UDC 616.8-089-01/-099+614.812+006.1
DOI: 10.56871/MHCO.2023.34.30.007

QUALITY MANAGEMENT SYSTEM IN THE PREVENTION OF COMPLICATIONS AND ERRORS IN NEUROSURGERY

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For citation: Shnyakin PG, Botov AV, Usatova IS. Quality management system in the prevention of complications and errors in neurosurgery. Medicine and health care organization (St. Petersburg). 2023;8(4):77-87. DOI: https://doi.org/10.56871/MHCO.2023.34.30.007

Received: 08.09.2023 **Revised: 16.10.2023** **Accepted: 15.12.2023**

ABSTRACT. Complications and side effects are undesirable but inevitable events in any medical specialty, including neurosurgery. The professionalism and experience of a specialist play an important role in the prevention and timely detection of negative events, but they cannot ensure complete patients' safety, which is largely determined by the entire work of the clinic and communications between various services and specialists. The quality management system (QMS), as a systematic approach to the prevention of negative events, has proven its effectiveness in medical practice. According to a number of studies, more than half of adverse perioperative cases can be avoided by implementing various systemic patients' safety strategies. The article presents a review of the literature on the implementation of various QMS tools in the work of neurosurgical departments and clinics. A number of studies have shown that the introduction of a surgical safety checklist into neurosurgical practice contributes to a significant reduction in the frequency of erroneous operations on the wrong side, reduces the number of infectious complications, and generally improves treatment outcomes. In addition to standardizing processes and introducing checklists, risk management tools are effective in reducing the number of complications and side effects associated with making clinical decisions and communication problems. According to some studies, risk management helps to reduce the number of adverse cases and choose the optimal tactics for managing patients with neurosurgical pathology. In general, it is worth noting that QMS tools primarily help prevent the most obvious and recurring undesirable cases, but do not always protect against exclusive ones. Nevertheless, this is quite justified, since it is not rare and exclusive, that most frequently recurring complications and errors contribute most to the unsatisfactory results of the treatment of neurosurgical patients.

KEY WORDS: complications; errors; neurosurgery; surgery; patient safety; standardization; checklist.

СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА В ПРОФИЛАКТИКЕ ОСЛОЖНЕНИЙ И ОШИБОК В НЕЙРОХИРУРГИИ

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Для цитирования: Шнякин П.Г., Ботов А.В., Усатова И.С. Система менеджмента качества в профилактике осложнений и ошибок в нейрохирургии // Медицина и организация здравоохранения. 2023. Т. 8. № 4. С. 77–87. DOI: https://doi.org/10.56871/MHCO.2023.34.30.007

Поступила: 08.09.2023 **Одобрена: 16.10.2023** **Принята к печати: 15.12.2023**

РЕЗЮМЕ. Осложнения и ошибки являются нежелательными, но неизбежными событиями в любых медицинских специальностях, в том числе в нейрохирургии. Профессионализм и опыт специалиста имеют большую роль в профилактике и своевременном выявлении негативных событий, однако не могут обеспечить полную безопасность пациента, определяемую во многом работой всей клиники и коммуникациями между различными службами и специалистами. Система менеджмента качества (СМК) как системный подход в профилактике негативных событий доказала свою эффективность в медицинской практике. По данным ряда исследований, более половины нежелательных периоперационных событий можно избежать при внедрении различных системных стратегий безопасности пациентов. В статье представлен обзор литературы по внедрению различных инструментов СМК в работу нейрохирургических отделений и клиник. В ряде исследований было доказано, что внедрение чек-листа хирургической безопасности в нейрохирургическую практику способствует значимому снижению частоты ошибочных операций с противоположной стороны от очага поражения, снижает количество инфекционных осложнений и в целом улучшает исходы лечения. Кроме стандартизации процессов и внедрения чек-листов, для снижения количества осложнений и ошибок, связанных с принятием клинических решений и проблемами с коммуникацией, эффективны инструменты риск-менеджмента. По данным некоторых исследований, риск-менеджмент помогает снизить количество неблагоприятных событий и выбрать оптимальную тактику ведения пациентов с нейрохирургической патологией. В целом стоит отметить, что инструменты СМК в первую очередь позволяют предотвратить наиболее очевидные и повторяющиеся нежелательные события, но не всегда защищают от эксклюзивных. Тем не менее это весьма оправданно, так как не редкие и эксклюзивные, а именно наиболее часто повторяющиеся осложнения и ошибки вносят наибольший вклад в неудовлетворительные результаты лечения нейрохирургических пациентов.

