

<https://doi.org/10.21320/1818-474X-2024-1-158-167>

Russian registry of Surgical OutcomeS — RuSOS: study protocol

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Национальный регистр послеоперационных исходов — RuSOS: протокол исследования

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Abstract

INTRODUCTION: Identification of risk factors that cause a high probability of an unfavorable outcome in the postoperative period is an urgent problem. The creation of national databases (registries) makes it possible to cover a certain patient population by identifying its risk predictors. Existing registries differ in the criteria for inclusion in the study, in the characteristics of the populations studied, and there is often no common view on the classification of postoperative outcomes. **OBJECTIVE:** Creation of a Russian national calculator for the risk of postoperative complications and mortality. **MATERIALS AND METHODS:** Two-level observational retrospective-prospective study. Setting: National multicenter study of surgical inpatients. Patients: Adult patients undergoing elective and emergency surgery. Types of interventions: obstetrics, gynecology, mammary gland, urology, endocrine surgery, maxillofacial surgery, orthopedics, traumatology, abdominal surgery, liver and biliary tract, thoracic surgery, vascular surgery, neurosurgery, cardiac surgery, other areas. **RESULTS:** The design was registered in the ClinicalTrials.gov database, the study was organized by the Federation of Anesthesiologists and Reanimatologists of Russia. Primary (30-day mortality, 30-day complications) and secondary (hospital mortality, hospital complications, length of stay in ICU, length of hospital stay, multiple organ failure (2 or more points on the SOFA scale), 90-day mortality, 90-day complications, post intensive care syndrome, readmission, 1-year mortality) outcomes; six primary and twelve secondary target points; criteria for inclusion, non-inclusion, exclusion. The required sample size and statistical analysis are described. The planned sample size to ensure the required power of the study is determined to be 60,800 observations for elective surgery and 20,000 observations for emergency surgery. The planned duration of the study is 2024–2028. **CONCLUSIONS:** The study has important scientific and medical-social significance; a Russian national calculator for the risk of postoperative complications and mortality will be developed. In the future, the developed calculator can become the basis for making medical decisions.

Реферат

АКТУАЛЬНОСТЬ: Выявление факторов риска, обуславливающих высокую вероятность неблагоприятного исхода в послеоперационном периоде, является актуальной проблемой. Создание национальных баз данных (регистров) позволяет максимально охватить определенную популяцию пациентов, выявив характерные для нее предикторы риска. Как показывают данные литературы, существующие регистры различаются в критериях включения в исследование, в характеристиках изучаемых популяций, часто отсутствует единый взгляд на классификацию послеоперационных исходов. **ЦЕЛЬ ИССЛЕДОВАНИЯ:** Создание российского национального калькулятора риска послеоперационных осложнений и летальности. **МАТЕРИАЛЫ И МЕТОДЫ:** Двухуровневое обсервационное ретроспективно-проспективное исследование. Условия: национальное многоцентровое исследование пациентов хирургических стационаров. Пациенты: взрослые пациенты, подвергающиеся плановым и экстренным оперативным вмешательствам. Виды вмешательств: в акушерстве, в гинекологии, на молочной железе, в урологии и на почках, в эндокринной хирургии, в челюстно-лицевой хирургии, в ортопедии и травматологии, на нижнем этаже брюшной полости, на печени и желчевыводящих путях, на верхнем этаже брюшной полости, в торакальной хирургии, в сосудистой хирургии, в нейрохирургии, в кардиохирургии, в других областях (с обязательной конкретизацией). **РЕЗУЛЬТАТЫ:** Разработанный дизайн был зарегистрирован в базе данных ClinicalTrials.gov, исследование организовано Федерацией анестезиологов и реаниматологов России. Определены первичные (30-дневная летальность, 30-дневные осложнения) и вторичные (госпитальная летальность, госпитальные осложнения, длительность пребывания в отделениях анестезиологии, реанимации и интенсивной терапии, длительность пребывания в стационаре, полиорганная недостаточность (2 балла и более по шкале SOFA (Sequential Organ Failure Assessment)), 90-дневная

REGISTRATION: Clinicaltrials.gov identifier: NCT06146270. Registered November 23, 2023.

