality of filling out the Protocols decreased by 24.3% (from 26.9% in 2019 to 2.6% in 2022; $T_{emp} < T_{cr}$ (0.01) - indicators after the implementation of the organizational and

functional model of lifetime pathological and anatomical diagnostics do not exceed the values before the implementation) (Figure 8).

The share of completely dissatisfied with the quality of filling out the Protocols decreased by 12.3% (from 17.1% in 2019 to 4.8% in 2022). In this case, the hypotheses are formulated as follows:

H_0: Indicators after model implementation are less than values of indicators before implementation;

H_1: Post-implementation metrics exceed pre-implementation metrics.

Empirical value T falls into the zone of insignificance $T_{emp} > T_{cr}$ (0.05). The H_0 hypothesis is rejected. Post-implementation metrics exceed pre-implementation metrics.

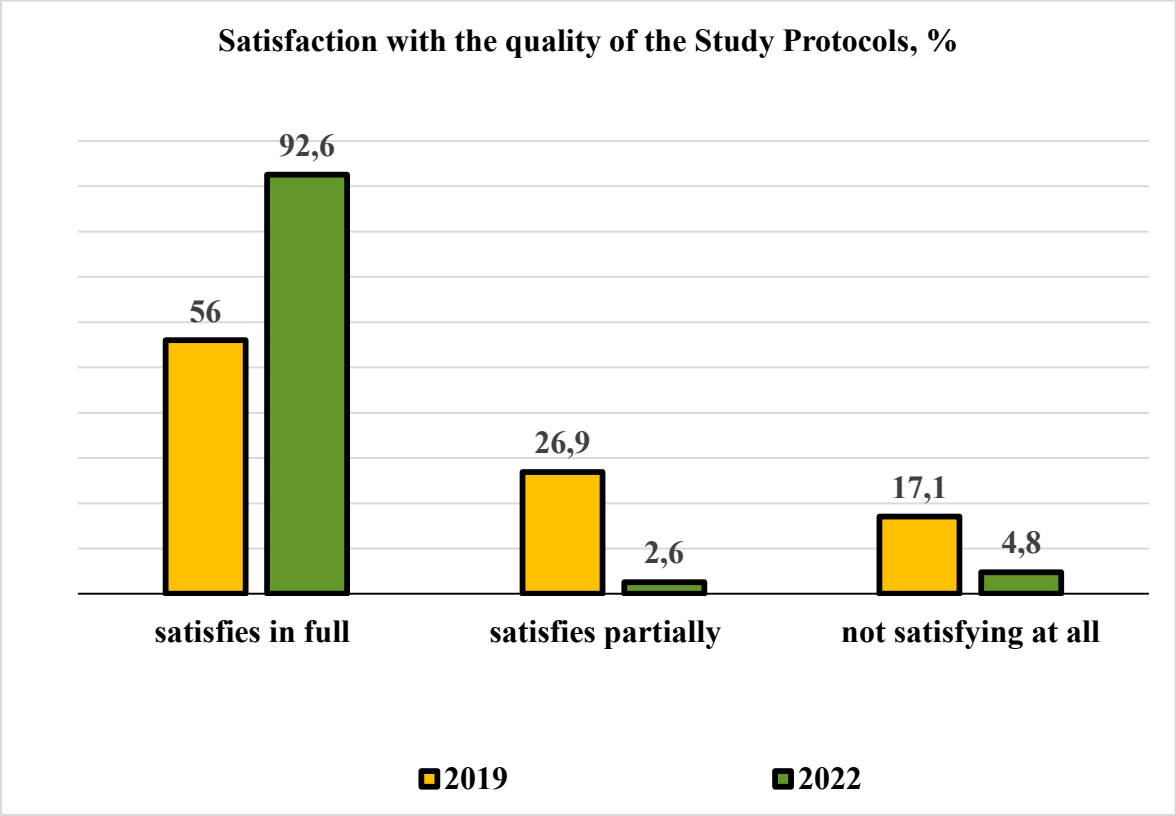


Figure 8 - Satisfaction with the quality of the Study Protocols after the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics

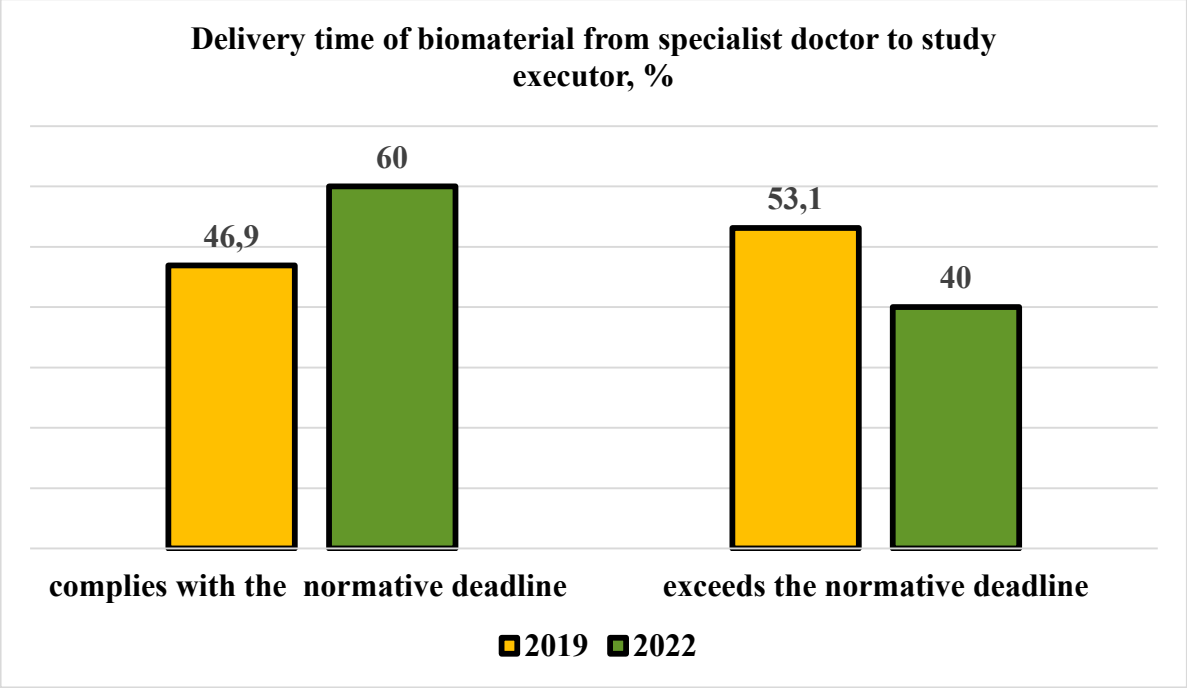


Figure 9 - Assessment of the delivery time of biological material from the specialist doctor to the investigator after the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics

When comparing the results of assessing the delivery time of biological material from a specialist doctor to a research contractor in 2019 and 2022. (Figure 9), there is a decrease in the proportion of respondents who reported exceeding the standard delivery time for biological material from 53.1% in 2019 to 40% in 2022. (by 13.1%), which is explained by the re-routing of diagnostic studies in accordance with the order of the Ministry of Health of the Novosibirsk Region in 2022.

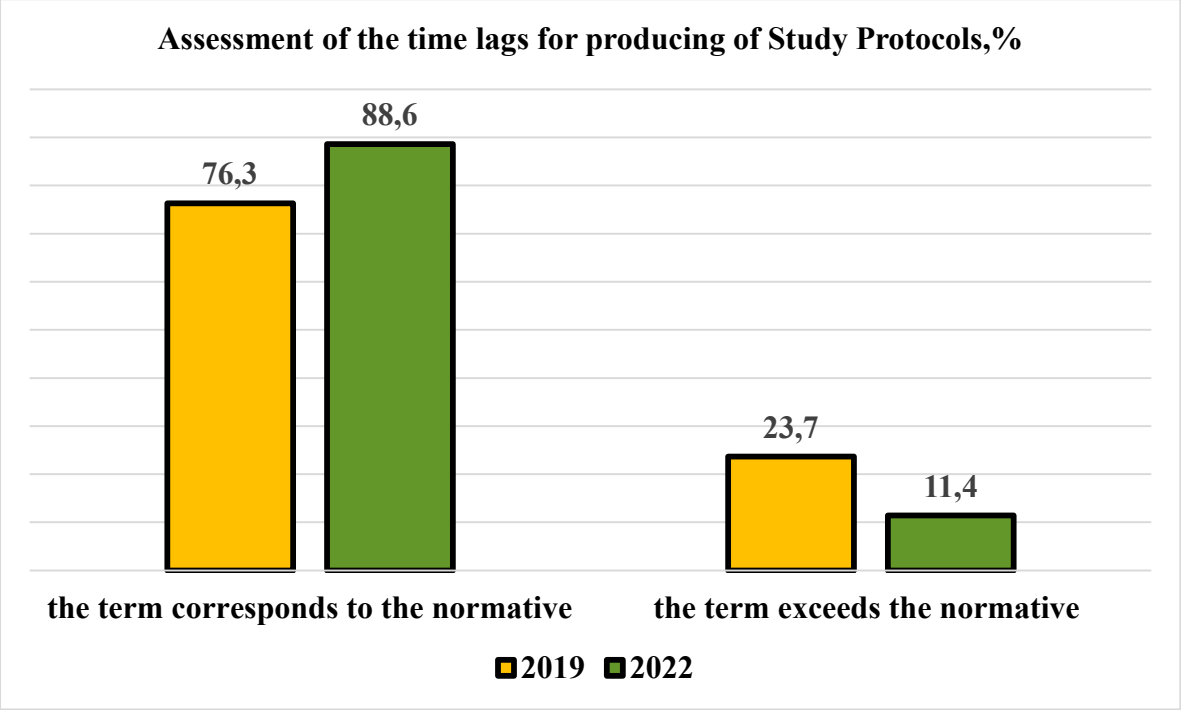


Figure 10 - Assessment of the terms for the provision of Study Protocols after the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics

A comparison of the results of the assessment by specialist doctors of the deadlines for the provision of Study Protocols in 2019 and 2022 showed that the proportion of respondents who assessed the provision of Protocols in accordance with the regulatory deadlines increased from 76.3% in 2019 to 88.6% in 2022 (by 12.3%) (Figure 10). Hypotheses are formed as follows:

H_0: Post-implementation metrics exceed pre-implementation metrics;

H_1: Post-implementation performance is less than pre-implementation performance.

In this case, the empirical value T falls into the zone of significance: $T_{emp} < T_{cr}(0,01)$. The H_0 hypothesis is accepted. Post-implementation metrics exceed pre-implementation metrics.

The share of respondents who noted the provision of study protocols with exceeding the regulatory period, respectively, decreased from 23.7% in 2019 to 11.4% in 2022.

In order to assess the medical effectiveness of the implementation of the organizational and functional model of intravital pathological and anatomical diagnostics of biopsy (surgical) material, monitoring was carried out, which included a repeated phased analytical assessment of the implementation of technological procedure standards during intravital pathological and anatomical diagnostics of biopsy (operative) material, in case of non-conformities detection - implementation of corrective measures, in case of risk situations detection - implementation of preventive actions with emphasis on weaknesses of organization of this type of diagnostics. 500 cases were studied in 2020-2022 (250 cases in 2020, 117 cases in 2021, 133 cases in 2022). As before the implementation of the model, criteria for assessing the implementation of technological standards were used depending on their prioritization and the degree of impact of inconsistencies on the research result. When evaluating the implementation of the standard of the Referral for in-life pathological and anatomical examination of the registration form No. 014/y, additional clinical information was provided in full in all cases, since the MIS of the Novosibirsk Region made it possible to integrate the records of clinicians during the initial examination of the patient, during the study, when drawing up the surgical protocol with the electronic layout of the Referral.

The implementation of the organizational and functional model did not affect the implementation of the standard for the collection and fixation of biological material, as well as the implementation of the deadlines for the delivery of biological material to the pathological and anatomical service: out of 500 cases, 105 cases (21%) revealed violations of preliminary fixation in terms of insufficient volume of the fixing agent, and in 97 cases (19.4%) the transportation of the biopsy (surgical) material taken exceeded the approved period, however, the revealed defects did not affect the study result. The decrease in defects in the fulfillment of the deadlines for the delivery of biopsy (surgical) material to the investigator (from 375 cases in 2019 to 97 cases for the period from 2020 to 2022) is explained by the rationally formed research routing

scheme approved by the Ministry of Health of the Novosibirsk Region. There were no violations of the standard for registration of biological material in the Log of registration of the receipt of biopsy (surgical) material and the issuance of the results of intravital pathological and anatomical studies of the registration form No. 014-2/y at the level of pathological and anatomical services after the introduction of the organizational and functional model. Macroscopic examination of the material, subsequent cutting of samples, the appointment of colors was carried out by a pathologist with the design of the relevant items in the electronic model of the Protocol.

During the assessment of the implementation of histological technologies for processing biological material, staining using autostainers, no violations were detected.

During the assessment of compliance with the conclusion standard in the Protocol of in-life pathological and anatomical study of biopsy (surgical) material of the registration form No. 014-1/y for the period from 2020 to 2022, 41 inconsistencies (8.2%) were revealed when the nosological diagnosis, size, histological type of tumor, degree of differentiation G were indicated, but the number of affected lymph nodes, pN stage, purity of the edge of the surgical incision were not indicated which are rated on a scale of 0.75. Of the 41 cases of inconsistencies, the largest number was detected in 2020 - 33 cases, in 2021 - 5 cases, in 2022 - 3 cases.

When assessing the fulfillment of the regulatory deadlines for the provision of Protocols for intravital pathological and anatomical studies of biopsy (surgical) material of registration form No. 014-1/, no violations were revealed by specialist doctors due to the fact that the Protocols are formed in the MIS of the Novosibirsk Region and are available for study by the attending physician by 4 working days from the date of receipt of biological material (in the absence of additional colors).

Results of determination of the quality level of lifetime pathological and anatomical studies of biopsy (surgical) material after the introduction of the organizational and functional model of the system of lifetime pathological and anatomical diagnostics are given in Annex F.

In 41 cases (8.2%), the quality level of in-life pathological and anatomical examination of biopsy (surgical) material was 0.938 (Table 47).

Table 47 - Quality Indicator for lifetime pathological and anatomical studies of biopsy (surgical) material after the implementation of the organizational and functional model of the system of lifetime pathological and anatomical diagnostics in the Novosibirsk Region

QILS	Number of cases	Total points
0,938	41	38,458
1,000	459	459,00
Total	500	497,458

The quality indicator equal to 0.938 was registered in 41 cases when the implementation of the conclusion standard in the Protocols was rated on a scale of 0.75 points.

The average value of the quality indicator after the implementation of the organizational and functional model of lifetime diagnosis of biopsy (surgical) material was 0.995 points.

A comparative assessment of the results of internal quality control of the Protocols of in-life pathological and anatomical studies of biopsy (surgical) material and external examinations of the quality of medical care before implementation (2019) and after implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics (2020-2022) was carried out using the example of GBUZ NSO GKB No. 1 (Table 48).