КЛЮЧЕВЫЕ СЛОВА: осложнения; ошибки; нейрохирургия; операция; безопасность пациента; стандартизация; чек-лист.

INTRODUCTION

In order to carry out preventive interventions for adverse medical events, including surgery, it is necessary to understand which adverse events are preventable and which are not. Thus, all negative events can be classified according to their preventability using the Likert scale. According to the scale, all negative events can be divided into several groups:

1) definitely impossible to prevent;
2) a probability of prevention is less than 50%;
3) a probability of prevention is more than 50%;
4) definitely preventable [14].

The first group includes rare types of complications associated with individual risk factors of a patient and a course of his/her disease, which are practically impossible to foresee, identify and/or influence in time. For example, there might be carotid-vertebrobasilar anastomoses,

which provide blood supply to the brainstem and cerebellum for a short time in the embryonic period, but in some cases continue to persist in adults. The primitive trigeminal artery is the most common, occurring in 0.1–0.3% of cases in the population. Some authors have reported that the presence of this artery can lead to difficulty in anatomical orientation and cause serious complications during skull base surgery [13, 24].

The second and third groups can include complications that are conditionally preventable and are determined by both risk factors on the part of the patient himself and the risks inherent in the therapeutic and diagnostic processes. For example, it is known that people with diabetes mellitus have an increased risk of postoperative infectious complications. When such patients undergo endoprosthesis replacement of large joints, there is an increased incidence of periprosthetic infection [10].

These groups require preventive measures aimed at correcting modifiable risk factors and improving the quality and safety of treatment and diagnostic processes.

The fourth group includes surgical errors associated with incorrect actions of a specialist, which must be prevented.

Thus, the majority of negative perioperative events can be avoided by preventive measures at the professional and system-organizational levels.

J.M. Wong et al. identified the following systemic measures that reduce negative perioperative events in a neurosurgical clinic:

1) development and implementation of a unified national registry of treatment outcomes;
2) widespread implementation of a surgical safety checklist;
3) standardization of processes;
4) greater specialization of neurosurgeons;
5) treatment based on clinical recommendations [34].

According to A.G. Nazarenko et al., more than 50% of complications of neurosurgical interventions can be avoided by implementing various systemic patient safety strategies [7]. These statements correspond with data of a number of researchers which indicate that most often adverse events happen not because of negligence or poor training of medical personnel, but due to systemic problems of medical institution performance [4, 5].

The article “Improving patient safety in neurologic surgery” written by S.J. Han et al. mention that for a long time any errors and complications in surgery were considered as individual problems of doctors, so it was believed that if doctors do their best not to make mistakes, there will be no errors. According to the authors, this is a deep misconception, and the only way to ensure safe surgical care is to develop systematic approaches to prevent negative perioperative events [15].

QUALITY MANAGEMENT SYSTEM IN MEDICAL PRACTICE

Systemic problems should be solved by systemic methods that can be universal for different types of activities. The quality management system (QMS) was first introduced in industrial enterprises to reduce losses and improve product quality. Subsequently, effective QMS tools and methods were introduced into medical practice.

At present, QMS in medicine implies the use of various methods of administrative influence (checklists, risk management, global triggers method, clinical decision aid system) aimed at achieving target indicators of quality and safety of patient treatment [2, 3, 11, 18, 31].

QMS is based on the standardization of processes, since it is difficult to conduct training and regular quality control and evaluation without it. It is difficult o standardize many interventions and procedures in medicine, and especially in surgery, nevertheless, it is possible and necessary to do so. Standardization helps to reduce a number of suboptimal or outright erroneous actions of specialists, especially when there is a lack of experience [27].

E. Suehiro et al. evaluated the impact of standardization on the mortality of patients with head injury. The study involved 869 medical centers in Japan and evaluated the period 2008–2022. The authors found that standardization had resulted in a progressive decrease in brain injury (BI) mortality since 2008. In addition, the standardization of processes enabled compliance with clinical guidelines for the management of patients with traumatic brain injury in 93.3% of cases [28].