KEYWORDS: hospital mortality, risk factors, concomitant diseases, registries, postoperative complications

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✉ *For citation:* Zabolotskikh I.B., Belkin A.A., Grigoryev E.V., Grigoryev S.V., Gritsan A.I., Dunts P.V., Ershov V.I., Kirov M.Yu., Kuzovlev A.N., Kulikov A.V., Musaeva T.S., Ovezov A.M., Protsenko D.N., Subbotin V.V., Trembach N.V., Khoronenko V.E., Shifman E.M., Shchegolev A.V., Lebedinskii K.M. Russian registry of Surgical OutcomeS — RuSOS: study protocol. *Annals of Critical Care*. 2024;1:158–167. <https://doi.org/10.21320/1818-474X-2024-1-158-167>

✉ *Received:* 01.11.2023

✉ *Accepted:* 08.11.2023

✉ *Published online:* 27.01.2024

летальность, 90-дневные осложнения, синдром последствий интенсивной терапии, повторная госпитализация, годовая летальность), исходы; 6 первичных и 12 вторичных целевых точек; критерии включения, невключения, исключения. Описаны необходимый размер выборки и методы статистического анализа. Планируемый объем выборки для обеспечения требуемой мощности исследования определен в 60 800 наблюдениях для плановых операций и 20 000 наблюдений для экстренных операций. Планируемые сроки проведения исследования — 2024–2028 гг. **Выводы:** Исследование имеет важное научное и медико-социальное значение, в результате анализа полученных данных будет разработан российский национальный калькулятор риска послеоперационных осложнений и летальности. В перспективе разработанный калькулятор может стать основой для принятия медицинских решений.

РЕГИСТРАЦИЯ: идентификатор Clinicaltrials.gov: NCT06146270. Зарегистрировано 23 ноября 2023 г.

КЛЮЧЕВЫЕ СЛОВА: больничная летальность, факторы риска, сопутствующие заболевания, регистр, послеоперационные осложнения

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✉ *Поступила:* 01.11.2023

✉ *Принята к печати:* 08.11.2023

✉ *Дата онлайн-публикации:* 27.01.2024

Introduction

Currently, the frequency of perioperative complications and mortality associated with surgery are minimized. Nevertheless, taking into account the significant number of surgical interventions performed worldwide (which is more than 300 million per year) [1], the total number of patients with complicated postoperative periods is high, and postoperative mortality ranks third in the structure of causes of death (7.7%), after coronary heart disease and stroke [2]. Moreover, even in discharged patients, complications that have developed can significantly reduce the quality of life and worsen the long-term prognosis [3]. To a greater extent, the aforementioned applies to high-risk patients, the identification of which is the priority task of anesthesiology.

Identification of risk factors that cause a high probability of an unfavorable outcome is currently unthinkable without comprehensive prospective population studies, which, on the one hand, allow us to assess the contribution of many variables to the risk of complications and mortality, and on the other hand, to maximize coverage of a certain population by identifying its characteristic predictors [4]. At the moment, several population-based studies and programs have been described in the literature, which have allowed the creation of national databases (registers) of postoperative outcomes. Such studies include several international (ISOS, EuSOS and ASOS) [5-7] and national ones, such as SweSOS [8] or ColSOS [9], which are at different stages of implementation. Of the national databases, the most well-known is the ACS-NSQIP database (the National Program for Improving the Quality of Surgical Care of the American College of Surgeons), which contains information on the outcomes of surgical treatment of more than 5 million patients from the United States since 1991 [10].

The obtained results of these studies often differ significantly, which was the result of a variety of approaches to the criteria for inclusion in the study, differences in the characteristics of the studied populations and the lack of a unified view on the classification of postoperative outcomes. When assessing mortality, the authors most often register a 30-day mortality, however, considering modern ideas about the role of perioperative factors and complications in the development of an unfavorable long-term outcome, it becomes obvious that it is necessary to determine the annual mortality. As the SweSOS national observational study showed, the mortality rate increases significantly over time, so the 30-day mortality rate was 1.8%, the 3-month mortality rate was 3.9%, and the 6-month and annual mortality rates were 5.0% and 8.5%, respectively [8].

