ORIGINAL STUDY ARTICLES

ORGANIZING THE LABORATORY TESTING PROCEDURES IN ISCHEMIC STROKE PATIENTS

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ABSTRACT

BACKGROUND: *Arranging the laboratory tests for the patients presenting with suspected ischemic stroke, represents an important task for medical organizations. Further treatment tactics may depend on the results of such tests, due to which, it is necessary to assure its high quality at all the stages of laboratory diagnostics.* ***AIM:*** *An optimization of the pre-analytical and analytical stages of laboratory testing for the admitted patients, shortening the testing turnaround time (TAT) along with drawing up the organizational decisions together with the clinicists and the quality control department.* ***METHODS:*** *The analysis and the rehearsal of the logistical aspects of all the processes related to the hospitalization of acute ischemic stroke patients were arranged by means of organizing the in-house drills and the time tracking of the operations at the admission ward and at the express-laboratory.* ***RESULTS:*** *After performing the in-house timed drills, a number of problems was revealed, both at the admission ward and at the express-laboratory, solving of which has allowed for optimizing the working processes, facilitating the pre-analytical stage and shortening the time of issuing the results. An in-house directive was issued on providing medical aid to the stroke patients, standard operations procedures were drafted and additional adjustments were introduced into the laboratory and medical information systems. The analysis of the regulatory basis has provided a possibility for specificating a number of immunohematological tests for stroke patients and shortening the costs of reagents and expendable materials.* ***CONCLUSION:*** *For the decreasing the total TAT down to 20 minutes for the purpose conforming the quality criteria, it is necessary to shorten the time of pre-analytical and analytical stages. Each medical organization is recommended to arrange the time tracking of all the processes of stroke patient admission for detecting the most time-intensive activities.*

Keywords: *ischemic stroke; laboratory tests; quality criteria; turnaround time, TAT.*

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BACKGROUND

The necessity of performing certain laboratory tests within the shortest possible period of time after hospitalization to the in-patient department for the patients with suspected ischemic stroke is regulated by a number of regulatory documents: the procedure of providing medical aid to the patients with cerebrovascular accidents (CVA) [1], the standard of specialized medical aid for cases of cerebral infarction [2], the clinical recommendations on ischemic stroke [3] and the Directive issued by the Ministry of Health on the criteria for evaluating the quality [4]. The main task with this background is the rapid obtaining the results for the purpose of ruling out the contraindications for undergoing thrombolytic therapy and conducting the differential diagnostics with other diseases having the similar clinical patterns. The lists of laboratory tests and the timings of fulfilling the tests in the abovementioned documents differ (table 1). One of four documents listed above regulates the timing of the tests as being 20 minutes from the admission of the ischemic stroke patient to the in-patient department. The Procedure of providing medical aid contains less strict requirements — 20 minutes from the moment of drawing the blood sample. Within this context, for the purpose of assuring the quality of providing medical aid, it is necessary to refer to the maximum list of tests (platelet count, blood glucose, activated partial thromboplastin time, international normalized ratio)

