



Review

RISKS OF HAIs: PROBLEMS AND PITFALLS

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At present, a major challenge in research that addresses risks of hospital-acquired infections (HAIs) is the lack of methodological and theoretical studies generalizing the available knowledge in the sphere whereas applied works are plentiful. In recent years, methods of influence on the epidemic process of HAIs have been reassessed and some experts believe transition to the risk-based approach to be quite promising in this respect. This approach makes it possible to take timely measures aimed at reducing risks of such infections in advance. Since the risk-based approach within epidemiological safety is only starting to be integrated into the whole system of healthcare safety, development and specification of its individual components seems to be a promising trend in healthcare support. The key role in creating an effective system for control and surveillance over hospital-acquired infections belongs to activities related to development of scientific approaches to systematizing and unifying indicators that describe the subject area of HAIs risks in healthcare organizations of various profiles; improvement of the methodology for analyzing HAIs risks, the risk-based approach and risk management technologies within surveillance over such infections; optimization of science-based approaches to decision-making that relies on the risk-based approach and HAIs risk management technologies; development of methodical guidelines on monitoring, assessment, and prediction of HAIs risks in healthcare organizations of various profiles.

Keywords: healthcare organizations, epidemic process, epidemiological safety, hospital-acquired infections, risks, risk parameters, risk management, risk-based approach.

This review aims to discuss the current state of HAIs risk examination and the risk-based approach within epidemiological safety of healthcare; another aim is to identify activities necessary for the development of theoretical approaches to systematizing and unifying indicators that describe the subject area of risk.

The World Health Organization (WHO) considers patient safety a serious challenge of

global healthcare that tends to get aggravated¹. Provision of patient safety, just as healthcare quality, remains a priority target of any national healthcare system² [1–11]. According to WHO expert estimates, the occurrence of adverse events, resulting from unsafe care, is likely to be one of the 10 leading causes of death and disability worldwide. Annually, millions of patients suffer due to unsafe healthcare in hospitals and as a result 2.6 million

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¹ Patient safety. WHO. Available at: https://www.who.int/health-topics/patient-safety#tab=tab_1 (April 12, 2023).

² Bezopasnost' patsienta: rukovodstvo [Patient safety: the guide]. In: N.A. Levkina ed.; E.L. Nikonov transl. form English. Moscow, GEOTAR-Media, 2010, 184 p. (in Russian).

people die in low- and middle-income countries alone³.

Globally as many as four out of 10 patients are harmed while receiving outpatient (ambulatory) care, with up to 80 % of the harm considered to have been preventable. Diagnostic errors contribute to approximately 10 % of patient deaths and account for 6–17 % of all unwanted harmful events in hospitals³. In high-income countries, each tenth patient is harmed when receiving inpatient care. Most harmful errors are related to diagnosis and prescription and the use of medicines [12]. According to the data reported in the meta-analysis by E.N. de Vries and others [13], which was based on examining more than 74,000 treatment cases, the median overall incidence of in-hospital adverse events was 9.2 %, with a median percentage of preventability of 43.5 %. Although more than half (56.3 %) of patients experienced no or minor disability, 7.4 % of events were lethal.

Hospital-acquired infections (HAIs; sometimes also called healthcare-acquired infections or HCAs) are a major challenge for patient safety as they annually do harm to hundreds of millions worldwide [9, 10, 14]. Although the risk of HAIs is universal and occurs in every healthcare organization worldwide, its global burden remains unknown due to difficulties in acquiring reliable diagnostic data. This is due to absence of any systems for monitoring over HAIs in most countries or unified guidelines that could be used to diagnose such infections.

Up to now, HAIs remain a rather hidden and complex problem; therefore, no hospital or no country either can state that they have managed to solve it [15]. HAIs are diagnosed in 5–10 % of patients treated in hospitals; they can affect between 9 and 37 % patients in intensive care units with the overall mortality rate varying between 12 and 80 % [16–18]. In

the Russian Federation, up to 30 thousand HAIs cases were registered annually (up to 2020) according to official statistical data (0.8 per 1000 patients); however, most experts believe the actual HAIs incidence is higher and equals not less than 2–2.5 million people [19]. The common criterion for considering an infection a HAI case is the direct association between its occurrence and healthcare. Most HAIs are associated with patients' risk factors due to concomitant illnesses, long stay in hospital, elevated susceptibility under high prevalence of invasive procedures and / or use of medical devices, and violation of aseptic and antiseptic rules, etc.