Table 48 - Comparative assessment of the results of internal quality control of the Protocols of lifetime pathological and anatomical studies of biopsy (surgical) material and external examinations of the quality of medical care for 2019-2022 at the State Budgetary Healthcare Institution NSO GKB No. 1

Indicators	2019	2020	2021	2022
Internal quality control of filling in the Protocol of lifetime pathological and anatomical examination of biopsy (surgical) material				
Scope of internal control performed, cases	500	250	117	133
The number of identified nonconformities with the standard for filling in the Protocol of in-life pathological and anatomical examination of biopsy (surgical) material of the registration form No. 014-1/y or the current clinical recommendations	102	33	5	3
Nature of nonconformities with the standard for filling in the Protocol of lifetime pathological and anatomical examination of biopsy (surgical) material	The number of examined and affected lymph nodes, stage pN, purity of the edge of the surgical incision are not indicated	The number of affected lymph nodes, stage pN, purity of the edge of the surgical incision are not indicated	The number of affected lymph nodes, stage pN, purity of the edge of the surgical incision are not indicated	The number of affected lymph nodes, stage pN, purity of the edge of the surgical incision are not indicated

Table 48 (continued)

Indicators	2019	2020	2021	2022
Number of identified violations of the deadlines and submission of Protocols for lifetime pathological and anatomical studies of biopsy (surgical) material	115	0	0	0
External examinations of the quality of medical care				
Scope of expertise in oncology profile (cases)	1 865	1 907	1 187	1 511
Scope of examination for "surgery" profile (cases))	1 208	1 178	1 552	1 401
The number of identified violations of the Protocols of in-life pathological and anatomical studies, total, incl.	102	25	12	2
- oncology profile	72	20	10	1
- on the profile "surgery"	30	5	2	1

End of Table 48

Indicators	2019	2020	2021	2022
Nature of violations				
- oncology profile	The absence of Protocols in the medical records of patients, the absence of the degree of differentiation of the G tumor in the Protocols, the absence of the number of studied lymph nodes, pN gradation, TNM, assessment of the purity of the surgical margin	The absence of Protocols in the medical records of patients, the absence of the degree of differentiation of the G tumor in the Protocols, the absence of the number of studied lymph nodes, pN gradation, TNM, assessment of the purity of the surgical margin	Absence in the Protocols of the number of examined lymph nodes, pN gradation, TNM, assessment of the purity of the surgical margin	Absence in Protocols TNM gradation, evaluation of operating edge cleanliness
- on the profile "surgery"	Lack of Protocols in patients' medical records	Lack of Protocols in patients' medical records	No description of the nature of the pathological process in the Protocols	Absence of a description of the nature of the pathological process in the Protocol
Amount of financial claim, thousand rubles	884,70	404,90	164,33	320,46

In 2019, during internal quality control, the number of identified violations of filling in the Protocols of lifetime pathological and anatomical studies of biopsy (surgical) material is equal to the number of similar defects registered during external quality examinations of SMO. In 2020, the number of violations of the Protocols

revealed during internal control exceeds the number of defects registered during external quality examinations (33 and 25, respectively). A set of corrective measures was implemented in GBUZ NSO "GKB No. 1" by introducing an organizational and functional model of lifetime pathological and anatomical diagnostics of biological material. Based on 100 cases of internal control, the number of violations identified: in 2019 amounted to 20.4 in 2020 - 13.2 in 2021 - 4.3, in 2022 - 2.26. Based on 100 examinations of the quality of medical care, the number of defects in 2019 is 3.32, in 2020 - 0.81, in 2021 - 0.44, in 2022 - 0.069. Based on 100 cases of expert control of SMO in the oncology profile, the number of defects was 3.86 in 2019, 1.05 in 2020, 0.84 in 2021, and 0.07 in 2022.

An increase in the volume of financial claims in 2022 against the background of a decrease in the number of violations, identified during external examinations of the quality of medical care, is explained by the entry into force of the order of the Ministry of Health of Russia dated 26.03.2021 No. 254n "On Amendments to the Rules of Compulsory Medical Insurance, approved by Order of the Ministry of Health of the Russian Federation of February 28, 2019 No. 108n, " approved new values of coefficients for determining incomplete payment of costs, as well as fines of a medical organization for late provision of medical care or provision of medical care of inadequate quality.

As part of the cost-effectiveness analysis, the ratio of costs per unit of efficiency was calculated in GBUZ NSO "GKB No. 1" before implementation (2019) and after implementation (2020-222) of the organizational and functional model of intravital pathological and anatomical diagnostics in the Novosibirsk Region. As an efficiency parameter, compliance of the quality of the Protocols of lifetime pathological and anatomical studies of biopsy (surgical) material with the approved standard per 100 cases of internal control was used.

The ratio of costs per unit of efficiency is calculated as a partial sum of direct and indirect costs of departments of pathological anatomy and clinical pathomorphology of GBUZ NSO "GKB No. 1" for the corresponding year for indicators of compliance with the standard for filling out Research Protocols and compliance of the deadline for

submitting Research Protocols with the approved standard for 100 cases of internal control (Table 49).

Table 49 - Comparative cost-effectiveness analysis of GBUZ NSO GKB No. 1 before and after the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics in the Novosibirsk Region

Indicators	2019	2020	2021	2022
Internal quality control of filling in the Protocol of lifetime pathological and anatomical examination of biopsy (surgical) material				
Scope of internal control performed, cases	500	250	117	133
Indicator of compliance with the standard of the Protocol for lifetime pathological and anatomical examination of biopsy (surgical) material per 100 control cases	79,6	86,8	95,7	97,7
Indicator of compliance of the lifetime pathological and anatomical examination with the approved standard	77	100	100	100
Expenses				
The sum of direct and indirect costs of departments of pathological anatomy and clinical pathomorphology, thousand rubles	55 934,87	54 242,86	41 786,64	61 741,49
Cost ratio for the quality efficiency of filling out Study Protocols	702,70	624,92	436,64	631,95
Cost ratio for the effectiveness of the deadline for submission of Study Protocols	726,43	0	0	0

Indicator of the ratio of the sum of all expenses of the departments of pathological anatomy and clinical pathomorphology of GBUZ NSO "GKB No. 1" per unit of the quality efficiency of filling in the Protocols of lifetime pathological and anatomical studies (calculated per 100 cases of internal control) decreased from 2019 to 2022 by 10.1%, the ratio of costs per unit of efficiency of the deadline for the submission of

Study Protocols in 2019 amounted to 726.43 thousand rubles, in 2022 - 0.

The dependence of changes in the labor productivity of nurses in the pathological and anatomical department on the degree of informatization and automation of processes during lifetime pathological and anatomical diagnostics of biopsy (surgical) material was also studied (data are presented in Table 50). To study the direction and nature of the relationship, the working hours of laboratory assistants were timed using a medical information system and automated systems for laboratory processing of biopsy (surgical) material, technological maps were formed. At the same time, several key stages have been identified.

1) The use of the Medical Information System (MIS) - a software and hardware complex that made it possible to combine and organize all processes during the lifetime pathological and anatomical research, eliminated gaps in communications, accelerated work at all stages of the study. Requirements for MIS as a tool for organizing a single information workspace for clinicians, pathologists and laboratory assistants have been formed. The equipment included in the system provides a high degree of automation and standardization of processes during lifetime pathological and anatomical studies of biopsy (surgical) material. The operation of the MIS is adapted to the number of workplaces and the operation of a certain set of devices in the departments. MIS made it possible to "link" images of micropreparations obtained using scanning microscopes to an electronic medical record. The results of the MIS are the combination of all stages of the study from the moment of sampling the material to the diagnosis and subsequent archiving of micropreparations; the ability to track the location of the sample at each stage of the study; reducing the impact of the human factor on the process, reducing the likelihood of error and misdiagnosis; Increase staff productivity by optimizing workflows and saving time (up to 50%) saving patient time (rapid diagnosis).

2) Macroscopic examination of biopsy (surgical) material and subsequent cutting of samples by a pathologist. The diagnostic feasibility of cutting out certain samples after a macroscopic examination of the surgical material is assessed only by a pathologist. At the same time, at present, it is not excluded that laboratory histologists accompany the procedure for cutting out biological material, which includes extracting

biological material from a vial, washing biological material, providing it to a doctor, marking a filling cassette, applying a registration number to the cassette, and placing it in a fixing liquid.

3) Wiring using a fabric processor type processor, which ensured the complete absence of harmful vapors during operation, vacuum accelerated wiring using reagents of any manufacturer, automatic change of consumables, three levels of filling the working chamber with automatic determination of the required volume of reagents, the possibility of remote service diagnostics. When using carousel processors, the standard for biological material objects per device per year is 15,000, respectively 10.14 objects per hour, i.e. 5.9 minutes (0.59 Conventional units of labor) per 1 object. When using a fabric processor type processor, the standard of objects per device per year is -60 000, respectively 40.57 objects per hour, i.e. 1.48 minutes (0.15 Conventional units of labor) for 1 object. The productivity growth rate at this stage was: Kp = 40.57/10.14 = 4.00. Thus, the performance at this stage has increased 4 times.

4 Microtomy using semi-automatic (motorized) rotational microtomes. The semi-automatic rotary microtome made it possible to standardize and automate this technological procedure. When using an automatic rotation microtome, it was possible to reduce the labor intensity of the microtomy process of one block by 2 times: from 1.2 Conventional units of labor to 0.6 Conventional units of labor.

5). The performance of the Sacura hardware complex (a device for concluding histological preparations under a film with a multisteiner) before the use of the robotic system was 60 glasses per hour (3 baskets of 20 glasses). The robotic system provided the ability to simultaneously work according to several painting protocols, use containers for reagents of various volumes with a capacity of 600 glasses per hour.

Table 50 - Laboriousness of the analyst's work depending on the degree of automation of processes during lifetime pathological and anatomical examination of material of category difficulty III

Process name	Laboriousness of the laboratory processing process material before the use of MIS and automatic system in Conventional labor units	Laboriousness of the laboratory processing process material when using the organizational and functional model in Conditional Labor Units	Dynamics in%
Receipt of biological material from a courier upon admission to the pathological and anatomical service	0,2	0,2	0
Registration in the Log of receipt of biopsy (surgical) material and issuance of the results of intravital pathological and anatomical studies of form No. 014-2/y, indication of a unique registration number in the direction	0,1	0,05	– 50 %
Support of the biological material cutting process performed by the pathologist	1,2	0,5	–58,3
Wiring (dewatering and paraffin impregnation)	0,59	0,15	–74,6
Paraffin grouting with fabrication of paraffin blocks	0,2	0,2	0
Microtomy and production of paraffin sections, mounting them on slides and drying	1,2	0,6	–50
Painting of paraffin sections on slide Conclusion of painted sections under the film	0,5	0,03	–94

Table 50 (continued)

Process name	Laboriousness of the laboratory processing process material before the use of MIS and automatic system in Conventional labor units	Laboriousness of the laboratory processing process material when using the organizational and functional model in Conditional Labor Units	Dynamics in%
Micro drugs sorting and direction sorting	0,1	0,05	–50
Accompanying the formation of a microscopic description of the protocol by a doctor (filling out under the dictation of a doctor)	0,21	0	0
Total	4,30	1,78	–58,6

The use of MIS in combination with automatic and robotic systems in histological technologies for processing biopsy (surgical) material reduced the complexity of the study by 58.6% (Table 50). Prior to the introduction of the components of the organizational and functional model of the system of intravital pathological and anatomical diagnostics, the laboratory assistant processed the 1 object in 1.4 hour, and 3.4 the object using MIS and automated methods. The productivity growth rate in this case is Kp = 3.4/1.4 = 2.4. Thus, productivity increased 2.4 times. It should be noted that in most pathological and anatomical services of the Novosibirsk Region, laboratory processing procedures are carried out not by one, but sequentially by two or three laboratory assistants. On average, three analysts perform laboratory treatment of 1,200 objects per week (30 hours). Taking into account the annual standard (for 1,482 hours) for 1 laboratory assistant for the III category of complexity of material, equal to 890 objects, each laboratory assistant per week must perform laboratory processing of 18 objects or 0.6 objects per hour. Automation of processes made it possible to increase the

number of processed objects to 13 per hour per analyst.

Analysis of the dynamics of quality indicators of resources, processes and results during in-life pathological and anatomical studies of biopsy (surgical) material was carried out using the final results model [32].

As part of the first group, indicators of the use of resources by the pathological and anatomical services of medical organizations of the Novosibirsk Region were considered: fund donation, load per unit of the main technological equipment, share of outdated equipment, staffing by individuals, labor intensity of the processes performed by the laboratory assistant within the framework of histological technologies, using the example of biological material of complexity category III. The group of quality indicators of diagnostic processes during the lifetime pathological and anatomical study of biopsy (surgical) material includes indicators of the implementation of histological technologies for processing biological material and the microscopic description standard in the Protocol of the lifetime pathological and anatomical study of biopsy (surgical) material.

To the group of quality parameters of the intravital pathological and anatomical examination of biopsy (surgical) material includes indicators of compliance with the conclusion standard in the Protocol of intravital pathological and anatomical examination of biopsy (operational) material, compliance with the regulatory deadlines for the implementation of studies and the provision of Protocols for intravital pathological and anatomical studies to the attending physicians, the number of non-compliances with the standard for filling in the Protocol for intravital pathological and anatomical studies or the approved deadline for the implementation of studies based on the results of internal quality control, the Quality Indicators of the lifetime pathological study (QILS) based on the results of internal quality control, the number of identified violations of filling in the Protocols of lifetime pathological and anatomical studies of biopsy (operational) material during external quality reviews of the QS, an indicator of satisfaction with the quality of filling in the Protocols of lifetime pathological and anatomical studies based on a survey of specialist doctors. The target (normative) value of each indicator is estimated in points that are determined by experts (from 0 to 1).

From the general list of indicators, the indicators of fund delivery and staffing by individuals were estimated at 0.5 points, all the rest - at 1 point [32].

The actual assessment of those quality indicators, the changes of which are considered positive when they grow, is calculated as the ratio of the actual value of the indicator to the normative value multiplied by the assessment of the normative indicator in points

$$AAI_p = AVI / NVI \times ANI_p,$$

where AAI_p – actual assessment of the indicator in points;

AVI – actual value of the indicator;

NVI – normative value of the indicator;

ANI_p – assessment of the normative indicator in points.

Actual assessment of those quality indicators, changes of which can be considered as positive if they decrease (load per unit of the main technological equipment, the share of outdated equipment, the complexity of the processes performed by the laboratory assistant during the conduct of histological technologies, the number of non-compliances with the standard for filling out the Protocol of intravital pathological and anatomical studies or the approved deadline for performing studies based on the results of internal quality control, the number of revealed violations of filling in the Protocols of intravital pathological and anatomical studies of biopsy (operational) material in the course of external quality examinations of the CMO) is calculated using the formula [32]:

$$AAI_p = NVI / AVI \times ANI_p,$$

where AAI_p – actual assessment of the indicator in points;

NVI – normative value of the indicator;

AVI – actual value of the indicator;

ANI_p – assessment of the normative indicator in points.