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ОРИГИНАЛЬНОЕ ИССЛЕДОВАНИЕ

ОРГАНИЗАЦИЯ ЛАБОРАТОРНЫХ ИССЛЕДОВАНИЙ ПРИ ОКАЗАНИИ ПОМОЩИ ПАЦИЕНТАМ С ИШЕМИЧЕСКИМ ИНСУЛЬТОМ

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АННОТАЦИЯ

Обоснование. *Организация лабораторных исследований пациентам, поступающим с подозрением на ишемический инсульт, является важной задачей для медицинской организации. От результатов этих исследований может зависеть дальнейшая лечебная тактика, в связи с чем необходимо обеспечение высокого качества на всех этапах лабораторной диагностики.* ***Цель исследования*** *— оптимизация преаналитического и аналитического этапа лабораторных исследований у поступающих пациентов, сокращение времени оборота теста (turnaround time, TAT) и выработка организационных решений совместно с врачами-клиницистами и отделом контроля качества.* ***Методы.*** *Изучение и отработка логистики всех процессов, касающихся госпитализации пациентов с острым ишемическим инсультом, проводились путём внутренних учений и хронометража в приёмном отделении и экспресс-лаборатории.* ***Результаты.*** *После внутренних учений и хронометража был выявлен ряд проблем как в приёмном отделении, так и в экспресс-лаборатории, решение которых позволило оптимизировать рабочие процессы, облегчить преаналитический этап и сократить время выдачи результатов. Был утверждён внутренний приказ по оказанию помощи пациентам с инсультом, разработаны стандартные операционные процедуры, внесены дополнительные настройки в лабораторную и медицинскую информационные системы. Анализ нормативной базы дал возможность конкретизировать перечень иммуногематологических исследований у пациентов с инсультом и сократить затраты на реагенты и расходные материалы.* ***Заключение.*** *Для уменьшения общего TAT до 20 минут в целях соответствия критериям качества необходимо сокращение времени на преаналитический и аналитический этапы. Каждой медицинской организации рекомендуется провести хронометраж всех процессов при поступлении пациента с инсультом для выявления наиболее времязатратных действий.*

Ключевые слова: *ишемический инсульт; лабораторные исследования; критерии качества; время оборота теста; TAT.*

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and the minimal time for issuing the result (20 minutes from the admission to the in-patient department).

Upon planning the opening of the Department for patients with acute cerebral circulation disorders, the laboratory of the Federal State Budgetary Institution “Federal Center of Brain Research and Neurotechnologies” under the Federal Medical-Biological Agency (FSBI FCBRN of the RFMBA) has received a task of organizing the procedures of conducting emergency laboratory tests for the presenting patients in accordance with the current regulatory documents — within 20 minutes from the hospitalization moment. This time interval includes the time required for assessing the patient, for issuing the referrals for testing, for drawing the blood sample, for the transportation of test tubes to the laboratory, the centrifugation, the testing procedures and the issuance of the result.

Research aim — optimizing the pre-analytical and analytical stages of laboratory tests with taking into consideration the time tracking data for all the procedures related to the laboratory tests among the presenting patients for the purpose of shortening the test turnaround time (TAT).

Table 1

The list of laboratory tests for stroke patients

Regulatory document	List of tests	Time to completion
Procedure of providing medical aid to CVA patients	• Platelet count • Glucose • INR • APTT	Within 20 min from the moment of drawing the blood sample
Standard of specialized medical aid in cases of cerebral infarction	• Glucose • Blood pH • INR • Blood group and rhesus-factor • Blood-transmitted infections • Coagulation tests • Clinical hematology panel • Blood biochemistry panel • Clinical urinalysis	Timings not provided*
Clinical recommendations on ischemic stroke	• Glucose • INR** • Thrombin time**	Timings not provided*
	• General (clinical) hematology panel • Blood biochemistry panel • Blood testing for evaluating the lipid metabolism disorders • Coagulation tests • Clinical urinalysis	Within 3 hours from the moment of admission
Directive issued by the Ministry of Health on the criteria for evaluating the quality	• Platelet count • Glucose • INR • APTT	20 min from the admission to the in-patient department

Note. * — tests are carried out at the diagnostics stage; ** — all the patients that are considered candidates for reperfusion therapy. CVA — cerebrovascular accident; INR — international normalized ratio; APTT — activated partial thromboplastin time.

METHODS

In order to understand and to process the logistics of all the processes related to the hospitalization of acute ischemic stroke patients, the in-house drills were arranged with the participation of the employees as volunteers.

The admission ward with intensive therapy units under the Federal State Budgetary Institution FCBRN of the Russian Federal Medical-Biological Agency is located at the 2nd floor and it is involved into registering the patients and issuing the referrals for testing, drawing and labeling the biomaterial, sending the test tubes to the express-laboratory by means of pneumatic transportation system. The express-laboratory is situated at the 10th floor with the pneumatic transportation system receiving terminal being located at a distance of 80m from the entrance to the laboratory. The laboratory testing request is compiled in the medical information system (MIS) and imported to the laboratory information system (LIS), where the express-laboratory staff member activates it, inputs the results and approves it. Later on, within half an hour, the result form is automatically uploaded into the MIS.