Recently, there has been a worldwide avalanche-like growth in interest in risk studies. The term 'risk' first appeared in European languages in the beginning of the 16th century; a theory says it is associated with the development of navigation and sea shipping. Probably, the original meaning of the verb 'to risk' occurred exactly in this sphere (from the Greek words 'rock' or 'cliff'); it meant tacking between rocks, going round a cliff (rock): the closer you get to rocks, the shorter and more dangerous your way is⁴ [20]. General scientific interpretation of the risk as a philosophical category (in the ontological sense) is that 'the risk is likelihood of known and unwanted events in the future that are yet to come' [21]. Differences in interpreting and harmonizing various definitions and interpretations of 'risk' as a concept occur commonly. The 'risk' as a concept is interpreted by different authors as 'the combination of probability of an event occurrence and its outcomes'; 'the probability of an adverse event'; 'the combination of likelihood and outcomes of adverse events'; 'an event / a group of similar accidental events that damage an object having this risk' etc.⁵ [22–25]. In the broad sense of the word, the term 'risk' most often means likelihood of an

³ 10 facts on patient safety. WHO, 2019. Available at: <https://www.who.int/news-room/photo-story/photo-story-detail/10-facts-on-patient-safety> (April 12, 2023).

⁴ Bol'shoi etimologicheskii slovar' russkogo yazyka [The big Russian etymological dictionary]; assembled by M.E. Klimova. Moscow, Dom slavyanskoi knigi, 2012, 960 p. (in Russian).

⁵ Fletcher R., Fletcher S., Vagner E. Klinicheskaya epidemiologiya: Osnovy dokazatel'noi meditsiny [Clinical epidemiology: Fundamentals of evidence-based medicine]. Moscow, Media Sfera, 1998, 352 p. (in Russian).

unwanted event involving various losses or damage (loss of property, financial losses, health harm, social condemnation, etc.)⁶ [21].

Methodological approaches to examining and assessing risks in healthcare first appeared in the Russian Federation in the second half of the last century when the first attempts were made to develop theoretical grounds for assessing prenosological states and premorbidity with respect to risks of probable human diseases [26]. Analysis of literature revealed that definitions used in studies focusing on risks, patient harm, or damage done to a healthcare organization, have different meanings [27, 28]. It is noteworthy that at present there are practically no articles or reviews that generalize knowledge concerning theoretical grounds of such a category as ‘the risk’. Despite long-term and diversified investigations of ‘the risk’ we still cannot unambiguously interpret the essence of this multi-dimensional category due to the concept being truly universal and the terminology being diverse and inconsistent [20]. These differences create complications when different research data are compared and lead to potential errors in the interpretation of obtained results.

The existing risk classifications are based on different attributes but, as a rule, they tend to rely on risk classifications accepted in business and often fail to consider healthcare peculiarities [24, 28, 29]. Risks can be divided into natural and anthropogenic ones with respect to human activities. Healthcare defects are particular cases of anthropogenic risks [28]. Such risks may be associated with actual provision of healthcare and include diagnostic risks (incorrect diagnosis, failed informational interaction, etc.); treatment-related risks (surgical risks, risks of pharmacotherapy, risks related to interactions between experts and continuity in healthcare, risks of complications and unwanted reactions to medicines); rehabilitation

risks (rehabilitation faults). In relation to healthcare, we can also consider risks of auxiliary processes possibly associated with finances (lack of funds); material support (absence of necessary medicines, cut-off of water or energy supply); risks related to patient diets (low quality foods, food poisonings); risks associated with cleaning in hospitals [28, 29]. Therefore, this antimony of terminological concepts and ambiguous interpretation of different risk signs indicate it is truly vital to unify concepts that describe the subject area of risks. According to Russian experts [23], this will promote objective assessment of epidemic process regularities, organization of epidemiological surveillance, and effective disease prevention.

At present, the ‘risk’ category is a key paradigm of the contemporary epidemiology [15, 20] and almost the most widespread concept [30, 31], medical literature included. The risk concept is applied in epidemiology to predict events, to identify a cause of a particular event, to identify diagnostic criteria and their reliability in assessing therapy and prevention⁷. The monograph *Risk in Epidemiology* published by B.L. Cherkasskii, RAS Academician, is among few efforts of such kind [32]. In this monograph, the academician provided scientific substantiation for the concept and methodology of risk management in epidemiology; he introduced the concepts of ‘epidemiological risk’ and ‘epidemiological hazard’, and explained differences between them that should be considered within risk-based epidemiological surveillance over communicable diseases. According to B.L. Cherkasskii, an epidemiological risk is a potential possibility that an epidemiological situation would get worse, this worsening either expected or having occurred due to harmful effects produced on the situation by certain risk factors [32].