The following formula [32] was used to calculate the integral quality index (IQI):

$$IQI = \sum (AVI / NVI \times ANI_p) + \sum (NVI / AVI \times ANI_p)$$

Table 51 - Dynamics of quality indicators of resources, processes and results during lifetime pathological and anatomical studies of biopsy (surgical) material before and after the introduction of the organizational and functional model of lifetime pathological and anatomical diagnostics in the Novosibirsk Region

Indicators	Units	normative value of the indicator	assessment of the normative indicator in points	actual value of the indicator				actual assessment of the indicator in points			
				2019	2020	2021	2022	2019	2020	2021	2022
Indicators of the quality of resource use during lifetime pathological and anatomical studies biopsy (surgical) material											
Capital productivity		2,5	0,5	1,0	1,0	2,0	1,9	0,2	0,2	0,4	0,4
Load per piece of equipment::											
- station for macroscopic study and cutting	objects per year	20 000	1	107 503	80 473	105 143	114 894	0,2	0,2	0,2	0,2
- fabric carousel processor	objects per year	15 000	1	30 101	20 863	30 041	29 972	0,5	0,7	0,5	0,5
- fabric processor type	objects per year	60 000	1	75 252	56 331	48 527	45 957	0,8	0,9	0,8	0,8
- station for filling and manufacturing of paraffin blocks	objects per year	20 000	1	75 252	46 943	45 061	43 085	0,3	0,4	0,4	0,5
- automatic coloring machine for histological preparations	microprepar ations per year	75 000	1	289 430	234 713	275 238	284 134	0,3	0,3	0,3	0,3

Table 51 (continued)

Indicators	Units	normative value of the indicator	actual assessment of the indicator in points	actual value of the indicator				actual assessment of the indicator in points			
				2019	2020	2021	2022	2019	2020	2021	2022
- machine for conclusion of histological preparations	microprepar ations per year	15 000	1	150 504	80 473	88 857	96 596	0,1	0,2	0,2	0,2
Indicators of the quality of resource use during lifetime pathological and anatomical studies biopsy (surgical) material											
Share of obsolete equipment	%	10	1	30,1	32,5	31,5	33,4	0,3	0,3	0,3	0,3
Staffing of medical personnel by individuals	%	100	0,5	60	63	67	69	0,30	0,32	0,33	0,35
Laboriousness of the processes performed by the laboratory assistant during the lifetime pathological and anatomical examination of the material of the category difficulty III	Conditional Labor Units	4,30	1	4,30	1,80	1,78	1,78	1	2,4	2,4	2,4

Table 51 (continued)

Indicators	Units	normative value of the indicator	assessment of the normative indicator in points	actual value of the indicator				actual assessment of the indicator in points			
				2019	2020	2021	2022	2019	2020	2021	2022
Quality Parameters of Diagnostic Processes During In-Life Pathological and Anatomical Examination biopsy (surgical) material											
Execution of histological technologies for biological material processing	%	100	1	91,2	100,00	100,00	100,00	0,91	1	1	1
Implementation of the microscopic description standard in the Protocol of lifetime Pathological and Anatomical Examination of Biopsy (Surgical) Material	%	100	1	95	100	100	100	0.95	1	1	1
Quality parameters of the result of lifetime pathological and anatomical examination biopsy (surgical) material											
Compliance with the conclusion standard in the Protocol of lifetime Pathological and Anatomical Examination of Biopsy (Surgical) Material	%	100	1	79,6	86,8	95,7	97,7	0,8	0,9	0,9	1,0

Продолжение Таблицы 51

Indicators	Units	normative value of the indicator	assessment of the normative indicator in points	actual value of the indicator				actual assessment of the indicator in points			
				2019	2020	2021	2022	2019	2020	2021	2022
Fulfillment of regulatory deadlines and submission of Protocols for lifetime pathological and anatomical studies of biopsy (surgical) material	%	100	1	77	100	100	100	0,8	1	1	1
The number of nonconformities with the standard for filling out the conclusion of the Study Protocol or the standard period for performing lifetime pathological and anatomical studies of biopsy (surgical) material based on the results of internal quality control	Units	15	1	217	33	5	3	0,07	0,5	3	5

Table 51 (continued)

Indicators	Units	normative value of the indicator	assessment of the normative indicator in points	actual value of the indicator				actual assessment of the indicator in points			
				2019	2020	2021	2022	2019	2020	2021	2022
Quality Indicator fof lifetime pathological and anatomical examination of biopsy (surgical) material based on the results of internal quality control	points	1,000	1	0,961	0,992	0,997	0,999	0,961	0,992	0,997	0,999
Number of Identified Violations of the Protocols of Lifetime Pathological and Anatomical Studies of Biopsy (Surgical) Material During External Quality Reviews of medical insurance organizations	Units	4	1	102	25	12	2	0,04	0,2	0,3	2,0

End of Table 51

Indicators	Units	normative value of the indicator	assessment of the normative indicator in points	actual value of the indicator				actual assessment of the indicator in points			
				2019	2020	2021	2022	2019	2020	2021	2022
Satisfaction with the quality of filling in the Protocols of lifeешьу pathological and anatomical studies of biopsy (surgical) material based on the results of a survey of specialist doctors	%	97	1	82,9	91,7	96,6	95,2	0,85	0,95	0,99	0,98
Integral quality index	points	—	17	—	—	—	—	9,381	12,462	15,017	18,929

According to Table 51, the actual score in the quality of resource use indicators from 2019 to 2022 increased by

1.95 points (from 4 points in 2019 to 5.95 points in 2022). Among the indicators of this group, the actual estimate of fund performance for the same period increased by 0.2 points, staffing by individuals - by 0.05 points, the actual estimate of labor intensity (taking into account that its decrease was considered positive changes) increased by 1.4 points.

The actual assessment of the quality indicators of diagnostic processes during the intravital pathological and anatomical study of biopsy (surgical) material for the period from 2019 to 2022 increased by 0.14 points (from 1.86 points to 2.0 points) with a predominant increase in the performance of histological technologies for processing biological material.

The actual assessment of the quality indicators of the result of a lifetime pathological and anatomical study of biopsy (surgical) material for the period from 2019 to 2022 increased by 7.458 points (from 3.521 points to 10.979 points, exceeding the target value of 6.0 points). The largest increase in the actual score was observed when assessing the dynamics of the number of non-compliances with the standard for filling out the study protocol or the standard period for performing lifetime pathological and anatomical studies of biopsy (operational) material based on the results of internal quality control (by 4.93 points exceeding the target value of 1 point) and the number of revealed violations of the Protocols of intravital pathological and anatomical studies of biopsy (operational) material during external quality reviews of the QS (by 1.96 points from 0.04 points in 2019 to 2.0 points in 2022). The correlation indicator of the results of internal control and external quality examinations $r = -0,991$ at $p = 0,060003$ confirms the inverse functional correlation.

The integral quality indicator of in-life pathological and anatomical studies of biopsy (surgical) material in 2019 was 9.381 points, in 2020 - 12.462 points, in 2021 - 15.017 points, in 2022 reached 18.929 points. Thus, the integral quality indicator after the introduction of the organizational and functional model of the system of intravital

pathological and anatomical diagnostics for the period from 2019 to 2022 increased by 9.548 points (2 times).

A study of the correlation between the assessment of the quality of the result of a lifetime pathological and anatomical study of biopsy (surgical) material and an integral quality indicator showed a direct close relationship between the signs with a correlation coefficient (r) equal to 0.976. Dependence of signs is statistically significant at p = 0,100.

SUMMARY

1. The financial and economic analysis of the activities of GBUZ NSO "GKB No. 1" for 2019-2022 showed the effectiveness of the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material:

- on an outpatient basis, in the Department of Clinical Pathomorphology, there is an increase in the number of cases of intravital pathological and anatomical studies of biopsy (surgical) material with a decrease in the labor intensity of 1 case of the study by 30.2% (from 59 UET in 2019 to 41.16 UET in 2022), an increase in fund-making indicators by 10.3%, fund-giving - by 90%, a decrease in fund-intensive indicator - by 50%; the predominant increase in the revenue from the sale of lifetime pathological and anatomical diagnostics services determined the absolute economic efficiency of the clinical pathomorphology department, which in 2022 amounted to 22,584,22 thousand rubles. (153.9%);

- in the conditions of a round-the-clock hospital in the pathological and anatomical department, with a decrease in the number of cases, the number of objects of intravital pathological and anatomical studies of biopsy (surgical) material per 25.3% increased (the number of objects per operation increased by 17.1%; there is an increase in fund-armament indicators by 25.2%, fund productivity - by 2.8 times, a decrease in the fund intensity indicator - by 2.6 times; Due to the predominant increase in revenue from the sale of in-life pathological and anatomical diagnostics services (3.3 times over the specified period), the absolute economic efficiency of the pathological and

anatomical department in 2022 amounted to 11,421,99 thousand rubles. (157.6%).

2. The improvement of the financial and economic performance indicators of GBUZ NSO NOCOD for 2019-2022 also allows us to talk about the effectiveness of the implementation of the organizational and functional model of intravital pathological and anatomical diagnostics of biopsy (surgical) material: an increase in the number of cases of intravital pathological and anatomical studies by 21.5%. On an outpatient basis, with a predominant increase in income from the sale of an increased volume of services, in 2022 an increase in the revenue part compared to the expenditure part by 2.3%, which amounted to 298.04 thousand rubles; in a 24-hour hospital, an increase in the number of cases of hospitalization with surgical treatment (by 12.4%) was accompanied by an increase in the number of cases of intravital pathological and anatomical studies of biopsy (surgical) material on the 14.3%. Against the background of growth in income from the sale of lifetime services pathological and anatomical diagnostics in a round-the-clock hospital (in 2022 relative to 2021 by 9.0%), the medical organization managed to achieve a significant reduction in the cost of this type of diagnostics (in 2022 relative to 2021 by 65.5%), which allows us to talk about the absolute economic efficiency of intravital pathological and anatomical diagnostics in a round-the-clock hospital in 2022 - 18,853.28 thousand rubles. In general, when providing outpatient care and specialized medical care in the round-the-clock hospital of the GBUZ NSO NOCOD, revenues from the sale of lifetime pathological and anatomical studies of biopsy (surgical) material in 2022 are 1.8 times higher than the costs of this type of diagnostics, the absolute economic efficiency of this type of diagnostics amounted to 19 151.32 thousand rubles (179.1%).

When analyzing the actual expenses of GBUZ NSO NOCOD for the provision of medical care on an outpatient basis and in a round-the-clock hospital for the period from 2019 to 2022, draws attention to the largest increase in labor costs and accruals for labor payments (in outpatient conditions - 2 times, in a 24-hour hospital - 2.2 times) and by the expense code "Increase in the cost of fixed assets" (in outpatient conditions - an increase of 3.5 times, in a round-the-clock hospital - 2.5 times).

3. 3. According to the results of the repeated survey of specialist doctors after the introduction of the organizational and functional model of the system of intravital pathological and anatomical diagnostics of biopsy (surgical) material, there was an increase in the quality of filling out the Study Protocols: in 2022, compared to 2019, the share of those who were fully satisfied with the quality of filling in the Protocols increased by 36.6%, the share of those who were completely dissatisfied with the quality of filling in the Protocols decreased by 12.3%.

4. The quality level of in-life pathological and anatomical examination of biopsy (surgical) material based on the results of internal quality control for the period from 2019 to 2022 increased by 4%: from 0.961 points to 0.999 points.

5. The introduction of an organizational and functional model using the Medical Information System and automated systems of technological equipment in the pathological and anatomical services of the Novosibirsk Region made it possible to exclude violations of the standard for laboratory processing of biological material and staining of micropreparations, standard terms for performing lifetime pathological and anatomical studies of biopsy (surgical) material. The use of electronic templates in the formation of conclusions in the Protocols of intravital pathological and anatomical studies of biopsy (surgical) material led to a decrease in inconsistencies with the standard for filling out the conclusion of the Study Protocol during internal control (from 102 cases in 2019 to 33 cases in 2020 and 3 cases in 2022).

When conducting external examinations of the quality of medical care, the number of detected violations of filling in the Protocols of intravital pathological and anatomical studies of biopsy (surgical) material decreased from 102 cases in 2019 to 25 cases in 2020 and 2 cases in 2022. For the period from 2019 to 2022, there is a decrease in the number of defective cases per 1 case of expert control of SMO in the oncology profile: from 0.04 in 2019 to 0.0007 in 2022. In 2022, compared to 2019, there is a decrease in the volume of financial claims for this group of violations by 63.8%. At the same time, against the background of a decrease in the number of violations in 2022 compared to 2021, there is an increase in the financial claim by almost 2 times (from 164.33 thousand rubles in 2021 to 320.46 thousand rubles in 2022), which is explained

by the approval of new coefficients to determine the amount of incomplete payment of expenses of medical organizations when violations are detected.

6 The integral quality indicator after the implementation of the organizational and functional model of the system of intravital pathological and anatomical diagnostics of biopsy (surgical) material for the period from 2019 to 2022 increased by 9.548 points (2 times).

A direct close correlation was determined between the quality indicators of the result of a lifetime pathological and anatomical study of biopsy (surgical) material and an integral quality indicator with a correlation coefficient (r) equal to 0.976. Dependence of signs is statistically significant at p = 0,100.

CONCLUSION

By the Decree of the President of the Russian Federation of 07.05.2018 No. 204 "On the national goals and strategic objectives of the development of the Russian Federation for the period up to 2024," a Passport of the national project "Healthcare" was developed, including eight federal projects, including "Fight against cancer." One of the target indicators of the federal project "Fight against cancer" is an increase in the proportion of malignant neoplasms detected in the early stages (I-II stages) from 55.6% by 31.12.2017 to 63.0% in 2024. The achievement of the target indicator of the federal project determines the need to improve the system for organizing lifetime pathological and anatomical diagnostics of biopsy (surgical) material and the relevance of the study.

Analysis of the state of the system of organization of in-life pathological and anatomical diagnostics of biopsy (surgical) material was carried out for the period from 2015 to 2022.

In the period from 2015 to 2022, in the Novosibirsk Region, there is an increase in the number of patients registered in the oncological dispensary by 15.7% of the volume of intravital pathological and anatomical diagnostics - by 30.1%. A more pronounced increase in the volume of intravital pathological and anatomical diagnostics is determined by the demand for morphological verification of pathological processes not only oncologists, but also surgeons. Positive dynamics was revealed in the early detection of malignant neoplasms in the Novosibirsk Region from 2018 to 2022: the proportion of detected malignant neoplasms in stages I-II increased from 55.3% in 2018 to 59.7% in 2022. The proportion of morphological verification over the specified period increased from 93.1% to 94.9%. The achievement of these indicators for the early detection of malignant neoplasms became possible due to the formation of new and expansion of the activities of existing centers for outpatient oncological care.

In the period from 2019 to 2022, in medical organizations of the Novosibirsk Region, there is an increase in the percentage of staffing with employed rates of pathologists from 80.6% in 2019 to 86.7% in 2022. The number of pathologists for the same period increased by 15% (from 60 to 69 people) with an increase in the percentage

of staffing of full-time positions by individuals from 45.1% to 46.9%. However, the shortage of pathologists remains at a high level and amounts to 78 people in 2022. The number of individuals of nurses (histologists) in the Novosibirsk Region in the period from 2019 to 2022 decreased by 14% (from 71 to 61 people).

The indicator of the availability of basic technological equipment remains at a low level (49%), the rate of renewal of technological equipment is inferior to the rate of its obsolescence (30.1% in 2019 and 33.4% in 2022 has a service life of more than 10 years). Light binocular microscopes (83 units) remain the basic microscopic equipment in the Novosibirsk Region, electron microscopy is represented by a single equipment.