The time tracking was conducted at the admission ward and at the express-laboratory after mastering of all the processes of the pre-analytical stage. The clinical-laboratory diagnostics physician and the Quality Control Department staff member were measuring the time required for compiling the request in the MIS, for labeling the test tubes, for drawing the blood sample, for delivering it to the pneumatic transportation system terminal, for its further transportation by means of the pneumatic system, for the transfer from the pneumatic transportation system terminal to the express-laboratory, for importing the samples to the LIS, placing them into the centrifuge and for centrifugating, for performing the clinical hematology panel for assessing the platelet concentration by means of the Nihon Kohden MEK-6500K hematology analyzer, for transferring the test tubes from the centrifuge to the analyzers, for measuring the activated partial thromboplastin time (APTT) and the international normalized ratio (INR) at the Sysmex CA-660 coagulometer, for measuring the glucose level by means of the Spotchem biochemistry express-analyzer and for approving the results by the clinical laboratory diagnostics physician.

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RESULTS

Problems, revealed based on the results of the drills

As a result of conducting the in-house drills, certain problems were revealed which may increase the time of issuing the result. Thus, at the admission ward stage, referrals were compiled and blood samples were drawn not only for emergency testing for platelet count, glucose, INR and APTT, but also for the tests which should be carried out both in the emergency and in the scheduled order (biochemistry panel, lipid profile, electrolytes, blood group and rhesus-factor, blood-transmitted infections), which was increasing the time of registration and drawing blood samples, on the one hand, while on the other — it was resulting in an over-consumption of test tubes in cases when the diagnosis was not confirmed, and the patient was not hospitalized or he (she) was transferred to another in-patient department. Compiling separate referrals for clinical hematology panel, INR/APTT and glucose was extending the compilation process: each referral required printing its own barcode via the MIS, which was only possible after pressing the "Send request to laboratory" button.

Upon sending the capsule with the test tubes by means of pneumatic transportation system, additional notice had to be given to the express-laboratory, for the pneumatic transportation system terminal was located remotely at a certain distance from the express-laboratory and its staff members could not immediately notice the delivery of the biomaterial.

Upon admission of the biomaterial to the express-laboratory, there could be a situation in which the required analyzers were in process of calibrating or measuring the reference samples, which was also causing a delay in issuing the results. The biochemistry analyzer, which was used to measure the glucose levels, could be currently in process of analyzing the blood samples from the patients admitted on a scheduled basis, due to which, certain time was required for stopping the operation and testing the emergency samples.

The neurologist could receive the results of laboratory tests with a delay caused by its uploading from the LIS to MIS once in 30 minutes.

Solving the revealed problems

In order to solve the detected issues, the following was proposed and implemented:

An in-house directive "On the provision of emergency medical aid to the patients with acute disorders of the cerebral circulation at the FSBI "FCBRN" under the Russian Federal Medical-Biological Agency" was approved, in which, a clear sequence of actions was established for implementation by the medical staff along with the methods of communication/notification on compiling the results with setting the specific housephone numbers.

Upon the patient's presenting to the admission ward, only 3 test tubes had to be filled in for performing the required test profile: the one containing gel and the clot activator, the one with sodium citrate and the one with EDTA (ethylenediaminetetraacetic acid). Blood samples for all the other tests are now drawn after the patient's transfer to the intensive care unit, where the referrals for these tests are compiled in the MIS.

A "CVA profile" was created in the LIS, the results of which are printed on a single sheet and which includes the general (clinical) hematology panel, the glucose level, the APTT and the INR. The profile testing request should be compiled in the MIS with bearing a single number and, respectively, a single barcode.

Changes were also introduced into the algorithm of compiling the request for laboratory tests in the MIS: it became possible to initially print the barcode, to attach it to the test tubes, to draw the blood sample and then, after the completion of all the procedures with the patient at the level of admission department, to send the request from the MIS to the LIS. Thus, the LIS is now showing the real time of sending the samples to the laboratory.

The express-laboratory was equipped with a sound alarm notifying about the receipt (by means of the pneumatic transportation system) of the capsule containing the biomaterial tubes.