There is also no unified approach to the registration of postoperative complications, and modern protocols include several systems, the most common of them are classification of the joint working group of ESA (European Society of Anesthesiologists, The European Society of Anesthesiologists) and ESICM (European Society

of Intensive Care Specialists, The European Society of Intensive Care Medicine) [11] and classification of ACS-NSQIP (National Program for Improving the Quality of Surgical Care of the American College of Surgeons, The American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP)) [12]. Although they are similar in many ways (complications are grouped into blocks according to the nature of the disorders), differences are also present, and even the same complication may have a different definition. In addition, some significant outcomes are not included in these classifications, which determines their underestimation.

Of course, one of the advantages of creating an extensive population database is the registration of a large number of potential predictors of an adverse outcome, followed by an assessment of their individual contribution to the complex perioperative risk. The type of surgery itself is already a factor that largely determines the likelihood of complications (Table 1).

Objective

The goal is to create a Russian national calculator for the risk of postoperative complications and mortality.

Primary outcomes

1. 30-day mortality rate.
2. 30-day complications.

Secondary outcomes

1. Hospital mortality.
2. Hospital complications.
3. Duration of stay in the UARIT.
4. Length of hospital stay.
5. Multiple organ failure (2 or more points on the SOFA (Sequential Organ Failure Assessment) scale).
6. 90-day mortality rate.
7. 90-day complications.
8. Post intensive care (PIC) syndrome.
9. Repeated hospitalization.
10. Annual mortality.

Primary target points

1. Creation of a national register of postoperative outcomes in various fields of surgery.
2. Determination of the frequency and structure of outcomes after planned and emergency surgical interventions.
3. Identification of predictors of an unfavorable outcome.
4. Development and validation of a model for predicting complications and mortality in various fields of surgery.

Table 1. Frequency of unfavorable outcome of surgery

The field of surgery	Lethality, %		Complications, %	
	Elective surgery	Emergency surgery	Elective surgery	Emergency surgery
Gynecology	0.2 [13]	—	3.7–6.5 [14, 15]	—
Obstetrics	0.8 [15]	—	0.4–2.8 [16–18]	—
Endocrine Surgery	0.41–0.5 [19–22]	—	0.4–22.1 [19–22]	—
Breast surgery	0.1 [5]	—	8.3 [5]	—
Urology	0.2 [5]	0.6 [23]	14.8 [5]	22 [24]
Maxillofacial surgery	0.0021 [25]	3.2 [26]	14–64 [27]	28–90 [26]
Orthopedics and traumatology	0.3 [5]	3.5–20.2 [28–30]	16.5 [5]	36 [29]
The lower abdominal cavity	1.0 [5]	34 [31]	24.3 [5]	67 [31]
Liver and biliary tract	0.6 [5]	7–26.7 [32, 33]	16 [5]	21–35 [32, 33]
The upper abdominal cavity	1.5 [5]	34 [31]	24.4 [5]	67 [31]
Thoracic surgery	0.9 [5]	7.4–11 [34, 35]	26.4 [5]	36 [35]
Vascular Surgery	0.9–5.3 [5, 36]	2.8–23.5 [37, 38]	25.6 [5]	44 [38]
Neurosurgery	1.5 [5]	23 [39]	38.8 [40]	70–90 [39]
Cardiac Surgery	2.3 [5]	11.1 [41]	57 [5]	59 [41]

Note. Links to references are indicated in square brackets.

5. Creation of calculators for the risk of postoperative complications and mortality in various fields of surgery and their integration into a single calculator.

6. Analysis of long-term results in patients with postoperative complications (90 days and a year after surgery).

Secondary target points

1. The role of concomitant diseases in the development of an unfavorable outcome.

2. The effect of age on primary and secondary postoperative outcomes.

3. The effect of the type of anesthesia on the course of the postoperative period.

4. The effect of oncological pathology and specific treatment on primary and secondary postoperative outcomes.

5. The impact of emergency surgery on the risk of an adverse outcome.

6. The effect of localization, access and duration of surgery on the postoperative outcome.

7. Assessment and validation of scales of surgical and anesthesiological risk of death (it is possible to list).

8. Assessment and validation of scales of surgical and anesthetic risk of primary and secondary outcomes.

9. Stratification of patients with high perioperative risk with details on cardiac, respiratory, neurological, renal, hepatic, hemostatic, infectious and others.

10. The influence of quality criteria for the implementation of FAR recommendations on the course of the postoperative period.

11. Analysis of the course of PIC syndrome in patients with complications and depending on the maximum score on the SOFA scale and the structure of PON in the postoperative period.