In the period from 2018 to 2022, the very structure of intravital pathological and anatomical studies of biopsy (surgical) material by complexity categories underwent changes: the share of cases of studies of the V category of complexity increased from 19.7% in 2018 to 49.3% in 2022. The increase in objects of the V category of complexity is accompanied by an increase in the number of additional colors, reactions and definitions, which is clearly traced from 2019 to 2022, when the number of additional colors, reactions increased by 4.6 times. The increase in research of the V category of complexity creates an additional burden on the medical staff of pathological and anatomical services.

Analysis of the forms of statistical reporting of medical organizations and the study of the state of the system for organizing lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region made it possible to identify the following negative factors:

1) the territorial remoteness of the specialist doctor of the outpatient medical organization as the customer of the study from the performing doctor;

2) violation of the terms of transportation of the taken biological material to the pathological and anatomical department (in particular, from remote areas of the Novosibirsk Region);

3) the medical information system of the Novosibirsk Region, used by medical organizations subordinate to the Ministry of Health of the Novosibirsk Region, is represented by automated workplaces of clinical doctors and pathologists who function

separately, do not form a single information environment and do not provide mutual exchange of diagnostic and medical information between medical organizations;

4) histological technologies and the manufacture of micropreparations are characterized by a low level of automation of the main processes, which leads to a decrease in the quality and effectiveness of research;

5) due to insufficient resource support, violation of the deadlines for obtaining Protocols of intravital pathological and anatomical studies of biopsy (surgical) material by a specialist doctor leads to an extension of the terms of diagnosis and treatment of patients;

6) the absence of a Reference Center with regulations for the quality control of pathological and anatomical studies on the territory of the Novosibirsk Region makes it difficult to obtain advice and a "second opinion" on research;

7) the shortage of technological equipment limits the conduct of remote consultations of full-format scanned images of micropreparations in federal reference centers.

The results of the study, based on the study of data from literary sources, regulatory documents, the current state of the system for organizing lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region, make it possible to scientifically substantiate priority areas for improving this type of diagnostics. New approaches to the system of organization of intravital pathological and anatomical diagnostics implemented through the introduction of territorial

organizational and functional model.

The organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region was formed on the basis of a process approach aimed at achieving certain resulting indicators of the activity of pathological and anatomical services.

The study was conducted in 2015-2022. on the basis of the Federal State Budgetary Educational Institution of Higher Education "Novosibirsk State Medical University" of the Ministry of Health of Russia, GBUZ NSO "City Clinical Hospital

No. 1," GBUZ NSO "Novosibirsk Regional Clinical Oncological Dispensary."

To solve the tasks, analytical, sociological, statistical methods, the method of expert assessments, multi-criteria analysis of decision-making, the method of mathematical modeling of final results, and system analysis were used.

According to the data of statistical observation forms No. 30 and analytical reports on the state of pathological and anatomical services of the constituent entities of the Russian Federation, indicators were calculated that characterize the state of the system for organizing lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region: indicators of the use of human resources, the provision of basic technological equipment for pathological and anatomical services, the percentage of equipment wear, volumetric indicators of the activity of pathological and anatomical departments (patients, cases, objects) and the dynamics in the structure of lifetime pathological studies by difficulty categories.

When conducting a sociological study, the opinion of

specialist doctors (350 questionnaires) and heads of medical organizations (in the amount of 100 survey cards) on the issue of violations that most affect the quality of intravital pathological and anatomical diagnostics of biopsy (surgical) material: clinical specialties more often noted violations of the standards for taking, fixing and directing biological material at the pre-analytical stage (26.6 ± 2.4)%), insufficient material and technical equipment of the pathological and anatomical service (26 ± 2.3) %) and lack of an effective logistics system (23.4 ± 2.3)%), heads of medical organizations more often noted insufficient material and technical equipment of the pathological and anatomical service (34 ± 4.7)%), weak quality management system for intravital pathological and anatomical diagnostics (24 ± 4.3)%), personnel deficit in pathological and anatomical services (23 ± 4.2)%). Response differences specialist doctors and heads of medical organizations are statistically significant: χ 2Emp is 26.422 and exceeds χ 20.01.

Of the specialist doctors, 161 doctors (46%) provide medical care in hospitals, 189 doctors (54%) - on an outpatient basis

A statistically significant difference was found in the quality of filling out the

Study Protocols by doctors of hospitals using the diagnostic capabilities of their own medical organization and doctors of outpatient medical organizations sending biological material for research to third-party organizations (χ^2_{emp} is 23.814 and exceeds $\chi^2_{0.01}$). Among the total number of specialist doctors who are satisfied with the quality of filling out the Research Protocols (290 people), the share of hospital doctors is greater (42.6 ± 3.0) %) than doctors of outpatient medical organizations (40.3 ± 3.0)%). Hospital doctors (n = 161) more often noted that they were fully satisfied with the quality of filling out the Protocols (73.9 ± 3.5) %). Among doctors of outpatient medical organizations (n = 189), the proportion of doctors who are fully satisfied with the quality of filling out the Study Protocols is less (40.7 ± 3.5) %), an almost equal proportion of doctors noted partial satisfaction with the quality of filling in the Protocols (33.9 ± 3.5) %).

The results of the satisfaction assessment with the quality of filling in the Protocols of lifetime pathological and anatomical studies by doctors-specialists of the Novosibirsk Region made it possible to calculate the integral satisfaction coefficient with the quality of the Protocols using a formula based on the study of the sum of cases of assessments of the study result when the result was "fully achieved," "partially achieved" and "completely not achieved."

According to a survey of doctors of clinical specialties in the Novosibirsk Region, the integral satisfaction coefficient with the quality of filling in the Protocols of lifetime pathological and anatomical studies is 0.389, which corresponds to a low level of quality.

Statistically significant differences were obtained during the assessment by doctors of hospitals and outpatient medical organizations of the deadlines for submitting study protocols. Among hospital doctors, the share of doctors who noted the fulfillment of the standard deadlines for the provision of Protocols is more (88.8 ± 2.5) %) than among doctors of outpatient medical organizations (65.6 ± 3.5) %).

As part of the expert method, the experts carried out an individual analytical assessment of the compliance of the procedures at each stage of diagnostics with the approved standards, analyzed the degree of impact of the identified non-conformities on the study result with the conclusion in the form of an Expert Assessment Report. The selection of specific experts was carried out from among the heads of the pathological and anatomical departments of medical organizations of the Novosibirsk Region based on a statistical analysis of the results of past activities as experts. 500 cases of intravital pathological and anatomical studies were investigated. In order to justify the selection of criteria for assessing the compliance of the procedures with the approved standards, the multi-criteria decision analysis (MCDA) method was used, which included an analysis of weaknesses in the organization of the stages of intravital pathological and anatomical diagnostics of biopsy (surgical) material, determination of significant criteria for a phased assessment of the compliance of the procedures with the approved standards, prioritization of criteria in terms of the greatest impact on the study result. The significance of each criterion is expressed by experts in points from 0 to 100.

The most significant criteria in terms of the impact on the study result were determined: the implementation of histological technologies for processing biological material, the standard for microscopic description of the micropreparation and the conclusion in the Study Protocol, the implementation of the approved deadlines for the submission of Study Protocols. Prior to the implementation of the organizational and functional model of intravital pathological and anatomical diagnostics, when assessing the implementation of histological technologies for processing biological material, staining and the manufacture of micropreparations, non-compliance with standards was revealed in 44 cases (8.8%), which led to a violation of the approved study deadline. When evaluating the implementation of the microscopic description standard, 25 cases (5.0%) of incomplete qualitative characteristics of the pathological process were revealed, when evaluating the implementation of the conclusion standard in the Protocol of study of accounting form No. 014-1/y - 102 cases (20.4%) of non-compliance with the standard. Assessment of compliance with the regulatory deadlines for the implementation of studies and the provision of Protocols showed that in 115 cases

(23%) the deadlines exceed the approved ones. Based on the results of individual expert assessments, an indicator of the quality level of the study was calculated for each case, which is the arithmetic mean of the values of the four specified criteria. Prior to the implementation of the organizational and functional model of diagnosis, it was revealed that in 183 cases (36.6%) the quality level of intravital pathological and anatomical examination of biopsy (surgical) material was less than 1,000. The average value of the quality indicator for lifetime pathological and anatomical studies for the entire volume of cases examined as part of the expert analysis was 0.961.

During external examinations of the quality of medical care by insurance medical organizations in the amount of 3073 cases in 2019, 102 violations of the quality of filling in the Protocols of intravital pathological and anatomical studies of biopsy (operational) material of registration form No. 014-1/y were revealed. In terms of 100 control cases, there were more violations of the Study Protocols during internal control than during external quality reviews (20.4 and 3.32, respectively), which indicates high-quality internal audits. The correlation indicator of the results of internal control and external quality examinations $r = -0,991$ at $p = 0.060003$ confirms the inverse functional correlation.

An expert assessment of the system for organizing in-life pathological and anatomical diagnostics of biopsy (surgical) material in state medical organizations of the Novosibirsk Region and an analysis of the consistency of expert opinion with the calculation of the Kendall's concordance coefficient ($W = 0.88$) showed a high degree of consistency of expert opinions on the importance of components that ensure the timeliness and quality of processes in the system for organizing in-life pathological and anatomical diagnostics of biopsy (surgical) material. The most significant components are: automation of technological procedures for lifetime pathological and anatomical studies ($\lambda = 0.09815$), the impact of the quality of lifetime pathological and anatomical diagnostics on the speed of determining treatment tactics ($\lambda = 0.08981$), the importance of remote advice from Reference Centers to improve the quality of research ($\lambda = 0.0787$), the use of a medical information system in the pathological and anatomical services of state medical organizations of the Novosibirsk Region ($\lambda = 0.07407$). These

factors made it possible to determine the main directions of improving the system for organizing lifetime pathological and anatomical diagnostics of biological material in state medical organizations of the Novosibirsk Region.

The study of the causal relationships of the decrease in the effectiveness of lifetime pathological and anatomical diagnostics of biopsy (surgical) material made it possible to speak about the need to change the system of organization of lifetime pathological and anatomical diagnostics in medical organizations of the Novosibirsk Region and to form an organizational and functional model of this type of diagnostics.

The organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region was formed on the basis of a process approach using the Medical Information System of the Novosibirsk Region, automation of individual histological technologies with additional microscopic control of colored drugs, remote consultation of digitized images of scanned micropreparations in pathological and anatomical Reference Centers.

The formation of the organizational and functional model began with the preparation and approval of local regulatory documents defining the Procedure for conducting intravital pathological and anatomical studies of biopsy (surgical) material in a medical organization, the organization and procedure for conducting internal quality control and safety of medical activities, the form of an internal quality control card for intravital pathological and anatomical studies of biopsy (surgical) material, standard operating procedures for conducting certain stages of the diagnostic process were formed and approved. In 2020, in connection with the implementation of accounting documentation forms for intravital pathological and anatomical diagnostics in the Medical Information System of the Novosibirsk Region (MIS NSO), a standard operating procedure was approved for the use of additional functionality of the MIS NSO by oncologists when forming research directions, pathologists - when forming Protocols for intravital pathological and anatomical studies of biopsy (operational) material.

With the expansion of the functionality (MIS NSO) in terms of the formation of accounting forms of medical documentation on intravital pathological and anatomical

diagnostics, instructions were formed and approved for filling in the MIS NSO services for intravital pathological and anatomical diagnostics of biopsy (surgical) material separately when providing medical care in the hospital and in outpatient conditions

The organizational and functional model of transformation of the system of lifetime pathological and anatomical diagnostics of biopsy (surgical) material was introduced into the practical diagnostic work of the Department of Pathological Anatomy and the Department of Clinical Pathomorphology of the outpatient link of the GBUZ NSO "City Clinical Hospital No. 1," as well as the Department of Pathological Anatomy of GBUZ NSO "Novosibirsk Regional Clinical Oncological Dispensary."

The Medical Information System of the Novosibirsk Region (hereinafter referred to as the MIS NSO) has been identified as a tool for using information and communication technologies. As part of the study, technical specifications were prepared to use the capabilities of the MIS NSO, implemented 12 standard operating procedures for biological material sampling and laboratory processing of biological material at the pre-analytical stage, preparation of the Study Referral Form No. 014 by the attending physician in the electronic medical record using the MIS NSO, formation of the Protocol of the in-life pathological and anatomical study of the registration form No. 014-1/by a pathologist in the patient's electronic medical record, filling out the biopsy log with a laboratory assistant (surgical) material and issuance of the results of lifetime pathological and anatomical studies of registration form No. 014-2/y. Templates were formed for filling in electronic fields by a pathologist (description of macroscopic examination, microscopy, pathological and anatomical diagnosis), counting of accounting units (cases) was implemented on the basis of the Protocols and complexity categories of the study material. Mechanisms have been developed to integrate the information specified by the specialist doctor during the initial examination, diagnostic examination with the taking of biological material, in the protocol of the operation and allowing to form Directions for lifetime pathological and anatomical examination of biopsy (surgical) material in an automatic mode, the functionality of integrating full-format scans of micropreparations into the patient's electronic medical record using MIS NSO has been formed. A User Guide has been

formed for the transfer of structured electronic medical documents (discharge reports and instrumental research protocols, including those accompanied by the procedure for taking biopsy material) from the MIS NSO to the integrated electronic medical record. In order to maximize the reliability and reproducibility of the information stored in the Integrated Electronic Medical Archive, structured electronic medical documents are subject to format-logical control upon admission to the integrated electronic medical record.

An important area that allows standardizing technological processes when conducting a lifetime pathological and anatomical study of biopsy (surgical) material is automation when staining sections on slides, which is achieved by unifying staining conditions, using autostainers and eliminating the influence of the human factor on the implementation of the technological standard.

Organizational and functional model of lifetime pathological and anatomical diagnosis of biopsy (surgical) material in the Novosibirsk Region allowed:

- integrate three accounting forms of lifetime pathological and anatomical diagnostics - Referral to lifetime pathological and anatomical examination of biopsy (surgical) material of record form No. 014/y, Log of receipt of biopsy (surgical) material and issuance of results of lifetime pathological and anatomical examinations of record form No. 014-2/y, Protocol of lifetime pathological and anatomical examination of record form No. 014-1/y;

- increase the rate of interchange of clinical and diagnostic information between specialist doctors and pathologists at their territorial distance from each other;

- ensure telemedicine consultations and obtaining a "second opinion" on the results of research in federal pathological and anatomical Reference Centers.

As a result of the improvement of the system of organization of intravital pathological and anatomical diagnostics in the Novosibirsk Region from 2019 to 2022 in the department of clinical pathomorphology of the outpatient link of the GBUZ NSO "GKB No. 1," the number of cases of lifetime pathological and anatomical studies of biological material in the calculation per 1 visit increased by 22.2% (from 0.09 to 0.11). The number of operations in the oncological and surgical services of the GBUZ NSO

"GKB No. 1" during this period increased by 7.1%, which was accompanied by an increase (by 17.1%) in the number of objects of intravital pathological and anatomical studies of biopsy (surgical) material.

The use of automation of processes during the procedure of staining of drugs, as well as the laboratory assistant after the completion of the control microscopy procedure, made it possible to exclude violations of the implementation of the technological standard of histological technologies.