Undoubtedly, there are situations in medicine when it is necessary to go beyond standards and recommendations due to the complexity

and/or uniqueness of a case. However, it should be recognized that in most cases, surgeons' actions may well fit into the standards of care developed by the professional community.

Standardization of processes helps not only to prevent errors and complications, but also to comply with clinical recommendations and achieve targets. Thus, the order of the Ministry of Health of the Russian Federation N 203n dated 10.05.2017 "On Approval of Criteria for Assessing the Quality of Medical Care" outlines the recommended quantitative indicators of treatment and diagnostic processes in various diseases, including neurosurgery [9]. According to A.M. Karsanov et al., the Order specifies the target indicators to which it is necessary to strive, but does not specify the ways to achieve them. According to the authors, QMS and process standardization are tools that allow to determine the ways to achieve the target indicators based on existing standards and clinical recommendations [2].

STANDARDIZATION OF SAFETY APPROACHES BY MEANS OF CHECKLIST METHOD

Checklists are one of the effective and simple methods of regular quality control and prevention of system errors. Checklists are quite common in industrial enterprises and serve as a reliable tool for preventing recurring undesirable events, primarily related to human factors. The positive experience of using checklists was subsequently introduced into medical practice. Thus, in 2009, the World Health Organization (WHO) developed a surgical safety checklist recommended for implementation in all surgical clinics.

According to WHO recommendations, three stages of surgery are distinguished, defining "time-outs" and checking key indicators on the following checklist:

1) the period of anaesthetic induction;
2) the period after the induction and before surgical incision;

До начала анестезии	До рассечения кожи	До того, как пациент покинет операционную
(в присутствии, как минимум, медсестры и анестезиолога)	(в присутствии медсестры, анестезиолога и хирурга)	(в присутствии медсестры, анестезиолога и хирурга)
Подтвердил ли пациент свое имя, место операции, процедуру и согласие? ☐ Да	☐ Подтвердите, что все члены бригады представились по имени и назвали свою роль	**Медсестра устно подтверждает:** ☐ Наименование процедуры ☐ Подсчет количества инструментов, тампонов и игл завершен ☐ Образцы маркированы (зачитывает надписи на образцах, включая имя пациента) ☐ Имеются проблемы с оборудованием, требующие устранения
Маркировано ли место операции? ☐ Да ☐ Не применимо	☐ Подтвердите имя пациента, процедуру и место, где будет проведено рассечение Проводилась ли антибиотикопрофилактика последние 60 минут? ☐ Да ☐ Не применимо	
Проведена ли проверка оборудования и лекарственных средств для анестезии ☐ Да		
Пульсоксиметр зафиксирован на пациенте и функционирует? ☐ Да	**Ожидаемые критические события:** С точки зрения хирурга: ☐ Критические или неожиданные меры ☐ Длительность операции? ☐ Ожидаемая кровопотеря?	**Хирург, анестезиолог и медсестра:** ☐ Каковы основные проблемы, касающиеся реабилитации и ведения данного пациента?
Имеется ли у пациента: Известная аллергия? ☐ Нет ☐ Да	С точки зрения анестезиолога: ☐ Специфичные для данного пациента проблемы?	
Проблемы дыхательных путей и риск аспирации? ☐ Нет ☐ Да, имеется оборудование / необходимая помощь	С точки зрения операционных сестер: ☐ Стерильность (включая показания приборов) подтверждена? ☐ Проблемы с оборудованием или иные вопросы?	
Риск кровопотери >500 мл (7 мл/кг у детей)? ☐ Нет ☐ Да, предусмотрены два устройства для в/в центрального доступа и жидкости для вливания	Визуализация необходимых изображений обеспечена? ☐ Да ☐ Не применимо	

Fig. 1. Checklist for safety control of surgical intervention

Рис. 1. Чек-лист контроля безопасности оперативного вмешательства

3) the period from wound closure to patients leaving the operating room (Fig. 1).

A.B. Haynes et al. evaluated the effectiveness of the WHO surgical safety checklist. Eight large hospitals in different countries participated in the study and 3955 operated patients were evaluated. They found that the mortality rate had been 1.5% before the checklist was introduced and decreased to 0.8% after the introduction (p=0.003). Inpatient complications occurred in 11.0% of patients before checklist introduction and in 7.0% after its implementation (p <0.001) [16].