12. Analysis of the effectiveness of rehabilitation measures in patients with PIC syndrome.

Inclusion criteria

A. Adult patients (age 18 and older) undergoing elective surgery performed with different access:

- in obstetrics;
- in gynecology;
- on the mammary gland;
- in urology and kidney surgery;
- in endocrine surgery;
- in maxillofacial surgery;
- in orthopedics and traumatology;
- on the lower floor of the abdominal cavity;
- on the liver and biliary tract;
- on the upper floor of the abdominal cavity;
- in thoracic surgery;
- in vascular surgery;
- in neurosurgery;
- in cardiac surgery;
- in other areas (with mandatory specification).

B. Adult patients (age 18 and older) undergoing emergency surgical interventions in these and other areas of surgery (for example, in purulent surgery).

Criteria for non-inclusion

1. Lack of informed consent of the patient.
2. Complications associated with the manipulations of an anesthesiologist-intensive care specialist.
3. Interventions without the participation of an anesthesiologist-resuscitator.

Exclusion criteria

1. Incomplete checklists.
2. Errors when filling out checklists.
3. Deviations from the Register protocol.

The design of the Register

The design of the Register is a two-level observational retrospective and prospective study.

The planned start date of the study is January 1, 2024.

The planned end date of the study is December 31, 2028

First level

Basic checklist: filled in for all patients with postoperative complications. At the same time, the total number of patients operated on in a particular center is taken into account quarterly, taking into account their distribution by areas of surgery.

Based on the data from the basic checklist, answers will be received to the following target points (3 primary and 2 secondary):

1. Creation of a national register of postoperative outcomes in various fields of surgery.
2. Determination of the frequency and structure of outcomes after planned and emergency surgical interventions.
3. Analysis of long-term results in patients with postoperative complications (90 days and a year after surgery).
4. Analysis of the course of PIC syndrome in patients with complications and depending on the maximum score on the scale and the structure of PON in the postoperative period.
5. Analysis of the effectiveness of rehabilitation measures in patients with PIC syndrome.

Second level

Basic checklist plus additional checklist: filled in for all operated patients within one selected week on a quarterly basis.

The total number of patients operated on in a particular center is also taken into account quarterly, taking into account their distribution by areas of surgery.

Based on the data from the basic and additional checklists, answers to the most important target points (3 primary and 10 secondary) will be received:

1. Identification of predictors of an unfavorable outcome.
2. Development and validation of a model for predicting complications and mortality in various fields of surgery
3. Creation of calculators for the risk of postoperative complications and mortality in various fields of surgery and their integration into a single calculator
4. The role of concomitant diseases in the development of an unfavorable outcome
5. The effect of age on primary and secondary postoperative outcomes
6. The effect of the type of anesthesia on the course of the postoperative period
7. The impact of oncological pathology and specific treatment on primary and secondary postoperative outcomes
8. The impact of emergency surgery on the risk of an adverse outcome
9. The effect of localization, access and duration of surgery on the postoperative outcome
10. Assessment and validation of scales of surgical and anesthesiological risk of death (it is possible to list)
11. Assessment and validation of scales of surgical and anesthetic risk of primary and secondary outcomes
12. Stratification of patients with high perioperative risk with details on cardiac, respiratory, neurological, renal, hepatic, hemostatic, infectious and others.
13. The influence of quality criteria for the implementation of FAR recommendations on the course of the postoperative period

The basic and additional checklists are presented in Appendices 1 and 2.

Statistical analysis

The planned sample size for the second level is at least 108,000 in the estimated cohort and at least 54,000 in the validation cohort. The sample size was calculated taking into account the fact that at least 10 cases of postoperative complications per factor included in the final regression model are required. The sample size was calculated for each area of surgery, taking into account the known frequency of postoperative complications and mortality in elective and emergency surgery (Table 2).

The nature of the distribution of the studied indicators will be assessed using the Kolmogorov-Smirnov criterion. Continuous data will be presented as the median and interquartile range for the nonparametric distribution and as the mean and standard deviation for the parametric distribution. Categorical variables will be presented in the form of the number of patients and a percentage of the total number of patients.