Protocols of lifetime pathological and anatomical studies of biopsy (surgical) material formed in the Medical Information System became available for study by the attending physicians within up to 4 working days (in the absence of additional colors). The number of identified violations of the conclusion filling standard in the Study Protocols decreased from 102 cases in 2019 to 3 cases in 2022 (from 2020 to 2022, 41 cases of such violations were detected). Thus, the number of violations identified for 3 years (from 2020 to 2022) is more than 2.5 times less than the number of violations identified in 2019. Based on 100 cases of internal control, the number of violations identified in 2019 was 20.4 in 2020 - 13.2 in 2021 - 4.3, in 2022 - 2.26. All violations identified within the framework of internal control have been eliminated.

Satisfaction with the quality of filling in the Protocols of lifetime pathological and anatomical studies after the introduction of the organizational and functional model of this type of diagnosis based on the results of a repeated survey of specialist doctors increased by 12.3% (in 2019 (82.9 ± 2.0) %), in 2022 - (95.2 ± 1.1) %.

A correlation coefficient was determined between the internal control revealed and eliminated violations of standards and the results of the doctors' opinion on the issue of satisfaction with the quality of filling out the Study Protocols. The magnitude of the correlation coefficient ($r = 1$) shows that the relationship between the factors is strong (very close).

When conducting external examinations of the quality of medical care, the number of detected violations of filling in the Protocols of lifetime pathological and anatomical studies of biopsy (surgical) material decreased after the introduction of the organizational and functional model of lifetime pathological and anatomical diagnostics

from 102 cases in 2019 up to 2 cases in 2022. Per 100 examinations of the quality of medical care, the number of defects in 2019 is 3.32, in 2020 - 0.81, in 2021 - 0.44, in 2022 - 0.069. In 2022, compared to 2019, there is a decrease in the volume of financial claims for this group of violations by 63.8%.

Based on 100 cases of expert control of SMO in the oncology profile, the number of defects was 3.86 in 2019, 1.05 in 2020, 0.84 in 2021, and 0.07 in 2022.

Financial and economic analysis of the activities of GBUZ NSO "GKB No. 1" for 2019-2022 showed:

- when conducting lifetime pathological and anatomical studies on an outpatient basis, an increase in the number of cases of lifetime pathological and anatomical studies of biopsy. (operational) material by 12.2%, with a decrease in the labor intensity of 1 study case by 30.2% (from 59 conventional labor units in 2019 to 41.16 conventional labor units in 2022), an increase in the indicators of fund-making at the 10.3%, fund-giving at the 90%, a decrease in the indicator of fund-consuming capacity - at the 50%, a predominant increase in the revenue side from the sale of lifetime pathological and anatomical diagnostics services, which determined the absolute economic efficiency of the clinical pathomorphology department, which in 2022 amounted to 22 584,22 thousand rubles. (153.9%);

- during lifetime pathological and anatomical studies of biopsy (operative) material in the pathological and anatomical department in a hospital, the growth of fund-armament indicators by 25.2%, fund-recovery - by 2.8 times, the decrease in fund-intensity indicator - by 2.6 times, the predominant increase in the revenue from the implementation of in-life pathological and anatomical diagnostics services (for the specified period 3.3 times) with absolute economic efficiency in 2022 11 421.99 thousand rubles. (157.6%).

In GBUZ NSO NOCOD, when providing outpatient care, the number of cases of lifetime pathological and anatomical studies of biological material per 1 visit increased by 2019 times from 2022 to 2.5 (from 0.02 to 0.05), in a 24-hour hospital, the number of cases with surgical treatment increased by 12.4%, the number of cases of lifetime pathological and anatomical studies of biological material per 1 case of hospitalization

with surgical treatment per 1.8% (from 4.40 to 4.48). Number of Subjects of In-Life Pathologic and Anatomical Studies per Calculation for 1 case of hospitalization with surgical treatment increased by 38% (from 5.0 to 6.9), which is explained by an increase in the proportion of objects of diagnostically complex studies of category difficulty V by 2 times (from 37 107 in 2019 to 74 087 in 2022).

Improvement of the financial and economic performance indicators of GBUZ NSO "NOCOD" for 2019-2022 allows us to talk about the effectiveness of the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material: an increase in the number of cases of intravital pathological and anatomical studies on an outpatient basis with a predominant increase in income from the sale of an increased volume of services determined in 2022 an increase in the revenue part compared to the expenditure part 2.3%, which amounted to 298.04 thousand rubles; in a 24-hour hospital against the background of growth in income from the sale of lifetime pathological and anatomical diagnostics services (in 2022 compared to 2021 by 9.0%), the medical organization managed to achieve a significant reduction in the cost of this type of diagnostics. (in 2022 as compared to 2021 as of 65.5%) with absolute cost-effectiveness of lifetime pathological and anatomical diagnostics in a 24-hour hospital in 2022 18,853,28 thousand rubles. In general, when providing outpatient care and specialized medical care in the round-the-clock hospital of the GBUZ NSO NOCOD, revenues from the sale of lifetime pathological and anatomical studies of biopsy (surgical) material in 2022 are 1.8 times higher than the costs of this type of diagnostics, the absolute economic efficiency of this type of diagnostics amounted to 19 151.32 thousand rubles (179.1%).

To assess the effectiveness of the implementation of the organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material and to analyze the dynamics of indicators of the quality of resources, processes and results during studies for the period from 2019 to 2022, the model of final results was used.

As part of the Resource Utilization Measure Group pathological and anatomical services of medical organizations of the Novosibirsk Region analyzed the dynamics of

indicators of fund output, the load per unit of the main technological equipment, the share of outdated equipment, staffing by individuals, the complexity of the processes performed by the laboratory assistant during laboratory processing using the example of biological material of category difficulty III.

In the group of quality indicators of diagnostic processes during the lifetime pathological and anatomical study of biopsy (surgical) material, changes in the performance indicators of technological standards for laboratory processing of biological material and microscopic description in the Protocol of lifetime pathological and anatomical examination of biopsy (surgical) material.

In the group of quality parameters of the lifetime pathological and anatomical examination of biopsy (surgical) material, the change in the performance indicators of the conclusion standard in the Protocol of lifetime pathological and anatomical examination of biopsy (surgical) material, the fulfillment of the regulatory deadlines for the implementation of studies and the provision of Protocols of lifetime pathological and anatomical examinations to the attending physicians, the number of inconsistencies with the standard for filling the Protocol of lifetime a pathological and anatomical study or an approved study deadline based on the results of internal quality control, the quality level of the pathological and anatomical study based on the results of internal quality control, the number of identified violations of filling in the Protocols of lifetime pathological and anatomical studies of biopsy (surgical) material during external quality examinations of the CMO, an indicator of satisfaction with the quality of filling in the Protocols of intravital pathological and anatomical studies based on the results of a survey of specialist doctors.

The target (normative) value of each indicator is estimated in points that are determined by experts (from 0 to 1). From the general list of indicators, the indicators of fund delivery and staffing by individuals were estimated at 0.5 points, all the rest - at 1 point.

The actual score in the Resource Use Quality Indicators scores from 2019 to 2022 increased by 1.95 points (from 4 points in 2019 to 5.95 points in 2022). Among the indicators of this group, the actual estimate of fund performance for the same period

increased by 0.2 points, staffing with individuals by 0.05 points, the actual estimate of labor intensity (taking into account that its decrease was considered positive changes) increased by 1.4 points.

The actual assessment of the quality indicators of diagnostic processes during the intravital pathological and anatomical study of biopsy (surgical) material for the period from 2019 to 2022 increased by 0.14 points (from 1.86 points to 2.0 points).

The actual assessment of the quality indicators of the result of a lifetime pathological and anatomical study of biopsy (surgical) material for the period from 2019 to 2022 increased by 7.458 points (from 3.521 points to 10.979 points, exceeding the target value of 6.0 points). The largest increase in the actual score was observed when assessing the dynamics of the number of non-compliances with the standard for filling out the study protocol or the standard period for performing lifetime pathological and anatomical studies of biopsy (operational) material based on the results of internal quality control (by 4.93 points exceeding the target value of 1 point) and the number of revealed violations of the Protocols of lifetime pathological and anatomical studies of biopsy (operational) material during external quality reviews of the QS (by 1.96 points from 0.04 points in 2019 to 2.0 points in 2022).

The integral quality indicator of lifetime pathological and anatomical studies of biopsy (surgical) material in 2019 amounted to 9.381 points, in 2020 - 12.462 points, in 2021 - 15.017 points, in 2022 it reached 18.929 points. Thus, the integral quality index after the implementation of the organizational and functional model of the lifetime system pathological and anatomical diagnostics for the period from 2019 to 2022 increased by 9.548 points (2 times).

A study of the correlation between the assessment of the quality of the result of a lifetime pathological and anatomical study of biopsy (surgical) material and an integral quality indicator showed a direct close relationship between the signs with a correlation coefficient (r) equal to 0.976. Dependence of signs is statistically significant at $p = 0,100$.

INFERENCES

1. The state of organization of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region is characterized by: persisting personnel deficit with an indicator of staffing of individuals by pathologists in 2019 45.1% and a load of 1 pathologist 1.79 rates, low provision of pathological and anatomical services with basic technological equipment (in 2019 - 49%) with a lag in the rate of its renewal from wear and tear and the share of obsolete equipment in 2019 30.1%, an increase in the number of cases of diagnostically complex studies of category difficulty V(for the period from 2015 to 2019 by more than 2 times). The resource deficit, combined with an insufficient level of automation of processes, determines the need for measures to improve the system for organizing lifetime pathological and anatomical diagnostics of biological material in the Novosibirsk Region.

2. A sociological study of the opinion of doctors of clinical specialties and heads of medical organizations on the issue of violations that most affect the quality of lifetime pathological and anatomical diagnostics of biopsy (surgical) material showed that doctors of clinical specialties indicated violations of the standards for taking, fixing and directing biological material at the pre-analytical stage (26.6 ± 2.4)%), insufficient material and technical equipment pathological and anatomical service (26 ± 2.3)%) and lack of an effective logistics system (23.4 ± 2.3)%), heads of medical organizations - insufficient material and technical equipment of the pathological and anatomical service (34 ± 4.7)%), weak quality management system of lifetime pathological and anatomical diagnostics (24 ± 4.3)%), personnel deficit in pathological and anatomical services (23 ± 4.2)%). The quality of filling in the Protocols of lifetime pathological and anatomical studies generally satisfies 290 specialist physicians (82.9 ± 2.0) %). However, among specialist doctors in hospitals, the proportion of respondents satisfied with the quality of filling out study protocols is greater (n = 161; (92.5 ± 2.0) %) than among specialist physicians providing outpatient care (n = 189; (74,6 ± 3,2) %). The integral satisfaction ratio with the quality of filling in the Protocols was 0.389, which corresponds to a low level of quality.

3. Using the multi-criteria decision analysis method, priority criteria were determined for a phased assessment of compliance of the procedures with approved technological standards. Depending on the degree of influence on the result, each criterion was evaluated in points (from 0.0 to 1,000). The most important for obtaining a timely and qualitative study result are the fulfillment of the technological standard for laboratory processing of biological material, the standard for microscopic description and conclusion in the Study Protocol, the fulfillment of the regulatory deadlines for submitting the Study Protocols to the attending physicians. During internal audits in the amount of 500 cases, 102 cases (20.4%) of non-compliance with the conclusion standard were revealed in the Study Protocol and 115 cases (23%) of Protocols provided in violation of the approved deadlines, during external quality examinations in the amount of 3,073 cases, 102 similar violations were revealed (3.3%).

The results of an expert assessment of the system for organizing lifetime pathological and anatomical diagnostics of biopsy (surgical) material in state medical organizations of the Novosibirsk Region and an analysis of the consistency of expert opinion with the calculation of the Kendall concordance coefficient made it possible to determine the most significant components in the system for organizing this type of diagnostics to ensure its timeliness and quality: automation of technological research procedures ($\lambda = 0.09815$), remote advice from Reference Centers ($\lambda = 0.0787$), the use of a medical information system in the pathological and anatomical services of state medical organizations in the Novosibirsk Region ($\lambda = 0.07407$). These factors made it possible to determine the main directions for improving the system for organizing lifetime pathological and anatomical diagnostics of biological material in state medical organizations.

4. Organizational and functional model of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region, formed on the basis of the process approach, allowed:

- integrate forms of medical records and increase the rate of interchange of clinical and diagnostic information between specialist doctors and pathologists;

- increase the number of cases of intravital pathological and anatomical studies of

biopsy (surgical) material per 1 visit on an outpatient basis (in GBUZ NSO "GKB No. 1" - by 22.2%, in GBUZ NSO "NOCOD" - 2.5 times), the number of research objects in the hospital in terms of

1 case of hospitalization with surgical treatment (in GBUZ NSO "GKB No. 1" by 17.1%, in GBUZ NSO "NOCOD" - by 38%);

- exclude violations of the implementation of histological technologies for processing biological material and the deadlines for submitting the Protocols of the studies performed to the attending physicians;

- ensure the receipt of a "second opinion" during consultations of fully scanned micropreparations in federal Reference Centers;

- to increase the satisfaction of specialist doctors with the quality of filling out the Study Protocols by 12.3% (in 2019 (82.9 ± 0.02)%), in 2022 - (95.2 ± 0.01)%;

- reduce the number of violations of the standard for filling out the conclusion in the Study Protocols during internal control (from 102 cases in 2019 to 3 cases in 2022), external quality examinations (from 102 cases in 2019 to 2 cases in 2022) and the volume of financial claims for this group of violations by 63.8%.

5. Assessment of the effectiveness of the implementation of the territorial organizational and functional model of intravital pathological and anatomical studies of biopsy (surgical) material showed:

- increase in income from the sale of lifetime pathological and anatomical studies with a decrease in the cost of this type of diagnostics (in GBUZ NSO "GKB No. 1" income growth by 2 times with a decrease in costs by 15.9%, in GBUZ NSO "NOCOD" income growth by 9% with a decrease in costs by 3 times with absolute economic efficiency in 2022 18,853 thousand rubles);

- increase in stock-making indicators in pathological and anatomical services (from 10% when providing medical care on an outpatient basis to 25% when providing medical care in a hospital);

- an increase in the values of the quality indicators of the use of resources of pathological and anatomical services, estimated in points using the model of final results, by 48.75% (from 4.0 to 5.95 points) with the largest increase in the fund output

indicator by 2 times and a decrease in the labor intensity of the processes performed by the laboratory assistant during laboratory processing of biological material by 2.4 times;

- increase in the value of the histological processing technology of biopsy (surgical) material by 9.95% (from 0.91 points to 1.0 points);

- increase in the values of quality indicators of the results of studies of biopsy (operational) material evaluated in points: compliance with the conclusion standard and the deadlines for submitting study protocols based on the results of internal control by 25% (from 0.8 points to 1.0) and a decrease in the number of violations in filling out study protocols identified during external quality examinations (from 102 cases to 2) exceeding the target of 4 cases per year;

- an increase in the integral quality index by 9.548 points (2 times) with a direct close correlation between the results of internal control of filling in the Protocols for studies of biopsy (surgical) material and the integral quality index (correlation coefficient (r) was 0.976, the dependence of signs is statistically significant at $p = 0.100$).

PRACTICAL RECOMMENDATIONS

1. To recommend to the regional ministries of health of the Russian Federation: formation in the medical information system (regional segment of the Unified State Medical Information System of the Russian Federation) of the module "Pathomorphological consultations in Federal Reference Centers" using full-format scanning of glasses and DICOM data standard; organization of interaction in a remote format of specialists of different profiles of various constituent entities of the Russian Federation in order to develop intelligent systems in the diagnostic process.