According to J.A. Vachhani et al., the introduction of a surgical safety checklist is an effective measure to prevent operations on the opposite side of the lesion [32]. This statement corresponds with J.D. Rolston et al. The authors revealed that neurosurgeons occupy the third place after orthopedists and general surgeons in terms of performing operations on a wrong side or at a wrong level [25]. According to A. Oszvald et al, after the introduction of the surgical safety checklist into the work of the neurosurgical department, they did not observe a single case of operations on the wrong side of the lesion. The authors emphasize that checklists and time-outs are particularly effective in emergency neurosurgery [23].

M. Lepänluoma et al. evaluated the effectiveness of using a surgical safety checklist in a neurosurgical clinic. According to the authors, after implementation of the checklist, unplanned re-hospitalizations decreased from 25 to 10% (p=0.02), wound complications decreased from 19 to 8% (p=0.04) [15].

M. Westman et al. conducted a systematic review of neurosurgical publications from 2008–2016 on the use of surgical safety checklists in neurosurgery. Twenty-six articles were selected. Thus, the authors concluded that implementation of a surgical safety checklist significantly reduced the number of hospital-acquired infectious complications [33].

According to a survey conducted by M.A. Lo-Presti et al. 97.2% of neurosurgeons believed that checklists and time-outs make surgery safer, and 94.6% of respondents agreed that checklists reduce the risk of operating on a wrong side or at a wrong level [19].

There is a view that the WHO surgical safety checklist should be modified to suit specific surgical specialties, particularly neurosurgery. Thus, Indian neurosurgeons V. Suresh et al. added another 21 points to the existing 19 points of the WHO checklist which were specific to neurosurgery. They also added two more time-outs to the existing 3 ones. The authors believe that implementing such a checklist does not lengthen operative time, but it does improve communication between the anesthesiologist, neurosurgeon and operating room nurse, which helps to reduce adverse events [29]. However, it is worth noting that 5 time-outs and 40 items to check are very difficult to implement in everyday practice.

In addition to standardization and implementation of checklists, other QMS management technologies, such as risk management, can be used in medicine [20, 26].

According to N. McLaughlin et al, during the period 2008–2012, the neurosurgery department received the highest number of lawsuits out of all surgical departments in the hospital (30 out of 176). Among these lawsuits, 21 were related to spinal pathologies and 9 were related to cranial pathologies. The most common adverse perioperative events were related to suboptimal clinical decisions (20 of 30), technical skills (19 of 30), and communication problems (6 of 30). The authors decided that risk management strategies should be implemented at the clinic level to address the most frequent factors influencing adverse events [21].

PRINCIPLES OF RISK MANAGEMENT

According to A.M. Karsanov et al. medecine should include the following components of risk management:

- timely detection of a real (potential) negative event or dangerous situation;
- effective analysis of its causes and consequences;
- informing the medical staff about an undesirable (negative) event that has occurred;
- constructive conclusions based on the analysis of errors;
- prevention of repetition of such a negative event [2, 3].

F. Ikawa et al. determined the most optimal tactics of treatment for patients with aneurysmal subarachnoid haemorrhage (SAH) in the older age group taking into account risk management [17].

New Zealand researchers S. Clark et al. analyzed a 5-year period of treatment of 18,375

neurosurgical patients and developed a risk scale for mortality in the first 30 days, as well as 1 and 2 years after surgery. Based on the data obtained, the authors created the NZRISK-NEURO calculator, which allows to generate an individual risk for neurosurgical patients, which in some cases may help to facilitate clinical decision making, and also allows to provide the patient and his relatives with an early probability of an unfavorable outcome [12]. Screenshots from https://www.nzrisk.com/#calculate are presented below. It is possible to calculate the risk of any neurosurgical procedure (Fig. 2).

The Global Trigger Tool is a type of risk management developed by the Institute for Healthcare Improvement (Institute for Healthcare Improvement, USA). Trigger is an indicator of possible unfavorable event development. The essence of this method is an automatic search for special triggers in a patient's medical history.

Triggers are divided into the following groups:

1) triggers of significant deterioration of the condition;
2) triggers of postoperative complications;
3) triggers of nosocomial infection;
4) triggers of undesirable drug reactions.

The trigger system allows both simplifying the search for an undesirable event and identifying implicit negative events [1].