Table 2. Minimum sample size for patients undergoing elective and emergency surgery

The field of surgery, <i>n</i>	Elective surgery		Emergency surgery	
	Drafting	Validation	Drafting	Validation
Obstetrics	2 000	1 000	1 000	500
Gynecology	4 000	2 000	2 000	1 000
Mammology	8 000	4 000	2 000	1 000
Urology	4 000	2 000	1 500	800
Endocrine surgery	4 000	2 000	1 500	800
Traumatology/orthopedics	3 500	2 000	1 000	500
Maxillofacial surgery	2 500	1 500	1 000	500
Neurosurgery	2 000	1 000	500	200
Liver and biliary tract	2 000	1 000	500	200
Thoracic surgery	1 500	1 000	500	200
The lower abdominal cavity	1 500	1 000	500	200
The upper abdominal cavity	1 500	1 000	400	200
Vascular surgery	1 000	500	400	200
Cardiac surgery	1 000	500	400	200
Simultaneous surgery	500	300	200	100
Total number of patients	40 000	20 800	13 400	6 600

To initially assess the association of the factor with postoperative complications, a single-factor analysis will be performed using the χ^2 criterion and the Mann-Whitney or Kruskal-Wallis criterion. All variables with a reliable relationship identified in the univariate analysis (p less than 0.05) will be included in the logistic regression if there is no colinearity between them (correlation coefficient less than 0.25). The logistic regression model will be carried out using a simultaneous inclusion procedure, in which the presence of complications and death will be a dependent variable. The criterion for excluding the factor will be set at a significance level of 0.05. Adjusted odds ratios and 95% confidence intervals will also be calculated.

The resulting predictive model will be evaluated in a validated group using ROC analysis and the Hosmer-Lemeshov criterion.

In relation to the development and validation of the obtained models and scales, such modern methodological approaches as:

- TRIPOD — Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (transparent reporting of a multiparametric prediction model for individual prognosis or diagnosis) [42];

- PROBAST — Prediction model Risk Of Bias ASsessment Tool (a tool for assessing the risk of deviations from the initial accuracy of the forecasting model) [43];
- SHAP — SHapley Additive exPlanation (assessment of the contribution of each variable to the prediction of the model from the perspective of risk/benefit) [44];
- The Brier score — the Brier score is an indicator of the accuracy of predicting binary outcomes [45].

Conclusion

For the first time in Russia, a multicenter study is planned to create a national registry to study the risk factors for an adverse outcome in elective and emergency surgery. This multicenter study will determine the role of disease predictors in the development of postoperative complications and death, as well as create a national model for assessing perioperative risk.

Disclosure. I.B. Zabolotskikh is the First Vice President of the All-Russian public organization “Federation of anesthesiologists and reanimatologists”; A.I. Gritsan is the Vice

President of the All-Russian public organization “Federation of anesthesiologists and reanimatologists”; A.N. Kuzovlev is the Vice President of the All-Russian public organization “Federation of anesthesiologists and reanimatologists”, Deputy Director of Federal Research and Clinical Center of Intensive Care Medicine and Rehabilitology and K.M. Lebedinskii is the President of the All-Russian public organization “Federation of anesthesiologists and reanimatologists”; E.M. Shifman is the Vice President of the All-Russian public organization “Federation of anesthesiologists and reanimatologists”. Other authors declare that they have no competing interests.

Author contribution. All authors according to the ICMJE criteria participated in the development

of the concept of the article, obtaining and analyzing factual data, writing and editing the text of the article, checking and approving the text of the article.

Ethics approval. This study will be approved by the local Ethical Committees of the research centers included in the study.

Registration of the study. The study was registered in the international database <https://clinicaltrials.gov> under the auspices of the All-Russian Public Organization “Federation of Anesthesiologists and Reanimatologists” (principal investigator I.B. Zabolotskikh), study number NCT06146270.