2. The heads of medical organizations should be recommended: the use of criteria for a phased assessment of the compliance of the implementation of procedures for intravital pathological and anatomical diagnostics of biopsy (surgical) material with technological standards and an analysis of the degree of impact of non-conformities on the result or term of the study.

3. It is recommended that pathological and anatomical services of medical organizations use: when performing stages of lifetime pathological and anatomical diagnostics - standard operating procedures, when assessing the activities of the pathological and anatomical service - indicators of the quality of use of resources, diagnostic processes and results, combined into a model of final results.

4. Oncological services are recommended: to organize, using telemedicine technologies and the functionality of the Medical Information System, a tumorboard uniting specialist doctors of different profiles and different specializations (including federal reference centers) to solve a specific clinical problem.

5. Specialist doctors (oncologists, obstetricians-gynecologists) are recommended to use: standard operating procedures for taking biological material for further lifetime pathological and anatomical examination; instructions for the formation of a Direction for lifetime in the Medical Information System pathological and anatomical examination of biopsy (surgical) material of registration form No. 014/y.

6. It is recommended that the Departments of Public Health and Health of Medical Universities use the model of final results in the educational process when

conducting lifetime pathological and anatomical studies of biopsy (surgical) material to assess the quality and determine the main directions for improving the system for organizing this type of diagnostics.

LIST OF ABBREVIATIONS AND SYMBOLS

MIS	Medical Information System
ISF	Integral satisfaction factor
QILS	Quality Indicator for lifetime pathological and anatomical studies
EHT	Evaluation of histological technology
EMD	Evaluation of microscopic description standard implementation in the Study Protocol
ECS	Evaluation of the conclusion standard in the Study Protocol
EPSP	Evaluation of the Study Protocol submission period
MCDA	Multi-Criteria Decision Analysis

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ILLUSTRATIVE MATERIAL LIST

ANNEX A

(informative)

Questionnaire for doctors of medical organizations of the Novosibirsk region

Dear colleagues!

In order to study the availability and quality of lifetime pathomorphological studies of surgical and biopsy material in the Novosibirsk Region, the administration of the state budgetary healthcare institution of the Novosibirsk Region "State Novosibirsk Regional Clinical Diagnostic Center" conducts an anonymous survey of doctors of medical organizations.

Please answer the questionnaire and mark the selected answers with "V." Your answers and suggestions will be taken into account when taking measures to improve the organization of medical care in the Novosibirsk Region.

1. Your specialty?
1.1. Doctor in the specialty "Oncology."
1.2. Doctor in the specialty "obstetrics-gynecology."

2. Work experience in healthcare.
2.1. Up to 3 years.
2.2. From 3 to 10 years.
2.3. Over 10 years.

3. Conditions for the provision of medical care in your specialty?
3.1. Outpatient settings
3.2. Outpatient + day hospital
3.3. 24-hour hospital
3.4. 24-hour hospital and day hospital

4. How do you assess the availability of lifetime pathological and anatomical diagnostics of biological material in the Novosibirsk Region on a 5-point scale?
4.1. 1 point
4.2. 2 points
4.3. 3 points
4.4. 4 points
4.5. 5 points

5. How do you assess the quality of filling in the Protocols of lifetime pathological and anatomical diagnostics in the Novosibirsk Region?
5.1. Satisfies fully
5.2. Satisfies partially

5.3. Partially does not satisfy

5.4. Does not satisfy at all

5.5. I find it difficult to answer

6. What shortcomings have the greatest impact on the quality of lifetime pathological and anatomical diagnostics of biopsy (surgical) material?

6.1. Violation of standard procedures for the collection, fixation and direction of biological material at the pre-analytical stage

6.2. Lack of an effective logistics system to ensure timely delivery of biological material and Protocols of performed studies

6.3. Insufficient material and technical equipment of the pathological and anatomical service

6.4. Staffing shortages in post-mortem services

6.5. Insufficient qualification of personnel in pathological and anatomical services

6.6. Weak quality management system for lifetime pathological and anatomical diagnostics

6.7. Other FIT) _____

7. How long is the delivery of biological material from your Medical Organization to the performer for lifetime pathological and anatomical studies?

7.1. In all cases, within 24 hours after the collection and conservation of biological material.

7.2. In most cases, within 24 hours after the collection and conservation of biological material.

7.3. Within 7 days after collection and preservation of biological material.

7.4. In 10 days after sampling and preservation of biological material.

7.5. Within 14 days after collection and preservation of biological material**.**

8. How do you assess compliance with the regulatory deadlines for the provision of the results of lifetime pathological and anatomical studies in the Novosibirsk Region?

For reference: regulatory deadlines for biological material that does not require decalcification and (or) additional colors - up to 4 working days; for biomaterial requiring decalcification and (or) application of colors, additional sections - up to 10 working days; for IHC up to 5 markers - up to 7 working days, more than 5 markers - up to 15 working days)

8.1. The results of lifetime pathological and anatomical studies are provided in accordance with the regulatory deadlines in all cases.

8.2. The results of lifetime pathological and anatomical studies are provided with exceeding the regulatory deadlines in some cases for objective reasons.

8.3. The results of lifetime pathological and anatomical studies are provided with exceeding the regulatory deadlines in some cases without objective reasons.

8.4. The results of lifetime pathological and anatomical studies are provided in excess of the regulatory deadlines in all cases.

9. The most frequent format of conclusions in the Protocols when conducting lifetime pathological and anatomical studies by the performer?

9.1. The protocol of lifetime pathological and anatomical examination of biological material always contains a descriptive description of the pathological process and a nosological diagnosis; in the tumor process, the purity of the resection margin, size, histological structure, degree of differentiation of the tumor G, the number and nature of the affected lymph nodes pN, stages T, N, M are indicated

9.2. The protocol of lifetime pathological and anatomical examination of biological material contains a nosological diagnosis, but does not contain a descriptive description of the pathological process, the size, histological structure of the tumor are indicated in the tumor process, but the number and nature of the affected lymph nodes, stages T, N, M are not indicated

9.3. The protocol of lifetime pathological and anatomical examination contains a nosological diagnosis, does not contain a descriptive description of the pathological process, with the tumor process, the size, histological structure of the tumor, the number and nature of the affected lymph nodes, stages T, N, M are indicated, but the purity of the resection margin is not indicated

9.4. The protocol of lifetime pathological and anatomical examination contains a nosological diagnosis, does not contain a descriptive description of the pathological process, the size, histological structure of the tumor are indicated during the tumor process, but the number and nature of the affected lymph nodes, stages T, N, M, and the purity of the resection margin are not indicated

10. How do you assess compliance with bioethics when interacting with the personnel of the medical organization performing pathological and anatomical studies (by phone, e-mail, etc.)?

10.1. Always observed
10.2. Complied with in most cases
10.3. In most cases, not observed
10.4. Never observed
10.5. I find it difficult to answer

11. How do you assess the possibility of obtaining the results of pathological and anatomical studies funded by medical insurance organizations without using the patient's personal funds?

11.1. Satisfies fully
11.2. Satisfies partially
11.3. Partially does not satisfy
11.4. Does not satisfy at all
11.5. I find it difficult to answer.

12. How do you assess the possibility of obtaining a "second opinion" based on consultation, expert assessment of the materials of the primary pathological and anatomical study?

12.1. Satisfies fully
12.2. Satisfies partially
12.3. Partially does not satisfy
12.4. Does not satisfy at all
12.5. I find it difficult to answer

13. Your suggestions for optimizing the interaction of Medical Organizations when conducting lifetime pathological and anatomical diagnostics of biological material (ENTER) _____

_____

Date of _____

ANNEX B

(informative)

SURVEY CARD FOR HEADS OF STATE MEDICAL ORGANIZATIONS OF THE NOVOSIBIRSK REGION

Dear colleagues!

In order to study the availability and quality of lifetime morphological studies of biological material in the Novosibirsk Region, the administration of the state budgetary healthcare institution of the Novosibirsk Region "State Novosibirsk Regional Clinical Diagnostic Center" conducts a survey of heads of state medical organizations.
We ask you to answer the questions of the expert map and mark the selected answers with the "V."

1. Conditions for the provision of medical care in your medical organization?

1.1. Outpatient settings
1.2. Outpatient + day hospital
1.3. 24-hour hospital
1.4. 24-hour hospital and day hospital

2. How do you assess the availability of lifetime pathological and anatomical diagnostics of biological material in the Novosibirsk Region on a 5-point scale?

2.1. 1 point
2.2. 2 points
2.3. 3 points
2.4. 4 points
2.5. 5 points

3. How do you assess the quality of filling in the Protocols of lifetime pathological and anatomical diagnostics in the Novosibirsk Region?

3.1. Satisfies fully
3.2. Satisfies partially
3.3. Partially does not satisfy
3.4. Does not satisfy at all
3.5. I find it difficult to answer

4. What shortcomings have the greatest impact on the quality of lifetime pathological and anatomical diagnostics of biopsy (surgical) material?

4.1. Violation of standard procedures for the collection, fixation and direction of biological material at the pre-analytical stage

4.2. Lack of an effective logistics system to ensure timely delivery of biological material and Protocols of performed studies

4.3. Insufficient material and technical equipment of the pathological and anatomical service

4.4. Staffing shortages in post-mortem services

4.5. Insufficient qualification of personnel in pathological and anatomical services

4.6. Weak quality management system for lifetime pathological and anatomical diagnostics

4.7. Other FIT) _____

5. How long is the delivery of biological material from your Medical Organization to the performer for lifetime pathological and anatomical studies?

5.1. In all cases, within 24 hours after the collection and conservation of biological material.

5.2. In most cases, within 24 hours after the collection and conservation of biological material.

5.3. Within 7 days after collection and preservation of biological material.

5.4. In 10 days after sampling and preservation of biological material.

5.5. Within 14 days after collection and preservation of biological material.

6. How do you assess compliance with the regulatory deadlines for the provision of the results of lifetime pathological and anatomical studies in the Novosibirsk Region?

For reference: regulatory deadlines for biological material that does not require decalcification and (or) additional colors - up to 4 working days; for biomaterial requiring decalcification and (or) application of colors, additional sections - up to 10 working days; for IHC up to 5 markers - up to 7 working days, more than 5 markers - up to 15 working days)

6.1. The results of lifetime pathological and anatomical studies are provided in accordance with the regulatory deadlines in all cases.

6.2. The results of lifetime pathological and anatomical studies are provided with exceeding the regulatory deadlines in some cases for objective reasons.

6.3. The results of lifetime pathological and anatomical studies are provided with exceeding the regulatory deadlines in some cases without objective reasons.

6.4. The results of lifetime pathological and anatomical studies are provided in excess of the regulatory deadlines in all cases.

7. How do you assess the possibility of obtaining the results of pathological and anatomical studies funded by medical insurance organizations without using the patient's personal funds?

7.1. Satisfies fully

7.2. Satisfies partially

7.3. Partially does not satisfy

7.4. Does not satisfy at all
7.5. I find it difficult to answer.

8. How do you assess the possibility of obtaining a "second opinion" based on consultation, expert assessment of the materials of the primary pathological and anatomical study?

8.1. Satisfies fully
8.2. Satisfies partially
8.3. Partially does not satisfy
8.4. Does not satisfy at all
8.5. I find it difficult to answer

9. What, in your opinion, are the advantages of using centralization and outsourcing of diagnostic functions when conducting lifetime pathological and anatomical diagnostics of biological material?

9.1. Stabilization or reduction of costs of own medical organization for this type of diagnostics
9.2. Greater third-party (outsourcer) responsibility to the ordering healthcare organization
9.3. Best Third-Party Specialty Research Quality
9.4. Ensuring continuous trouble-free operation, since the functions of employees absent in their own medical organization are provided by a third-party organization (outsourcer)
9.5. Redistribution of risks, including financial ones (for example, related to rising prices for reagents) to a third-party medical organization (outsourcer).

10. What, in your opinion, are the disadvantages of using centralization and outsourcing of diagnostic functions when conducting lifetime pathological and anatomical diagnostics of biological material?

10.1. Possible risks of non-performance or improper performance of contracts.
10.2. Increased costs associated with the need to monitor third-party (outsourcer) compliance with legal requirements and contract terms
10.3. Threat of confidentiality (possibility of disclosure of information related to medical confidentiality)
10.4. Reduce the quality of third-party research to reduce costs due to insufficient financial support
10.5. Reducing the speed of making management decisions and creating dependence on a third-party organization if it is necessary to introduce additional functions or modernize the medical information system

Date of _____

THANK YOU FOR YOUR PARTICIPATION AND ASSISTANCE!

ANNEX C

(informative)

ACT

EXPERT EVALUATION OF STANDARD PROCEDURE IMPLEMENTATION LIFETIME PATHOLOGICAL AND ANATOMICAL STUDIES OF BIOPSY (SURGICAL) MATERIAL

1.F.I. Patient's name _____ gender _____ age ____
2. MO sending biomaterial _____
3. Date of examination _____ Expert _____
4. Registration number of the object (glass) _____
5. Date of biomaterial submission _____
6. Date of receipt of biomaterial in the pathological and anatomical department _____
7. Diagnosis of the underlying disease _____
8. Study difficulty category _____
9. Inconsistencies identified in the assessment of the implementation of standard procedures of the analytical and post-analytical stages of the lifetime pathological and anatomical study

№ п/п	Indicator	Nonconformance	Number of nonconformances	
			Absolute quantity	%
Analytical stage				
1.	Implementation of the technological standard for laboratory processing of biological material (wiring, filling, microtomy of paraffin blocks, drying, dyeing and manufacturing of micropreparations)	Violations of technological standards for laboratory processing of biological material, which led to an increase in the duration of studies		
2.	Implementation of the microscopic description standard in the Protocol of Intravital Pathological and	Microscopic description does not fully justify the diagnosis, contains an incomplete qualitative characteristic of the pathological process		
		Microscopic description is not a justification for the diagnosis, does not contain a		

	Anatomical Examination of Biopsy (Surgical) Material of Registration Form No. 014 -1/y	qualitative characteristic of the pathological process		
3.	Compliance with the conclusion standard in the Protocol of Intravital Pathological and Anatomical Examination of Biopsy (Surgical) Material, Registration Form No. 014 -1/y	In the conclusion of the Protocol of in-life pathological examination of biopsy (surgical) material, a nosological diagnosis is indicated, in the tumor process, the histological type of the tumor, the degree of differentiation G are indicated, but the stages T, N, M, the number of studied and affected lymph nodes, the purity of the borders of the surgical incision are not indicated		
		In the conclusion in the Protocol of the in-life pathological examination of biopsy (surgical) material, only nosological diagnosis is indicated		
	Indicator	Nonconformance	Number of nonconformances	
			Absolute	%
Post-analytical stage				
4.	Implementation of the technological standard for recording the results of the study in the "Log of registration of the receipt of biopsy (surgical) material and the issuance of the results of intravital pathological and anatomical studies" (registration form No. 014 -2/y)	Registration of the date of issue of the original Study Protocol in the Logbook of Receipt of Biopsy (Surgical) Material and Issuance of the Results of In-Life Pathological and Anatomical Studies (Registration Form No. 014-2/y) is not indicated		
5.	Fulfillment of the regulatory deadlines for submission of Protocols for in-life pathological and anatomical studies of biopsy (surgical) material of registration form No. 014-1/to the attending physicians	The regulatory deadlines for the submission of the Protocol of pathological and anatomical studies of biopsy (surgical) material (registration form No. 014-1/y) were reasonably exceeded (due to the untimely provision of additional clinical information)		
		The regulatory deadlines for submission of the Protocol of pathological and anatomical studies of biopsy (surgical) material (registration form No. 014-1/y) were unreasonably exceeded, which influenced the timeliness of determining treatment tactics		

6. Quality Indicator for lifetime pathological and anatomical studies by an expert

_____

7. Characterization of the impact of inconsistencies on the result of lifetime pathological and anatomical examination.

ANNEX D

(informative)

Sheet of expert assessment of the system of organization of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in state medical organizations of the Novosibirsk Region

Dear colleagues! Please act as an expert and complete the proposed survey sheet.