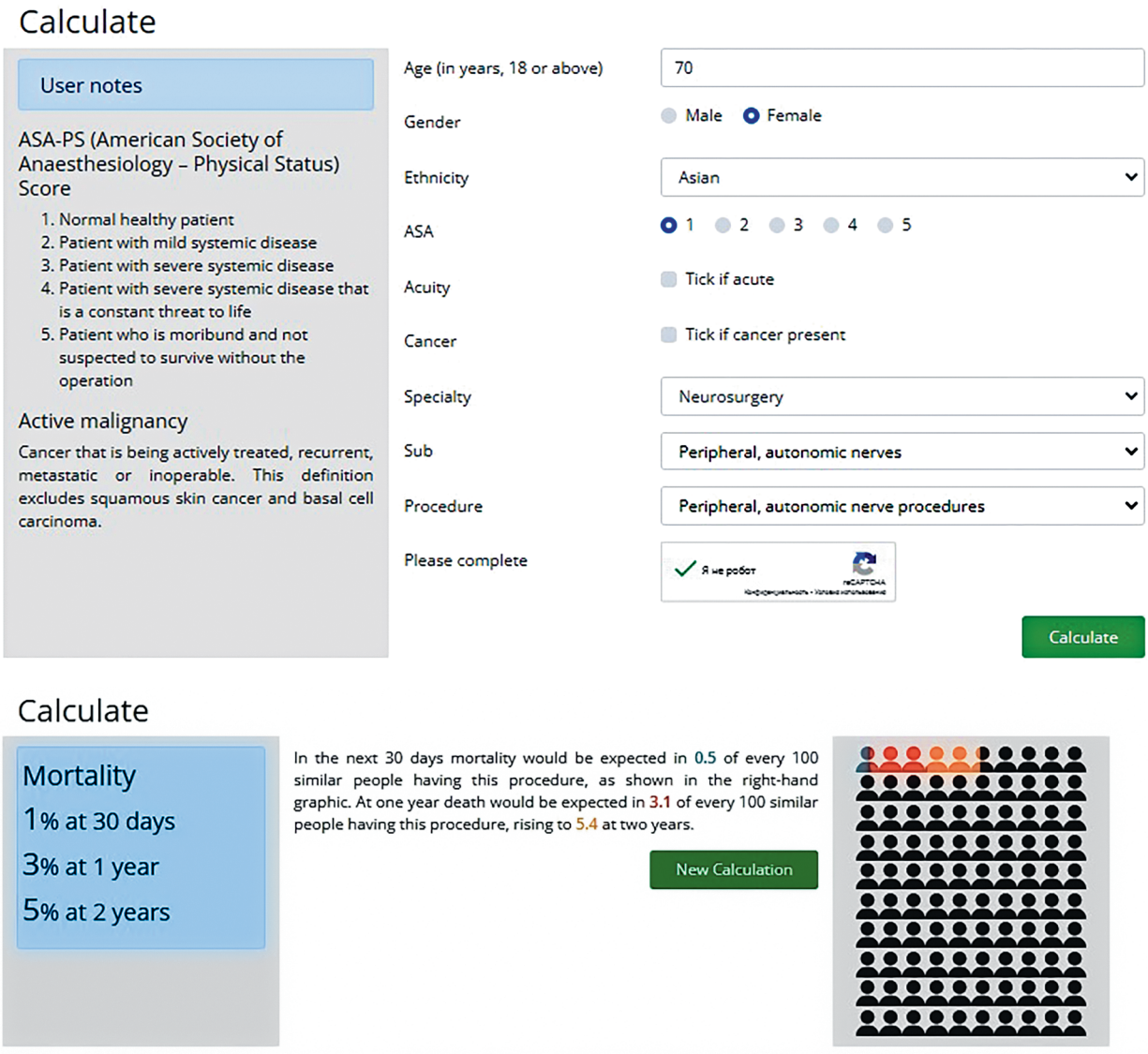

Fig. 2. Neurosurgical procedure risk calculator

Рис. 2. Калькулятор риска нейрохирургической процедуры

The book 'Key Quality Indicators of Neurosurgical Clinic Performance' wrote by A.G. Nazarenko et al. identified the following triggers for the development of postoperative complications in neurosurgery:

a) unplanned resuscitation activities within 24 hours after surgery;
b) artificial lung ventilation (ALV) for more than 24 hours after surgery;
c) unplanned repeated surgical interventions in one hospitalization;
d) haemotransfusion above the planned volumes within 24 hours after surgery;
e) increase of cytosis in the liquor more than 2-fold, etc. [7].