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References

- [1] Weiser T.G., Haynes A.B., Molina G., Lipsitz S.R. Size and distribution of the global volume of surgery in 2012. *Bull World Health Organ.* 2016; 94(3): 201–9F. DOI: 10.2471/BLT.15.159293
- [2] Nepogodiev D., Martin J., Biccard B., et al. National Institute for Health Research Global Health Research Unit on Global Surgery. Global burden of postoperative death. *Lancet.* 2019; 393(10170): 401. DOI: 10.1016/S0140-6736(18)33139-8
- [3] Khuri S.F., Henderson W.G., DePalma R.G., et al. Determinants of long-term survival after major surgery and the adverse effect of postoperative complications. *Ann Surg.* 2005; 242(3): 326–43. DOI: 10.1097/01.sla.0000179621.33268.83
- [4] Seese L., Sultan I., Gleason T.G., et al. The impact of major postoperative complications on long-term survival after cardiac surgery. *Ann Thorac Surg.* 2020; 110(1): 128–35. DOI: 10.1016/j.athoracsur.2019.09.100
- [5] International Surgical Outcomes Study group. Global patient outcomes after elective surgery: prospective cohort study in 27 low-, middle- and high-income countries. *Br J Anaesth.* 2016; 117(5): 601–9. DOI: 10.1093/bja/aew316
- [6] Pearse R.M., Moreno R.P., Bauer P., et al. Mortality after surgery in Europe: a 7 day cohort study. *Lancet.* 2012; 380(9847): 1059–65. DOI: 10.1016/S0140-6736(12)61148-9
- [7] Biccard B.M., Madiba T.E., Kluytset H.L., et al. Perioperative patient outcomes in the African Surgical Outcomes Study: a 7-day prospective observational cohort study. *Lancet.* 2018; 391(10130): 1589–98. DOI: 10.1016/S0140-6736(18)30001-1
- [8] Jawad M., Baigi A., Oldner A., et al. Swedish surgical outcomes study (SweSOS): An observational study on 30-day and 1-year mortality after surgery. *Eur J Anaesthesiol.* 2016; 33(5): 317–25. DOI: 10.1097/EJA.0000000000000352
- [9] Pérez-Rivera C.J., Lozano-Suárez N., Velandia-Sánchez A, et al. Perioperative mortality in Colombia: perspectives of the fourth indicator in The Lancet Commission on Global Surgery - Colombian Surgical Outcomes Study (ColSOS) - a protocol for a multicentre prospective cohort study. *BMJ Open.* 2022; 12(11): e063182. DOI: 10.1136/bmjopen-2022-063182
- [10] Khuri SF, Daley J, Henderson W, et al. The National Veterans Administration Surgical Risk Study: risk adjustment for the compar-