⁶ Matvienko D.A., Popova E.V., Savinskaya D.N. *Riskologiya: uch. posobie* [Riskology: manual]. Krasnodar, I.T. Trubillin’s Kuban State Agrarian University Publ., 2014 (in Russian); Ryagin Yu.I. *Riskologiya: uch. posobie v 2-kh ch.* [Riskology: manual in 2 parts]. Moscow, Yurait, 2017 (in Russian).

⁷ Kornysheva E.A., Platonov D.Yu., Rodionov A.A., Shabashov A.E. *Epidemiologiya i statistika kak instrumenty dokazatel'noi meditsiny: izd. 2-e ispr. i dop.* [Epidemiology and statistics as tools of evidence-based medicine: the 2nd ed., corrected and expanded]. Tver’, 2009, 80 p. (in Russian).

When interpreting epidemiological safety, contemporary authors consider the risk a potential probability of infectious complications in patients or healthcare workers with different outcomes, right up to death [25]. Basing on up-to-date requirements to formulating scientific definitions, S.N. Shugaeva and others [23] suggested their variant of how to define the concept of epidemiological risk that would be eligible for the epidemiology of both communicable and non-communicable diseases. This risk is ‘likelihood of negative influence on incidence (and / or its outcomes) among certain population groups exerted by external and / or internal factors occurring at a certain time and on a certain territory’. Many diverse terminological concepts and ambiguous interpretation of different risk signs determine the challenge of systematizing and unifying parameters (key concepts) that describe the subject area of risks in order to identify these risks and effectively manage them.

The risk is a key concept in etiological studies (risk factors), diagnostics (likelihood of identifying a disease provided there is one), treatment (likelihood of an adverse outcome or recovery), prevention, and prognosis⁷. At present, some deviations can be found in literature sources as regards understanding of definitions and interpretation of such superordinate concepts as ‘risk factor’, ‘risk group’, ‘risk territory’, and ‘risk time’ [23]. The term ‘risk factor’ was first introduced by William Kannel in 1961 in the epidemiological study that had started as far back as in 1947 in Framingham [33]. Those long-term observations made it possible to identify factors affecting occurrence and progression of cardiovascular diseases, atherosclerosis included. A theory of risk factors for diseases caused by atherosclerosis was developed⁸ [34, 35]. The epidemiological dictionary by G.M. Last (2009) provides the following definition of a risk factor:

‘a risk factor is an aspect of personal behavior or life-style, an environmental exposure, or an inborn or inherited characteristic, that, on the basis of epidemiologic evidence, is known to be associated with health-related condition(s) considered important to prevent’⁹. The WHO experts define a risk factor as ‘a property or a characteristic of a person, or a certain exposure that are associated with higher likelihood of a disease or injury’ [36]. Definitions of a risk factor that are similar in their sense but still have some differences from those outlined above are provided in other literature sources, some manuals and reference books¹⁰ [37].

HAIs risk factors are diverse and specific for each type of HAIs. In general, basic factors that determine most HAIs include patient characteristics (age, the number and severity of a primary and concomitant illness), epidemiological safety of employed medical technologies and in-hospital environment, as well as some other causes (duration of staying in hospital, availability of beds, a possibility to have an individual hospital room, etc.). HAIs risks are very different for different medical technologies and their levels can be identified. According to international data, HAIs risks are the highest in intensive care units, burn units, oncological and urological units, as well as units for treating injuries [38, 39]. Inadequate infection control also contributes to risks of these infections [14, 25].

By now, a considerable number of applied studies have been published with their focus on particular profiles of risk factors relevant to individual nosologies [40–45]. But at the same time, there are very few publications in the sphere that generalize knowledge about theoretical grounds of this epidemiological category [37]. Given that, it is still vital to fulfill a task outlined in the National Concept for Prevention of Healthcare-Associated Infections [19], a solution to which should help develop

⁸ Vnutrennie bolezni. Kniga 5 [Internal diseases. Book 5]. In: E. Braunwald, K.G. Isselbacher, R.G. Petersdorf, D.D. Wilson, D.B. Martin, A.S. Fuchi eds; D.G. Katkovskii, S.Yu. Martsevich transl. from English. Moscow, Meditsina, 1995, pp. 361–417 (in Russian).

⁹ Epidemiologicheskii slovar' [The epidemiological dictionary]. In: G.M. Last ed. Moscow, 2009, 316 p. (in Russian).