The staff of the admission department uses the telephone to notify the express-laboratory personnel about the planning admission (by means of the ambulance crew) in case of a stroke patient (the data used are taken from the "Stacionar" automated information system): this allows for preparing the analyzers and, if necessary, for delaying the scheduled rinsing, calibration and quality control procedures.

For the purpose of measuring the serum glucose concentration, a "dry chemistry" express-analyzer is now being used.

For the purpose of rapid obtaining the results, now the Neurology physician is not waiting for the results to be uploaded to the MIS, he immediately calls the express-laboratory. The reverse approach of notifying a neurologist by the laboratory personnel is not deemed rational, for the neurologist could go to the medical procedure room, to the magnetic resonance or computed tomography office, while searching for his (her) exact location could take a certain time.

The next stage included a time tracking of the procedures at the pre-analytical, analytical and post-analytical stages of laboratory testing for patients presenting with ischemic stroke.

The phase of registering a request in the MIS together with labeling the tubes took 8 minutes. Transportation of test tubes from floor 2 to floor 10 took 2.07 minutes, activation in the LIS — 0.15 minutes, placing into the centrifuge — 0.3 minutes, centrifugation — 10.28 minutes (taking into consideration the time of stopping the centrifuge). The clinical hematology panel was done in 1.12 minutes during the centrifugation of the other test tubes. The placement of the test tube into the coagulometer and the coagulation testing itself took 10.24 minutes. During the coagulation testing, glucose level was measured using the "dry chemistry" analyzer, which took 6.47 minutes (for comparison — the measurements performed using the "Sapfir 400" takes 14.2 minutes). Approval of the results — 0.15 minutes; total TAT — 32 minutes, laboratory TAT (from the moment of sample admission to the laboratory) — 24 minutes, with the 2/3 of the total TAT taken by the non-laboratory pre-analytical (compilation of the request, drawing the blood and transportation — 9.12 minutes) and by the intra-laboratory pre-analytical (centrifugation — 10.58 minutes) stages. The minimal time of performing the laboratory tests is limited to the operating speed of the coagulometer — 10.24 minutes. The measurements of the duration of performing only the APTT as more time-consuming test comparing to the INR, has shown the result of 9.09 minutes. The possible solutions here can include the use of test tubes with the clot activator and thrombin for performing the biochemistry tests (thrombin shortens blood clotting time, which allows for avoiding repeated centrifugation) and for lowering the centrifugation time down to 5 minutes. Shortening the time required for measuring the APTT and the INR can be aided by using the semi-automatic coagulometers with manual addition of reagents. Measuring the APTT in that case takes up to 5 minutes, while the INR requires up to 4 minutes. The hemostasis analyzers recently introduced into the market, capable of, in particular, measuring the INR in whole blood, as well as the "dry chemistry" principle-based analyzers, according to our own experience, do not comply to the criteria of recommending them for usage: the comparison of the results obtained using 22 plasma samples with the data from ACL Top 300 coagulometer, has revealed a mean overestimation of 23%. Such a distribution is unacceptable, especially when dealing with the patients that are candidates for reperfusion therapy.

Within the framework of the general activities directed at increasing the quality of laboratory tests, in accordance with the national standard [5] and practical recommendations from the Federal Service for Surveillance in Healthcare on the internal quality control at the medical laboratory [6], standard operations procedures were developed and approved on the rules of rejecting the biomaterial, on the archivation of referrals and of the biomaterial, on the critical values for the laboratory results, as well as on the rules of operating the pneumatic transportation systems. The LIS allows for selecting the type of defect for rejection, which facilitates the analytical operations and the determination of the corrective actions. The critical values shall be marked in the LIS using flags, upon seeing which, the clinical-laboratory diagnostics physician immediately calls the attending physician and registers the result in the Critical Result Report Log.

A certain part of patients presenting with suspected ischemic stroke, required differential diagnostics with alcohol or narcotic poisoning. For such cases, an agreement for performing the chemical-toxicological testing was signed with the external laboratory related to the Department of Healthcare of Moscow City. The biomaterial intended for defining the levels of ethanol and narcotic/psychoactive drugs, is drawn from the patient on admission and later transferred for further testing. Due to the fact that chemical-toxicological tests are regulated by the separate regulatory documents [7], a specific standard operation procedure was developed on drawing, labeling and transportation of the biomaterial for performing such tests, with the SOP being provided for familiarization to all the staff members of the express-laboratory and of the clinical departments, which has accelerated the process of drawing and preparing the biomaterial for transportation and which has decreased the probability of rejecting it by the chemical-toxicological laboratory.