Thank you for your assistance!

1. Assess the level of professional knowledge of personnel in the pathological and anatomical services of state medical organizations of the Novosibirsk Region on a 5-point scale

a) 1 point (unsatisfactory)

b) 2 points (rather unsatisfactory)

c) 3 points (satisfactory)

d) 4 points (good)

e) 5 points (excellent)

2. Rate the level of technical equipment in the pathological and anatomical services of state medical organizations of the Novosibirsk Region on a 5-point scale

a) 1 point (unsatisfactory)

b) 2 points (rather unsatisfactory)

c) 3 points (satisfactory)

d) 4 points (good)

e) 5 points (excellent)

3. Use a 5-point scale to assess the impact of standardization of technological processes on the quality of research during lifetime pathological and anatomical diagnostics in the pathological and anatomical services of state medical organizations in the Novosibirsk Region

a) 1 point (minimum)

b) 2 points (minor)

c) 3 points (moderate)

d) 4 points (significant)

e) 5 points (maximum)

4. Evaluate on a 5-point scale the possibility of free research during lifetime pathological and anatomical diagnostics in the pathological and anatomical services of state medical organizations of the Novosibirsk Region

a) 1 point (unsatisfactory)

b) 2 points (rather unsatisfactory)

c) 3 points (satisfactory)

d) 4 points (good)

e) 5 points (excellent)

5. Assess on a 5-point scale the degree of influence of the complexity of technological processes on the quality of lifetime pathological and anatomical research in the pathological and anatomical services of state medical organizations of the Novosibirsk Region

a) 1 point (minimum)

b) 2 points (minor)

c) 3 points (moderate)

d) 4 points (significant)

e) 5 points (maximum)

6. Assess on a 5-point scale the degree of influence of the use of a medical information system on the optimization of document flow in the pathological and anatomical services of state medical organizations of the Novosibirsk Region

a) 1 point (minimum)

b) 2 points (minor)

c) 3 points (moderate)

d) 4 points (significant)

e) 5 points (maximum)

7. Use a 5-point scale to assess the impact of the use of equipment with a high degree of wear on the quality of the processes of lifetime pathological and anatomical studies of biological material in the pathological and anatomical services of state medical organizations in the Novosibirsk Region

a) 1 point (minimum)

b) 2 points (minor)

c) 3 points (moderate)

d) 4 points (significant)

e) 5 points (maximum)

8. On a 5-point scale, assess the significance of remote advice from Reference Centers to improve the quality of lifetime pathological and anatomical studies of biopsy (surgical) material

a) 1 point (minimum)

b) 2 points (minor)

c) 3 points (moderate)

d) 4 points (significant)

e) 5 points (maximum)

9. Assess on a 5-point scale the level of availability of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region

a) 1 point (low)

b) 2 points (rather low)

c) 3 points (average)

d) 4 points (sufficient)

e) 5 points (high)

10. Assess on a 5-point scale the quality of lifetime pathological and anatomical diagnostics of biopsy (surgical) material in the Novosibirsk Region

a) 1 point (low)

b) 2 points (rather low)

c) 3 points (mean)

d) 4 points (good)

e) 5 points (excellent)

11. Evaluate on a 5-point scale the system of archiving materials of lifetime pathological and anatomical studies in the pathological and anatomical services of state medical organizations of the Novosibirsk Region

a) 1 point (unsatisfactory)

b) 2 points (rather unsatisfactory)

c) 3 points (satisfactory)

d) 4 points (good)

e) 5 points (excellent)

12. Use a 5-point scale to assess the impact of the quality of lifetime pathological and anatomical diagnostics of biopsy (surgical) material on the speed of determining treatment tactics

a) 1 point (minimum)

b) 2 points (minor)

c) 3 points (moderate)

d) 4 points (significant)

e) 5 points (maximum)

13. Rate on a 5-point scale the level of participation of personnel of pathological and anatomical services in making management decisions in state medical organizations of the Novosibirsk Region

a) 1 point (unsatisfactory)

b) 2 points (rather unsatisfactory)

c) 3 points (satisfactory)

d) 4 points (good)

e) 5 points (excellent)

14. Evaluate on a 5-point scale the possibility of strategic planning of activities in the pathological and anatomical services of state medical organizations of the Novosibirsk Region

a) 1 point (unsatisfactory)

b) 2 points (rather unsatisfactory)

c) 3 points (satisfactory)

d) 4 points (good)

e) 5 points (excellent)

15. On a 5-point scale, assess the impact of the lack of incentives to increase the productivity of pathological and anatomical personnel on the quality and timeliness of lifetime pathological and anatomical diagnostics of biological material

a) 1 point (minimum)

b) 2 points (minor)

c) 3 points (moderate)

d) 4 points (significant)

e) 5 points (maximum)

16. Assess on a 5-point scale the degree of impact of the introduction of a medical information system on the quality of processes and the timeliness of lifetime pathological and anatomical studies of biological material in the pathological and anatomical services of state medical organizations in the Novosibirsk Region

a) 1 point (minimum)

b) 2 points (minor)

c) 3 points (moderate)

d) 4 points (significant)

e) 5 points (maximum)

17. Use a 5-point scale to assess the impact of process automation on the quality of processes and the timeliness of lifetime pathological and anatomical studies of biological material in the pathological and anatomical services of state medical organizations in the Novosibirsk Region

a) 1 point (minimum)

b) 2 points (minor)

c) 3 points (moderate)

d) 4 points (significant)

e) 5 points (maximum)

18. On a 5-point scale, assess the degree of influence of logistics functions when sending biological material on the quality of lifetime pathological and anatomical studies in the Novosibirsk Region

a) 1 point (minimum)

b) 2 points (minor)

c) 3 points (moderate)

d) 4 points (significant)

e) 5 points (maximum)

19. Evaluate the quality of the Protocols for lifetime pathological and anatomical diagnosis of biopsy (surgical) material in the Novosibirsk Region on a 5-point scale

a) 1 point (low)

b) 2 points (rather low)

c) 3 points (mean)

d) 4 points (good)

e) 5 points (excellent)

20. On a 5-point scale, assess the impact of the lack of an effective logistics system on the timeliness of obtaining the results of lifetime pathological and anatomical studies of biopsy (surgical) material

a) 1 point (minimum)

b) 2 points (minor)

c) 3 points (moderate)

d) 4 points (significant)

e) 5 points (maximum)

Administration of GBUZ NSO "GKB No. 1"

ANNEX E

(informative)

Quality Indicators for Lifetime Pathologic and Anatomical Studies of Biopsy (Surgical) Material Prior to Implementation of the Organizational and Functional Model of Lifetime Pathologic and Anatomical Diagnostics in the Novosibirsk Region

№	EHT	EMD	ECS	EPSP	Sum	Quality Indicators for Lifetime Pathologic and Anatomical Studies
1	0,50	0,90	1,00	0,75	3,150	0,788
2	1,00	0,90	1,00	0,75	3,650	0,913
3	1,00	1,00	0,75	1,00	3,750	0,938
4	0,50	0,90	0,75	0,75	2,900	0,725
5	1,00	0,90	1,00	0,75	3,650	0,913
7	1,00	1,00	0,75	0,75	3,500	0,875
8	1,00	1,00	0,75	1,00	3,750	0,938
9	1,00	0,90	0,75	1,00	3,650	0,913
10	0,50	0,90	0,75	0,75	2,900	0,725
11	0,50	1,00	0,75	0,75	3,000	0,750
12	1,00	1,00	1,00	1,00	4,000	1,000
13	1,00	1,00	0,75	1,00	3,750	0,938
14	0,50	1,00	0,75	0,75	3,000	0,750
15	0,50	1,00	1,00	0,75	3,250	0,813
16	1,00	1,00	1,00	1,00	4,000	1,000
17	1,00	1,00	0,75	1,00	3,750	0,938
18	0,50	0,90	0,75	0,75	2,900	0,725
19	1,00	1,00	0,75	1,00	3,750	0,938
20	0,50	1,00	0,75	0,75	3,000	0,750
21	1,00	0,90	0,75	1,00	3,650	0,913
22	1,00	1,00	0,75	1,00	3,750	0,938
23	0,50	1,00	0,75	0,75	3,000	0,750
24	1,00	1,00	1,00	1,00	4,000	1,000
25	1,00	1,00	0,75	0,75	3,500	0,875
26	1,00	0,90	0,75	0,75	3,400	0,850
27	1,00	1,00	1,00	1,00	4,000	1,000
28	1,00	0,90	1,00	0,75	3,650	0,913
29	1,00	0,90	1,00	1,00	3,900	0,975

30	1,00	1,00	1,00	1,00	4,000	1,000
31	1,00	0,90	0,75	1,00	3,650	0,913
32	1,00	0,90	0,75	1,00	3,650	0,913
33	1,00	1,00	0,75	0,75	3,500	0,875
34	1,00	0,90	0,75	0,75	3,400	0,850
35	1,00	0,90	0,75	0,75	3,400	0,850
36	1,00	1,00	1,00	0,75	3,750	0,938
37	0,50	0,90	1,00	0,75	3,150	0,788
38	1,00	0,90	1,00	0,75	3,650	0,913
39	1,00	1,00	1,00	0,75	3,750	0,938
40	1,00	0,90	0,75	0,75	3,400	0,850
41	1,00	1,00	0,75	0,75	3,500	0,875
44	1,00	0,90	1,00	0,75	3,650	0,913
43	1,00	0,90	0,75	1,00	3,650	0,913
44	1,00	1,00	0,75	0,75	3,500	0,875
45	1,00	1,00	1,00	0,75	3,750	0,938
46	1,00	0,90	1,00	0,75	3,650	0,913
47	1,00	0,90	1,00	1,00	3,900	0,975
48	1,00	1,00	1,00	0,75	3,750	0,938
49	1,00	1,00	1,00	0,75	3,750	0,938
50	1,00	1,00	1,00	0,75	3,750	0,938
51	1,00	0,90	0,75	1,00	3,650	0,913
52	1,00	1,00	0,75	0,75	3,500	0,875
53	1,00	1,00	0,75	1,00	3,750	0,938
54	1,00	0,90	0,75	0,75	3,400	0,850
55	1,00	0,90	0,75	1,00	3,650	0,913
56	1,00	1,00	1,00	0,75	3,750	0,938
57	1,00	1,00	0,75	0,75	3,500	0,875
58	1,00	1,00	0,75	0,75	3,500	0,875
59	1,00	1,00	1,00	0,75	3,750	0,938
60	0,50	1,00	1,00	0,75	3,250	0,813
61	0,50	1,00	0,75	0,75	3,000	0,750
62	1,00	1,00	0,75	0,75	3,500	0,875
63	0,50	1,00	0,75	0,75	3,000	0,750
64	0,50	1,00	0,75	0,75	3,000	0,750
65	1,00	1,00	1,00	0,75	3,750	0,938
66	1,00	1,00	0,75	0,75	3,500	0,875
67	0,50	1,00	0,75	0,75	3,000	0,750
68	0,50	1,00	1,00	0,75	3,250	0,813
69	1,00	1,00	1,00	0,75	3,750	0,938
70	1,00	1,00	1,00	0,75	3,750	0,938
71	0,50	1,00	1,00	0,75	3,250	0,813
72	1,00	1,00	1,00	0,75	3,750	0,938
73	1,00	1,00	1,00	0,75	3,750	0,938
74	0,50	1,00	1,00	0,75	3,250	0,813
75	0,50	1,00	1,00	0,75	3,250	0,813

76	1,00	1,00	1,00	0,75	3,750	0,938
77	0,50	1,00	1,00	0,75	3,250	0,813
78	0,50	1,00	1,00	0,75	3,250	0,813
79	1,00	1,00	1,00	0,75	3,750	0,938
80	0,50	1,00	1,00	0,75	3,250	0,813
81	1,00	1,00	1,00	0,75	3,750	0,938
82	1,00	1,00	1,00	0,75	3,750	0,938
83	0,50	1,00	1,00	0,75	3,250	0,813
84	1,00	1,00	1,00	0,75	3,750	0,938
85	0,50	1,00	0,75	0,75	3,000	0,750
86	1,00	1,00	0,75	0,75	3,500	0,875
87	0,50	1,00	0,75	0,75	3,000	0,750
88	0,50	1,00	0,75	0,75	3,000	0,750
89	1,00	1,00	1,00	0,75	3,750	0,938
90	1,00	1,00	0,75	0,75	3,500	0,875
91	1,00	1,00	0,75	0,75	3,500	0,875
92	1,00	1,00	1,00	0,75	3,750	0,938
93	1,00	1,00	1,00	0,75	3,750	0,938
94	1,00	1,00	1,00	0,75	3,750	0,938
95	0,50	1,00	1,00	0,75	3,250	0,813
96	0,50	1,00	1,00	0,75	3,250	0,813
97	1,00	1,00	1,00	0,75	3,750	0,938
98	0,50	1,00	1,00	0,75	3,250	0,813
99	1,00	1,00	1,00	0,75	3,750	0,938
100	1,00	1,00	1,00	0,75	3,750	0,938
101	1,00	1,00	1,00	0,75	3,750	0,938
102	1,00	1,00	1,00	0,75	3,750	0,938
103	1,00	1,00	1,00	0,75	3,750	0,938
104	1,00	1,00	1,00	0,75	3,750	0,938
105	0,50	1,00	1,00	0,75	3,250	0,813
106	1,00	1,00	0,75	0,75	3,500	0,875
107	0,50	1,00	0,75	0,75	3,000	0,750
108	0,50	1,00	0,75	0,75	3,000	0,750
109	1,00	1,00	0,75	0,75	3,500	0,875
110	1,00	1,00	1,00	0,75	3,750	0,938
111	1,00	1,00	0,75	0,75	3,500	0,875
112	1,00	1,00	1,00	0,75	3,750	0,938
113	1,00	1,00	1,00	0,75	3,750	0,938
114	1,00	1,00	1,00	0,75	3,750	0,938
115	1,00	1,00	1,00	0,75	3,750	0,938
116	1,00	1,00	1,00	0,75	3,750	0,938
117	1,00	1,00	1,00	1,00	4,000	1,000
118	1,00	1,00	1,00	1,00	4,000	1,000
119	0,50	1,00	1,00	1,00	3,500	0,875
120	1,00	1,00	1,00	1,00	4,000	1,000
121	0,50	1,00	1,00	0,75	3,250	0,813