Another useful tool for quality and safety management in surgery is the clinical decision support and decision-making system. A.S. Orlov et al. developed an information system for clinical decision support in neurology and neurosurgery. This system takes into account orders of the Ministry of Health of the Russian Federation, treatment standards, clinical recommendations, and treatment protocols for each clinical case. The authors rightly emphasize that these documents are quite voluminous and it is not easy for a doctor to incorporate them. That is the reason the information system of decision support was developed [8].

PRINCIPLES OF IMPLEMENTING QMS TOOLS

It should be noted that the implementation of a number of QMS technologies and tools requires certain skills and knowledge. According to the QMS, it is necessary to answer three questions when implementing a process [6]:

1. What are we trying to achieve?
2. How do we know that the planned changes will lead to a better result?
3. What changes should we make to achieve the targets?

In the next stage of implementation, it is optimal to use Deming's Plan-Do-Study-Act (PDSA-cycle), which is well known in management. The cycle consists of the following steps:

- P (plan) — "plan". Develop an implementation plan to improve results.
- D (do) — "do". Practical implementation of the intended actions.
- S (study) — "study". Analyzing the results obtained and comparing them with those anticipated at the planning stage.
- A (act) — "influence". Final implementation of the intended changes or their correction.

The sequence of steps of the PDSA-cycle can be repeated many times using the knowledge obtained in the previous stages [6, 22, 30].

After all the data presented, one may get the impression that the high art of neurosurgery is reduced to simplified standards and algorithms of action. Undoubtedly, it is not so. Apart from a number of actions regulated by standards and guidelines, surgery, more than any other medical specialty, has a capacity to go far beyond. This includes surgery itself and unforeseen situations where clinical thinking, experience and skills of a specialist are required. Nevertheless, as seen in this review, standardization of processes and management tactics in accordance with approved clinical guidelines contribute to reduction of complications and errors in neurosurgery. The words of Academician V.A. Kubyshkin sound very appropriate in this regard: 'When making a decision in surgical disciplines concerning a rational sequence of diagnostic methods and even a method of surgery, "voluntarism" has special consequences' [5].

CONCLUSION

The quality management system, developed in the first half of the XX century to optimize processes in industrial enterprises, has found wide application in medicine in the XXI century. Numerous studies have proven that various QMS tools such as standardization of processes, implementation of checklists, risk management, decision support system, etc., help to reduce the number of complications and errors in everyday medical practice. This is especially relevant for surgical specialties, where the initial risk of various perioperative negative events is high.

It is worth noting that QMS tools primarily prevent the most obvious and recurrent negative events, but do not always protect against exclusive ones. Nevertheless, this is quite justified, since these complications are not rare and exclusive. These are most frequently repeated complications and errors that contribute the most to unsatisfactory treatment results.

In order to implement standardization successfully and without meeting great resistance from some specialists, it is necessary to familiarize doctors with the results of such imple-

mentation in other clinics of the same or higher level. For instance, if surgeons are familiarized with the results of implementing the WHO check-list of surgical safety in a number of foreign clinics, which led to excluding a possibility of surgery on an opposite side of the lesion, a twofold decrease in the number of infectious complications and repeated surgeries, then the check-list will be implemented with less resistance, and in some cases, it might be accepted with enthusiasm.

ADDITIONAL INFORMATION

Author contribution. Thereby, all authors made a substantial contribution to the conception of the study, acquisition, analysis, interpretation of data for the work, drafting and revising the article, final approval of the version to be published and agree to be accountable for all aspects of the study.

Competing interests. The authors declare that they have no competing interests.

Funding source. This study was not supported by any external sources of funding.

ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ

Вклад авторов. Все авторы внесли существенный вклад в разработку концепции, проведение исследования и подготовку статьи, прочли и одобрили финальную версию перед публикацией.

Конфликт интересов. Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, связанных с публикацией настоящей статьи.

Источник финансирования. Авторы заявляют об отсутствии внешнего финансирования при проведении исследования.

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