- ative assessment of the quality of surgical care. *J Am Coll Surg* 1995; 180(5): 519–31.
- [11] *Jammer I., Wickboldt N., Sander M., et al.* Standards for definitions and use of outcome measures for clinical effectiveness research in perioperative medicine: European Perioperative Clinical Outcome (EPCO) definitions: a statement from the ESA-ESICM joint taskforce on perioperative outcome measures. *Eur J Anaesthesiol.* 2015; 32(2): 88–105. DOI: 10.1097/EJA.000000000000118
- [12] User Guide for the 2010 Participant Use Data File. Chicago, IL: American College of Surgeons National Surgical Quality Improvement Program, 2011. Last accessed November 11, 2023 Available at <https://www.facs.org/media/rpka3vts/ug10.pdf>
- [13] *Erekson E.A., Yip S.O., Ciarleglio M.M., et al.* Postoperative complications after gynecologic surgery. *Obstet Gynecol.* 2011; 118(4): 785–93. DOI: 10.1097/AOG.0b013e31822dac5d
- [14] *Kaya A.C., Radosa M.P., Zimmermann J.S.M. et al.* Intraoperative and postoperative complications of gynecological laparoscopic interventions: incidence and risk factors. *Arch Gynecol Obstet* 2021; 304(5): 1259–69. DOI: 10.1007/s00404-021-06192-7
- [15] *Филиппов О.С., Гусева Е.В.* Материнская смертность в Российской Федерации в 2019 г. *Проблемы репродукции.* 2020; 26(6–2): 8–26. DOI: 10.17116/rep2020260628 [*Filippov O.S., Guseva E.V.* Maternal mortality in the Russian Federation in 2019. *Russian Journal of Human Reproduction.* 2020; 26(6–2): 8–26. DOI: 10.17116/rep2020260628 (In Russ)]
- [16] *Maronge L, Bogod D.* Complications in obstetric anaesthesia. *Anaesthesia.* 2018; 73(Suppl 1): 61–6. DOI: 10.1111/anae.14141
- [17] *Lim G., Facco F.L., Nathan N., et al.* A Review of the Impact of Obstetric Anesthesia on Maternal and Neonatal Outcomes. *Anesthesiology.* 2018; 129(1): 192–215. DOI: 10.1097/ALN.0000000000002182
- [18] *Роненсон А. М., Шифман Е. М., Куликов А. В.* Неврологические осложнения в акушерской анестезиологии. *Вестник акушерской анестезиологии.* 2020; 4(30): 11–7. [*Ronenson A.M., Shifman E.M., Kulikov A.V.* Neurological complications in obstetric anesthesiology. *Obstetric Anesthesia Digest* 2020; 4(30): 11–7. (In Russ)]
- [19] *Bohatch Júnior M.S., Mendes R.A., da-Silva A.F.V., et al.* Evaluation of postoperative complications in elderly patients submitted to parotidectomy. *Avaliação das complicações pós-operatórias em pacientes idosos submetidos à parotidectomia.* *Rev Col Bras Cir.* 2018; 45(4): e1896. DOI: 10.1590/0100-6991e-20181896
- [20] *Henneman R., Berger D.M.S., Karakullukcu M.B., et al.* Surgical site complications after parotid gland surgery for benign tumors in a centralized setting: A Clavien-Dindo class cohort analysis. *Eur J Surg Oncol.* 2020; 46(2): 258–62. DOI:10.1016/j.ejso.2019.10.028
- [21] *Lukinović J., Bilić M.* Overview of Thyroid Surgery Complications. *Acta Clin Croat.* 2020; 59(Suppl 1): 81–6. DOI:10.20471/acc.2020.59.s1.10
- [22] *Pandey A.K., Maithani T., Agrahari A., et al.* Postoperative Complications of Thyroid Surgery: A Corroborative Study with an Overview of Evolution of Thyroid Surgery. *Int J Head Neck Surg* 2015; 6(4): 149–54. DOI:10.5005/jp-journals-10001-1245
- [23] *AlSowaiegh R., Naar L., El Moheb M., et al.* The Emergency Surgery Score is a powerful predictor of outcomes across multiple surgical specialties: Results of a retrospective nationwide analysis. *Surgery.* 2021; 170(5): 1501–7. DOI: 10.1016/j.surg.2021.05.040
- [24] *Brodak M., Tomasek J., Pacovsky J., et al.* Urological surgery in elderly patients: results and complications. *Clin Interv Aging.* 2015; 10: 379–84. DOI: 10.2147/CIA.S73381
- [25] *Mortazavi H., Baharvand M., Safi Y.* Death Rate of Dental Anaesthesia. *J Clin Diagn Res.* 2017; 11(6): ZE07–ZE09. DOI: 10.7860/JCDR/2017/24813.10009
- [26] *Kim Y.K.* Complications associated with orthognathic surgery. *J Korean Assoc Oral Maxillofac Surg.* 2017; 43(1): 3–15. DOI: 10.5125/jkaoms.2017.43.1.3
- [27] *Lone P.A., Wani N.A., Ain Q.U., et al.* Common postoperative complications after general anesthesia in oral and maxillofacial surgery. *Natl J Maxillofac Surg.* 2021; 12(2): 206–10. DOI: 10.4103/njms.NJMS_66_20
- [28] *Шубняков И.И., Воронцова Т.Н., Богопольская А.С. и др.* Летальность у пациентов с переломами проксимального отдела бедренной кости при консервативном и оперативном лечении. *Хирургия. Журнал им. Н.И. Пирогова.* 2022; 4: 60–8. DOI: 10.17116/hirurgia202204160 [*Shubnyakov I.I., Vorontsova T.N., Bogopolskaya A.S., et al.* Mortality in patients with proximal femur fractures undergoing conservative and surgical treatment. *Pirogov Russian Journal of Surgery = Khirurgiya. Zhurnal im. N.I. Pirogova.* 2022; 4: 60–8. DOI: 10.17116/hirurgia202204160 (In Russ)]
- [29] *Гуманенко Е.К., Завражнов А.А., Супрун А.Ю. и др.* Тяжелая сочетанная травма и политравма: определение, классификация, клиническая характеристика, исходы лечения. *Политравма.* 2021; 4: 6–17. DOI: 10.24412/1819-1495-2021-4-6-17 [*Gumanenko E.K., Zavrazhnov A.A., Suprun A.Yu., et al.* Severe combined trauma and polytrauma: definition, classification, clinical characteristics, treatment outcomes. *Polytrauma.* 2021; 4: 6–17. DOI: 10.24412/1819-1495-2021-4-6-17 (In Russ)]
- [30] *Gurney J.K., McLeod M., Stanley J., et al.* Postoperative mortality in New Zealand following general anaesthetic: demographic patterns and temporal trends. *BMJ Open.* 2020; 10(9): e036451. DOI: 10.1136/bmjopen-2019-036451
- [31] *Cauley C.E., Panizales M.T., Reznor G., et al.* Outcomes after emergency abdominal surgery in patients with advanced cancer: Opportunities to reduce complications and improve palliative care. *J Trauma Acute Care Surg.* 2015; 79(3): 399–406. DOI: 10.1097/TA.0000000000000764
- [32] *Brooks A., Joyce D., La Valle A., et al.* Improvements over time for patients following liver trauma: A 17-year observational study. *Front Surg.* 2023; 10: 1124682. DOI: 10.3389/fsurg.2023.1124682
- [33] *Lai E.C., Chu K.M., Lo C.Y., et al.* Surgery for malignant obstructive jaundice: analysis of mortality. *Surgery.* 1992; 112(5): 891–6.
- [34] *Lundin A., Akram S.K., Berg L. et al.* Thoracic injuries in trauma patients: epidemiology and its influence on mortality. *Scand J Trauma Resusc Emerg Med.* 2022; 30(1): 69. DOI: 10.1186/s13049-022-01058-6
- [35] *Dyas A.R., Thomas M.B., Bronsert M.R., et al.* Emergency thoracic surgery patients have worse risk-adjusted outcomes than non-emergency patients. *Surgery.* 2023; 174(4): 956–63. DOI: 10.1016/j.surg.2023.06.034
- [36] *Mazzaccaro D., Righini P., Giannetta M., et al.* Factors associated with perioperative mortality after late open conversion for failed endovascular aortic repair. *J Cardiovasc Surg (Torino).* 2023; 64(3): 297–303. DOI: 10.23736/S0021-9509.22.12491-2