Separate attention should be paid to the blood group testing in patients during the most acute period of ischemic stroke. Initially, for CVA patients, the planned prescriptions included a complete immunohematology profile — blood group (AB0 system) and rhesus-factor, phenotyping of Rhesus-antigens and antierythrocytic antibodies. The justification of this was the possible necessity of blood transfusion at the intensive care unit, but performing a full set of the tests mentioned above to all the patients with suspected CVA is unjustifiably cost-intensive, for the immunohematological tests at the FSBI "FCBRN" under the Russian Federal Medical-Biological Agency are carried out using the gel

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cards, the net cost of which is quite high. The analysis of the regulatory basis has shown that the requirements for performing the immunohematological tests in the given groups of patients are controversial. Thus, in the Procedure of providing medical aid to CVA patients, in the Directive on the establishing the criteria for evaluating the quality of medical aid, as well as in the Clinical recommendations on ischemic stroke, the testing for blood group and rhesus-factor are not included into the list of necessary laboratory tests. The Standard of medical aid for stroke patients (upon providing specialized medical aid) states only the detection of the main blood group antigens (A, B, 0) and the testing for rhesus-status. The detection of K (Kell) antigen and of the antierythrocytic antibodies, in accordance with the Decree issued by the Government of the RF on June 22, 2019 No. 797 [8], is indicated to the patients requiring blood transfusion, while the detection of C, c, E, e antigens in red blood cells — to female patients aged under 18 years and to the women of child-bearing age; to the recipients that have indications for repeated blood transfusions; to the recipients which were ever diagnosed as having alloimmune antibodies, as well as to the recipients with a history of incompatible blood transfusions. Thus, for decreasing the costs of reagents and expendable materials, as well as for decreasing the load of the laboratory personnel, the decision drawn was to detect only the blood group (AB0) and the rhesus-factor among the presenting CVA patients and, if blood transfusion is necessary, to perform additional testing of the phenotype and antibody profile.

Based on the conducted research, we can propose our algorithm of actions upon the admission of CVA patients for the purpose of decreasing the TAT (Fig. 1).