122	1,00	1,00	1,00	1,00	4,000	1,000
123	0,50	1,00	1,00	0,75	3,250	0,813
124	1,00	1,00	1,00	1,00	4,000	1,000
125	1,00	1,00	1,00	1,00	4,000	1,000
126	1,00	1,00	1,00	0,75	3,750	0,938
127	1,00	1,00	1,00	0,75	3,750	0,938
128	1,00	1,00	1,00	0,75	3,750	0,938
129	0,50	1,00	1,00	0,75	3,250	0,813
130	1,00	1,00	1,00	1,00	4,000	1,000
131	0,50	1,00	1,00	0,75	3,250	0,813
132	1,00	1,00	1,00	0,75	3,750	0,938
133	0,50	1,00	1,00	0,75	3,250	0,813
134	1,00	1,00	1,00	1,00	4,000	1,000
135	0,50	1,00	1,00	0,75	3,250	0,813
136	1,00	1,00	1,00	1,00	4,000	1,000
137	0,50	1,00	1,00	0,75	3,250	0,813
138	1,00	1,00	1,00	1,00	4,000	1,000
139	0,50	1,00	1,00	0,75	3,250	0,813
140	1,00	1,00	1,00	1,00	4,000	1,000
141	0,50	1,00	1,00	0,75	3,250	0,813
142	1,00	1,00	1,00	1,00	4,000	1,000
143	0,50	1,00	1,00	0,75	3,250	0,813
144	0,50	1,00	1,00	0,75	3,250	0,813
145	1,00	1,00	1,00	1,00	4,000	1,000
146	1,00	1,00	1,00	1,00	4,000	1,000
147	1,00	1,00	1,00	1,00	4,000	1,000
148	1,00	1,00	1,00	1,00	4,000	1,000
149	1,00	1,00	1,00	0,75	3,750	0,938
150	1,00	1,00	1,00	0,75	3,750	0,938
151	1,00	1,00	1,00	0,75	3,750	0,938
152	1,00	1,00	1,00	0,75	3,750	0,938
153	1,00	1,00	1,00	1,00	4,000	1,000
154	1,00	1,00	1,00	0,75	3,750	0,938
155	1,00	1,00	1,00	0,75	3,750	0,938
156	1,00	1,00	1,00	1,00	4,000	1,000
157	1,00	1,00	1,00	1,00	4,000	1,000
158	1,00	1,00	1,00	1,00	4,000	1,000
159	1,00	1,00	1,00	1,00	4,000	1,000
160	1,00	1,00	1,00	1,00	4,000	1,000
161	1,00	1,00	1,00	1,00	4,000	1,000
162	1,00	1,00	1,00	1,00	4,000	1,000
163	1,00	1,00	1,00	1,00	4,000	1,000
164	1,00	1,00	1,00	1,00	4,000	1,000
165	1,00	1,00	0,75	1,00	3,750	0,938
166	1,00	1,00	0,75	1,00	3,750	0,938
167	1,00	1,00	0,75	1,00	3,750	0,938

168	1,00	1,00	0,75	1,00	3,750	0,938
169	1,00	1,00	1,00	1,00	4,000	1,000
170	1,00	1,00	0,75	1,00	3,750	0,938
171	1,00	1,00	1,00	1,00	4,000	1,000
172	1,00	1,00	1,00	1,00	4,000	1,000
173	1,00	1,00	1,00	1,00	4,000	1,000
174	1,00	1,00	1,00	1,00	4,000	1,000
175	1,00	1,00	1,00	1,00	4,000	1,000
176	1,00	1,00	0,75	1,00	3,750	0,938
177	1,00	1,00	0,75	1,00	3,750	0,938
178	1,00	1,00	0,75	1,00	3,750	0,938
179	1,00	1,00	0,75	1,00	3,750	0,938
180	1,00	1,00	1,00	1,00	4,000	1,000
181	1,00	1,00	0,75	1,00	3,750	0,938
182	1,00	1,00	1,00	1,00	4,000	1,000
183	1,00	1,00	1,00	1,00	4,000	1,000
184	1,00	1,00	1,00	1,00	4,000	1,000
185	1,00	1,00	1,00	1,00	4,000	1,000
186	1,00	1,00	0,75	1,00	3,750	0,938
187	1,00	1,00	0,75	1,00	3,750	0,938
188	1,00	1,00	0,75	1,00	3,750	0,938
189	1,00	1,00	0,75	1,00	3,750	0,938
190	1,00	1,00	1,00	1,00	4,000	1,000
191	1,00	1,00	1,00	1,00	4,000	1,000
192	1,00	1,00	1,00	1,00	4,000	1,000
193	1,00	1,00	1,00	1,00	4,000	1,000
194	1,00	1,00	0,75	1,00	3,750	0,938
195	1,00	1,00	0,75	1,00	3,750	0,938
196	1,00	1,00	0,75	1,00	3,750	0,938
197	1,00	1,00	0,75	1,00	3,750	0,938
198	1,00	1,00	1,00	1,00	4,000	1,000
199	1,00	1,00	1,00	1,00	4,000	1,000
200	1,00	1,00	0,75	1,00	3,750	0,938
201	1,00	1,00	0,75	1,00	3,750	0,938
202	1,00	1,00	0,75	1,00	3,750	0,938
203	1,00	1,00	0,75	1,00	3,750	0,938
204	1,00	1,00	1,00	1,00	4,000	1,000
205	1,00	1,00	1,00	1,00	4,000	1,000
206	1,00	1,00	1,00	1,00	4,000	1,000
207	1,00	1,00	1,00	1,00	4,000	1,000
208	1,00	1,00	1,00	1,00	4,000	1,000
209	1,00	1,00	1,00	1,00	4,000	1,000
210	1,00	1,00	1,00	1,00	4,000	1,000
211	1,00	1,00	0,75	1,00	3,750	0,938
212	1,00	1,00	0,75	1,00	3,750	0,938
213	1,00	1,00	0,75	1,00	3,750	0,938

214	1,00	1,00	0,75	1,00	3,750	0,938
215	1,00	1,00	1,00	1,00	4,000	1,000
216	1,00	1,00	1,00	1,00	4,000	1,000
217	1,00	1,00	0,75	1,00	3,750	0,938
218	1,00	1,00	0,75	1,00	3,750	0,938
219	1,00	1,00	0,75	1,00	3,750	0,938
220	1,00	1,00	0,75	1,00	3,750	0,938
221	1,00	1,00	1,00	1,00	4,000	1,000
222	1,00	1,00	1,00	1,00	4,000	1,000
223	1,00	1,00	1,00	1,00	4,000	1,000
224	1,00	1,00	1,00	1,00	4,000	1,000
225	1,00	1,00	1,00	1,00	4,000	1,000
226	1,00	1,00	1,00	1,00	4,000	1,000
227	1,00	1,00	1,00	1,00	4,000	1,000
228	1,00	1,00	1,00	1,00	4,000	1,000
229	1,00	1,00	1,00	1,00	4,000	1,000
230	1,00	1,00	1,00	1,00	4,000	1,000
231	1,00	1,00	0,75	1,00	3,750	0,938
232	1,00	1,00	0,75	1,00	3,750	0,938
233	1,00	1,00	0,75	1,00	3,750	0,938
234	1,00	1,00	0,75	1,00	3,750	0,938
235	1,00	1,00	1,00	1,00	4,000	1,000
236	1,00	1,00	1,00	1,00	4,000	1,000
237	1,00	1,00	1,00	1,00	4,000	1,000
238	1,00	1,00	1,00	1,00	4,000	1,000
239	1,00	1,00	0,75	1,00	3,750	0,938
240	1,00	1,00	0,75	1,00	3,750	0,938
241	1,00	1,00	0,75	1,00	3,750	0,938
242	1,00	1,00	0,75	1,00	3,750	0,938
243	1,00	1,00	1,00	1,00	4,000	1,000
244	1,00	1,00	1,00	1,00	4,000	1,000
245	1,00	1,00	0,75	1,00	3,750	0,938
246	1,00	1,00	0,75	1,00	3,750	0,938
247	1,00	1,00	0,75	1,00	3,750	0,938
248	1,00	1,00	0,75	1,00	3,750	0,938
249	1,00	1,00	1,00	1,00	4,000	1,000
250	1,00	1,00	0,75	1,00	3,750	0,938
251	1,00	1,00	0,75	1,00	3,750	0,938
252	1,00	1,00	0,75	1,00	3,750	0,938
253	1,00	1,00	0,75	1,00	3,750	0,938
254	1,00	1,00	0,75	1,00	3,750	0,938
255	1,00	1,00	0,75	1,00	3,750	0,938
256	1,00	1,00	0,75	1,00	3,750	0,938
257	1,00	1,00	0,75	1,00	3,750	0,938
258	1,00	1,00	0,75	1,00	3,750	0,938
259	1,00	1,00	1,00	1,00	4,000	1,000

260	1,00	1,00	1,00	1,00	4,000	1,000
261-500	1,00	1,00	1,00	1,00	4,000	1,000

ANNEX F

(informative)

Quality Indicators for Lifetime Pathologic and Anatomical Studies of Biopsy (Surgical) Material after Implementation of the Organizational and Functional Model of Lifetime Pathologic and Anatomical Diagnostics in the Novosibirsk Region

№	EHT	EMD	ECS	EPSP	Sum	Quality Indicators for Lifetime Pathologic and Anatomical Studies
1	1,00	1,00	1,00	1,00	4,000	1,000
2	1,00	1,00	1,00	1,00	4,000	1,000
3	1,00	1,00	1,00	1,00	4,000	1,000
4	1,00	1,00	1,00	1,00	4,000	1,000
5	1,00	1,00	1,00	1,00	4,000	1,000
7	1,00	1,00	1,00	1,00	4,000	1,000
8	1,00	1,00	1,00	1,00	4,000	1,000
9	1,00	1,00	1,00	1,00	4,000	1,000
10	1,00	1,00	0,75	1,00	3,750	0,938
11	1,00	1,00	0,75	1,00	3,750	0,938
12	1,00	1,00	1,00	1,00	4,000	1,000
13	1,00	1,00	0,75	1,00	3,750	0,938
14	1,00	1,00	0,75	1,00	3,750	0,938
15	1,00	1,00	1,00	1,00	4,000	1,000
16	1,00	1,00	1,00	1,00	4,000	1,000
17	1,00	1,00	0,75	1,00	3,750	0,938
18	1,00	1,00	0,75	1,00	3,750	0,938
19	1,00	1,00	0,75	1,00	3,750	0,938
20	1,00	1,00	0,75	1,00	3,750	0,938
21	1,00	1,00	0,75	1,00	3,750	0,938
22	1,00	1,00	0,75	1,00	3,750	0,938
23	1,00	1,00	0,75	1,00	3,750	0,938
24	1,00	1,00	1,00	1,00	4,000	1,000
25	1,00	1,00	0,75	1,00	3,750	0,938
26	1,00	1,00	0,75	1,00	3,750	0,938
27	1,00	1,00	1,00	1,00	4,000	1,000
28	1,00	1,00	1,00	1,00	4,000	1,000
29	1,00	1,00	1,00	1,00	4,000	1,000
30	1,00	1,00	1,00	1,00	4,000	1,000
31	1,00	1,00	0,75	1,00	3,750	0,938
32	1,00	1,00	0,75	1,00	3,750	0,938

33	1,00	1,00	0,75	1,00	3,750	0,938
34	1,00	1,00	0,75	1,00	3,750	0,938
35	1,00	1,00	0,75	1,00	3,750	0,938
36	1,00	1,00	1,00	1,00	4,000	1,000
37	1,00	1,00	1,00	1,00	4,000	1,000
38	1,00	1,00	1,00	1,00	4,000	1,000
39	1,00	1,00	1,00	1,00	4,000	1,000
40	1,00	1,00	0,75	1,00	3,750	0,938
41	1,00	1,00	0,75	1,00	3,750	0,938
44	1,00	1,00	1,00	1,00	4,000	1,000
43	1,00	1,00	0,75	1,00	3,750	0,938
44	1,00	1,00	0,75	1,00	3,750	0,938
45	1,00	1,00	1,00	1,00	4,000	1,000
46	1,00	1,00	1,00	1,00	4,000	1,000
47	1,00	1,00	1,00	1,00	4,000	1,000
48	1,00	1,00	1,00	1,00	4,000	1,000
49	1,00	1,00	1,00	1,00	4,000	1,000
50	1,00	1,00	1,00	1,00	4,000	1,000
51	1,00	1,00	0,75	1,00	3,750	0,938
52	1,00	1,00	0,75	1,00	3,750	0,938
53	1,00	1,00	0,75	1,00	3,750	0,938
54	1,00	1,00	0,75	1,00	3,750	0,938
55	1,00	1,00	0,75	1,00	3,750	0,938
56	1,00	1,00	1,00	1,00	4,000	1,000
57	1,00	1,00	0,75	1,00	3,750	0,938
58	1,00	1,00	0,75	1,00	3,750	0,938
59	1,00	1,00	1,00	1,00	4,000	1,000
60	1,00	1,00	1,00	1,00	4,000	1,000
61	1,00	1,00	0,75	1,00	3,750	0,938
62	1,00	1,00	0,75	1,00	3,750	0,938
63	1,00	1,00	0,75	1,00	3,750	0,938
64	1,00	1,00	0,75	1,00	3,750	0,938
65	1,00	1,00	1,00	1,00	4,000	1,000
66	1,00	1,00	0,75	1,00	3,750	0,938
67	1,00	1,00	0,75	1,00	3,750	0,938
68	1,00	1,00	1,00	1,00	4,000	1,000
69	1,00	1,00	1,00	1,00	4,000	1,000
70	1,00	1,00	1,00	1,00	4,000	1,000
71	1,00	1,00	1,00	1,00	4,000	1,000
72	1,00	1,00	1,00	1,00	4,000	1,000
73	1,00	1,00	1,00	1,00	4,000	1,000
74	1,00	1,00	1,00	1,00	4,000	1,000
75	1,00	1,00	1,00	1,00	4,000	1,000
76	1,00	1,00	1,00	1,00	4,000	1,000
77	1,00	1,00	1,00	1,00	4,000	1,000
78	1,00	1,00	1,00	1,00	4,000	1,000

79	1,00	1,00	1,00	1,00	4,000	1,000
80	1,00	1,00	1,00	1,00	4,000	1,000
81	1,00	1,00	1,00	1,00	4,000	1,000
82	1,00	1,00	1,00	1,00	4,000	1,000
83	1,00	1,00	1,00	1,00	4,000	1,000
84	1,00	1,00	1,00	1,00	4,000	1,000
85	1,00	1,00	0,75	1,00	3,750	0,938
86	1,00	1,00	0,75	1,00	3,750	0,938
87	1,00	1,00	0,75	1,00	3,750	0,938
88	1,00	1,00	0,75	1,00	3,750	0,938
89	1,00	1,00	1,00	1,00	4,000	1,000
90	1,00	1,00	0,75	1,00	3,750	0,938
91	1,00	1,00	0,75	1,00	3,750	0,938
92	1,00	1,00	1,00	1,00	4,000	1,000
93	1,00	1,00	1,00	1,00	4,000	1,000
94	1,00	1,00	1,00	1,00	4,000	1,000
95	1,00	1,00	1,00	1,00	4,000	1,000
96	1,00	1,00	1,00	1,00	4,000	1,000
97	1,00	1,00	1,00	1,00	4,000	1,000
98	1,00	1,00	1,00	1,00	4,000	1,000
99	1,00	1,00	1,00	1,00	4,000	1,000
100-500	1,00	1,00	1,00	1,00	4,000	1,000