¹⁰ Briko N.I., Zueva L.P., Pokrovskii V.I., Sergiev V.P., Shkarin V.V. Epidemiologiya: uchebnik: v 2-kh t. [Epidemiology: manual: in 2 volumes]. Moscow, Meditsinskoe informatsionnoe agentstvo, 2013, vol. 1, 832 p. (in Russian); Shkarin V.V., Blagonravova A.S. Terminy i opredeleniya v epidemiologii [Terms and definitions in epidemiology]. Nizhny Novgorod, NSMA Publ., 2010, 298 p. (in Russian).

scientific research aimed at identifying HAIs risk factors for specific patient groups treated in different healthcare organizations [15, 19].

Risk realization often leads to a situation when actual results obtained by application of medical technologies deviate from those planned for a particular patient; as a result, there are medical, moral, social, and financial consequences [25]. Despite all the successes achieved by modern healthcare, surgical interventions have not yet become completely safe and postoperative complications as well as mortality due to HAIs are still very frequent [46]. HAIs prevalence varies between 0.1 to 290 cases per 1000 patients depending on a type of a unit, initial severity of a patient state, aggressiveness of employed medical technologies, and effectiveness of implemented epidemiological safety measures. Prevalence of infections in the area where a surgical intervention took place equals 15–118 cases per 1000 operated patients; bloodstream infections, 3.5–12.2 cases per 1000 days of central venous catheterization; urinary tracts infections, 4.1–8.8 cases per 1000 days of catheterization; and post-ventilation pneumonia, 7.9–23.9 cases per 1000 days of artificial ventilation [21, 47]. Given that, it becomes especially vital to develop and implement conceptual approaches to the interpretation and assessment of HAIs risks, algorithms for assessing HAIs risks with respect to different medical technologies in hospitals of various profiles. Up-to-date approaches to HAIs prevention should rely on the concept of risk factors. But it is hardly sufficient to have a simple idea of what risk factors are relevant for a specific disease; instead, we should understand a level (rate) of risk created by each factor, their hierarchy and interaction [48].

Apart from identifying risk factors, some efforts should be taken to perform complex analysis of risk groups and spatial-temporal characteristics (risk time and territory) of incidence and / or its outcomes [32]. Identification of risk groups is a major task within epidemi-

ological risk analysis. According to S.N. Shugaeva and others, a risk group (contingent) should be considered a part of population for which higher incidence and / or its consequences are identified or among which an epidemiological event is more prevalent [23].

Analysis of literature data has revealed that the existing systems for risk assessment have considerable drawbacks and only limited prognostic value. To identify cause-effect relations of HAIs occurrence and development, it is advisable to concentrate on stratification of risk groups. Stratification is the only way to examine and control values of other (apart from an exposure and a disease) variables in data analysis. In addition, stratification analysis basically aims to assess and, if necessary, to control ‘interfering’ factors. Over the last decade, some progress has been made as regards standardization of studies addressing risk stratification. Specifically, national registers are being created that provide an opportunity to obtain reliable predictors of unfavorable outcomes among patients, including those who have high perioperative risks [46]. Experts often use several approaches to stratify risk groups (risk – cohort) including demographic, social, occupational or clinical ones (premorbid background, physiological or pathological state, comorbidity, and others). It is noteworthy that it is impossible to create a spatial-temporal risk profile (risk time and territory) without a detailed epidemiological description of what caused an unfavorable situation on a given territory, that is, without identifying risk factors and groups, but this subject deserves a separate discussion.

In recent years, methods of influence on the epidemic process of HAIs have been reassessed and some experts believe transition to the risk-based approach to be quite promising in this respect. This approach makes it possible to take timely measures aimed at reducing risks of such infections in advance¹¹ [20, 49, 50]. The authors proceed from the outstanding

¹¹ Noskova O.A. Epidemiologicheskie osobennosti i osnovnye napravleniya profilaktiki generalizovannykh gnoino-septicheskikh infektsii v pediatrii [Epidemiological peculiarities and basic trends in prevention of generalized purulent-septic infections in pediatrics]: the dissertation ... for the Candidate of Medical Sciences degree. Irkutsk, 2020, 170 p. (in Russian).

necessity existing now within epidemiological surveillance and control of such infections. Namely, it is necessary to switch from a strategy that involves correction of an epidemic process based on incidence (following an adverse event that has already happened) to a risk assessment strategy together with developing and implementing a system for epidemiological safety based on this approach [20, 25, 51]. Since the risk-based approach within epidemiological safety is only starting to be integrated into the whole system of healthcare safety, development and specification of its individual components seems to be a promising trend in healthcare support [52].