- [37] Schlacter J.A., Ratner M., Siracuse J.J., et al. Urgent endarterectomy for symptomatic carotid occlusion is associated with a high mortality. *J Vasc Surg.* 2023; 78(2): 423–9. DOI:10.1016/j.jvs.2023.02.029
- [38] Juneja A., Garuthara M., Talathi S., et al. Predictors of poor outcomes after lower extremity revascularization for acute limb ischemia. *Vascular.* 2023; 17085381231154290. DOI: 10.1177/17085381231154290
- [39] Ahmadian A., Mizzi A., Banasiak M., et al. Cardiac manifestations of subarachnoid hemorrhage. *Heart Lung Vessel.* 2013; 5(3): 168–78.
- [40] Moiyadi A.V., Shetty P.M. Perioperative outcomes following surgery for brain tumors: Objective assessment and risk factor evaluation. *J Neurosci Rural Pract.* 2012; 3(1): 28–35. DOI: 10.4103/0976-3147.91927
- [41] Kim K.M., Arghami A., Habib R., et al. The Society of Thoracic Surgeons Adult Cardiac Surgery Database: 2022 Update on Outcomes and Research. *Ann Thorac Surg.* 2023; 115(3): 566–74. DOI: 10.1016/j.athoracsur.2022.12.033
- [42] Moons K.G., Altman D.G., Reitsma J.B., et al. Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD): explanation and elaboration. *Ann Intern Med.* 2015; 162(1): W1–W73. DOI: 10.7326/M14-0698
- [43] Wolff R.F., Moons K.G.M., Riley R.D., et al. PROBAST: A Tool to Assess the Risk of Bias and Applicability of Prediction Model Studies. *Ann Intern Med.* 2019; 170(1): 51–8. DOI: 10.7326/M18-1376
- [44] Hu C., Li L., Huang W., et al. Interpretable Machine Learning for Early Prediction of Prognosis in Sepsis: A Discovery and Validation Study. *Infect Dis Ther.* 2022; 11(3): 1117–32. DOI: 10.1007/s40121-022-00628-6
- [45] Yang W., Jiang J., Schnellinger E.M., et al. Modified Brier score for evaluating prediction accuracy for binary outcomes. *Stat Methods Med Res.* 2022; 31(12): 2287–96. DOI: 10.1177/09622802221122391