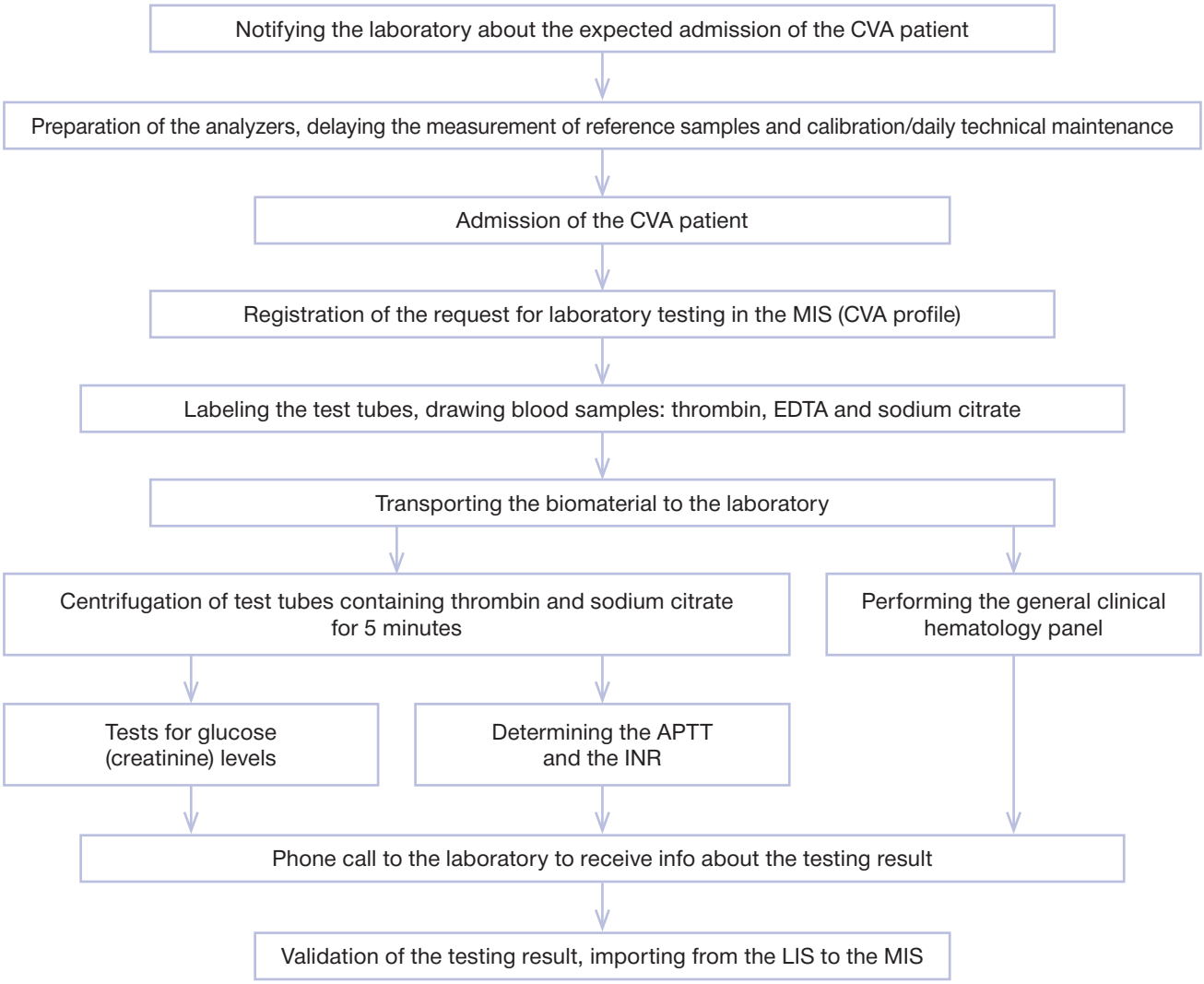

Fig. 1. Operation algorithm upon the admission of the patient with an acute disorder of the cerebral circulation. CVA — cerebrovascular accident; MIS/LIS — medical and laboratory information systems; APTT — activated partial thromboplastin time; INR — international normalized ratio; EDTA — ethylenediaminetetraacetic acid.

DISCUSSION

In order to decrease the total TAT for conforming the quality criteria, shortening the time of pre-analytical and analytical stages is required. Shortening the duration of pre-analytical stage can be achieved by training the medium-level medical personnel of admission department on maximally rapid algorithms of compiling the request in the MIS, as well as by decreasing the time of sample centrifugation down to 5 minutes with the setting of using the vacuum test tubes containing the clot activator and thrombin for faster clot formation. Shortening the analytical stage is possible by means of using the portable express-coagulometer, capable of testing the whole blood samples (though requiring the procedure of measuring the repeatability of the result with comparing them to the classic clot-method), or a semi-automated coagulometer, which should allow for shortening the time of testing. In case of a large number of presenting CVA patients, it is more practicable to locate the express-laboratory, equipped with a centrifuge, hematology analyzer, express-biochemistry analyzer and express-coagulometer, at the admission ward, which shall allow for decreasing the time of biomaterial transportation.

CONCLUSION

The high quality of laboratory tests for patients with ischemic stroke is assured by operating in accordance with the standard operation procedures, which strictly regulate the sequence of operations, as well as by the coordinated interactions between the laboratory and clinical department personnel, as well as by using the optimized MIS/LIS operations at the medical organizations.

ADDITIONAL INFORMATION

Author contribution. *O.V. Lyang* — conducting research, making recommendations, writing the text and final editing of the article; *Yu.V. Novozhenova* — conducting timekeeping in the laboratory, writing the text of the article; *I.A. Zhirova* — search and analytical work, writing the text of the article. The authors made a substantial contribution to the conception of the work, acquisition, analysis, interpretation of data for the work, drafting and revising the work, final approval of the version to be published and agree to be accountable for all aspects of the work.

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