Several parameters determine effectiveness of the risk-based approach. They include completeness and quality of information flows (epidemiological and microbiological monitoring, epidemiological monitoring of invasive procedures safety, monitoring of antimicrobial resistance and sensitivity of HAIs agents to disinfectants and bacteriophages, etc.), quality and effectiveness of epidemiological diagnostics, as well as risk management aimed at detecting, identifying, monitoring and assessing risks [25, 53], developing specific activities that should eliminate or minimize possible negative outcomes of risks.

Risk management is a discipline that aims to investigate adverse outcomes of healthcare by identifying and analyzing them, the ultimate goal being the development of effective prevention strategies [22]. At the same time, although quality management systems have been developed quite intensively in many spheres, healthcare has long remained a sphere where quality is associated only with personnel's education and experience¹². In conformity with the National Standard GOST R ISO 31000-2019 Risk Management: Principles and Guide, the essence of risk man-

agement is to create a system of measures within an organization that prevents risks by identifying, analyzing, and assessing them¹³. It is noteworthy that risk managements systems have already been implemented in healthcare systems in foreign countries [24]. Different countries rely on different approaches to building up an organizational structure for a risk management system. Risk management in healthcare can be accomplished at four different levels: federal, regional, organizational (a healthcare organization), and a personal one (a healthcare worker) [28]. Few publications can be found in Russian literature that address risk management at the organizational level in healthcare organizations and rely on using qualitative HAIs indicators [48, 54]. We have not been able to find any studies that concentrate on managing HAIs risks at the regional level.

Risk management is based on a system or a set of activities aimed at analyzing all the incidents that concern patient safety. However, healthcare workers do not provide any information about unwanted events and errors in healthcare in 50–96 % of such cases [55]. International experts in patient safety have established several optimal methods to identify and assess errors and adverse events in health care. Such methods are anonymous data collection about incidents; retrospective analysis of patient case histories; questioning (interviewing) of healthcare workers and their patients; observing directly how healthcare is provided; reports about errors and adverse events made by healthcare workers; analysis of patients' complaints or legal actions taken by them; computer monitoring of electronic databases with medical data; autopsy studies; conducting clinical and anatomical conferences.

In their studies, foreign authors show effectiveness of such an approach since it al-

¹² Kornysheva E.A., Platonov D.Yu., Rodionov A.A., Shabashov A.E. *Epidemiologiya i statistika kak instrumenty dokazatel'noi meditsiny: izd. 2-e ispr. i dop.* [Epidemiology and statistics as tools of evidence-based medicine: the 2nd ed., corrected and expanded]. Tver', 2009, 80 p. (in Russian).

¹³ GOST R ISO 31000-2019. Risk Management. Principles and guidelines: the RF National Standard; approved and implemented by the Order of the Federal Agency on Technical Regulation and Metrology on December 10, 2019 No. 1379-st. *KODEKS: electronic fund for legal and reference documentation*. Available at: <https://docs.cntd.ru/document/1200170125> (April 07, 2023) (in Russian).

lows identifying hidden risks that are never registered or investigated [56–58]. Various tools can be used to estimate effectiveness of a risk management system. A methodology based on specialized reference books has been developed; these books estimate key elements of a risk management system relying on quantitative expert evaluations [59]. At the same time it is noted that in Russian Federation any voluntary report about defects often leads to inspections, fines, and orders. As a result, healthcare workers are totally demotivated to perform risk monitoring and report any defects [28]. Risk management is a multidisciplinary task that considers contributions made by all the healthcare workers employed by a hospital: doctors, nurses, laboratory personnel, medical engineers, administrative staff, and others. Therefore, a basic goal in increasing healthcare safety is to create a risk management system within the Russian public healthcare together with the development of risk management technologies and a methodology for analyzing effectiveness of HAIs risk management.

To sum up, it is noteworthy that the key role in creating an effective system for control and surveillance over hospital-acquired infections belongs to the following activities:

- development of scientific approaches to systematizing and unifying indicators (key concepts) that describe the subject area of HAIs risks in healthcare organizations of various profiles;
- improvement of the methodology for analyzing HAIs risks, the risk-based approach and risk management technologies within surveillance over such infections;
- optimization of science-based approaches to decision-making that relies on the risk-based approach and HAIs risk management technologies, their implementation into healthcare practices;
- development of methodical guidelines on monitoring, assessment, and prediction of HAIs risks in healthcare organizations.

Funding. The research was not granted any sponsor support.

Competing interests. The authors declare no competing interests.

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Received: 18.04.2023

Approved: 10.05.2023

Accepted for publication: 02.06.2023