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## The Actual Epidemiological Effectiveness of Assessing and Improving the System for Ensuring the Epidemiological Safety of Medical Care for Catheterized Patients

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### SUMMARY

The basis of optimized conventional system of surveillance and control for catheter-related bloodstream infections (CRBI) was priority in detection and risk assessment an infectious complication of puncture catheterization that substantially justified with inclusion of two main components as an addition to the existing system: monitoring of puncture catheterization, which allows to obtain and analyze data on risk factors for infections associated with the catheterization procedure and subsequent manipulations of the device, standardize approaches to working with a venous catheter and improve the diagnosis of CRBI; assessment of ensuring the epidemiological safety of medical care for catheterized patients. Epidemiological efficiency risk-based surveillance, primarily determined to reduce the incidence of CRBI by 1.8 times compared to initially defined real incidence: 12.5‰ (95% CI — CI 11.8–13.2) vs 22.8‰ (95% CI 21.1–24.5) catheterized patients,  $p=0.0001$ .

**Keywords:** infections associated with the provision of medical care, catheter-associated infections, epidemiological safety, quality and safety, quality management system  
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AA – antiseptic agents

CI – confidence interval

HCRI – health care-related infections

CABI – catheter-associated bloodstream infections

ICU – Intensive Care Unit

SOP – Standard Operating Procedures

CHB – chlorhexidine bigluconate

CVC – central venous catheter

## INTRODUCTION

The urgent task of modern healthcare is to ensure the safety and quality of medical care [1, 2]. One of the requirements for the conditions for the provision of medical services is the epidemiological safety of the patient and staff, and in particular the prevention of infections related with the provision of health care (HCRI) [2, 3].

In the general structure of HCRI morbidity, catheter-associated bloodstream infections (CABI) occupy one of the leading positions. CABI, being an infectious complication of vascular puncture catheterization, is underestimated in the Russian Federation as an infectious disease with a wide range of microorganisms, both pathogenic and opportunistic. There are scattered over time and non-systemic data on the incidence of CABI, which is aggravated by the lack of use of stratified incidence rates in epidemiological studies [4–6].

Based on our own comprehensive long-term studies [7–9], it should be said that there is insufficient effectiveness of the traditional system of epidemiological surveillance and control of HCRI and SOP in relation to CABI, namely:

- classical methods of epidemiological diagnostics - retrospective analysis of morbidity and prospective observation, even organized using a standard case definition of HCRI and their active detection – increase the detection of CABI and the assessment of morbidity, but do not allow for high-quality epidemiological diagnostics: to calculate stratified incidence rates, to carry out identification and complete an assessment of the epidemic situation (which is associated with difficulties in collecting data for calculating stratified morbidity rates, identifying and assessing the risks of complications associated with the procedure for setting and caring for a venous catheter); assess the provision of procedures for the operation of a central venous catheter (CVC); to assess the provision of the epidemiological safety of medical care for catheterized patients with vascular catheters, etc.;

- there is no standardization of invasive manipulation "puncture catheterization of vessels", which complicates the assessment of the risk of infectious complications, namely: there is no unified approach to the procedure execution algorithm and its control, assessment of the key properties of the technology, methods of collecting information on the characteristics of manipulation and its processing;

- there is no comprehensive assessment of ensuring epidemiological safety in the provision of medical care to patients with vascular catheters.

Based on the literature data, analysis of regulatory and methodological documents, in particular guidelines and recommendations for HCRI and CABI, it should be said that a comprehensive scientifically substantiated study of the problem of infectious complications of puncture catheterization of vessels and the introduction of optimized components of epidemiological surveillance and control based on the principle of priority detection and assessing the risk of CABI, but not cases of disease.

The results of our own research, obtained at the first stages of work, and the modern doctrine of HCRI prevention [10] became the basis for the theoretical development and further practical implementation of a model of risk-based epidemiological surveillance and control of CABI in three resuscitation and intensive care units (ICU) of an adult multidisciplinary hospital in the period from 2015 to 2019 with a further assessment of its actual epidemiological effectiveness.

## MATERIAL AND METHODS

The study used a complex of epidemiological types of research: 1) descriptive and evaluative studies: longitudinal (monitoring) and transverse (epidemiological screening) - to assess various determinants of the epidemic process of CAIC; 2) experimental studies: an uncontrolled epidemiological experiment to assess the actual epidemiological effectiveness of the risk-based epidemiological surveillance and control model of the CAIC. Microbiological studies were carried out within the framework of microbiological monitoring.

The clinical base of the study was a multidisciplinary hospital for adults. Microbiological studies were carried out on the basis of problematic scientific laboratories of microbiology and PCR studies (polymerase chain reaction studies) of the Research Institute of Preventive Medicine of the Volga Research Medical University of the Ministry of Health of the Russian Federation, the reference laboratory of the human microbiome and means of its correction on the basis of the "Nizhny Novgorod Research Institute of Epidemiology and microbiology named after acad. I.N. Blokhina" Rosпотребнадзор.

Objects of study – patients with an indwelling or temporary vascular catheter installed in the central vein, and patients with infectious complications after catheterization: 2186 catheterized patients, 113 patients with CAIC according to retrospective data; plus 2590 catheterized patients, 54 patients with CAIC according to prospective data. Research materials: 10,770 medical documents, 408 samples of clinical material, 267 cultures of microorganisms, 5379 laboratory tests performed. The system for ensuring the epidemiological safety of medical care for catheterized patients was assessed using the document "Proposals (practical recommendations) of Roszdravnadzor on the organization of internal quality control and safety of medical activities in a medical organization (hospital)" [11], developed by the Federal State Budgetary Institution "National Institute of Quality" of Roszdravnadzor.

## RESULTS AND CONCLUSIONS

According to an in-depth retrospective analysis based on average long-term data, the incidence of CAIC in a medical organization was 11.7 ‰ (95% confidence interval – CI 11.5–11.9) and exceeded the official registration data by 4.3 times – 2.7 ‰ (95% CI 2.62–2.78) in catheterized patients ( $p=0.001$ ). In a comprehensive assessment of the risk of CAIC, associated with the peculiarities of the technology of puncture catheterization of the central veins, carried out mainly in the ICU, the following approaches were used:

- assessment according to various criteria: catheterization load, duration of catheterization, characteristics of installed catheters, etc.;
- general assessment of the system of epidemiological safety of medical technology, including the application of criteria directly and indirectly related to the puncture of blood vessels under the section "Epidemiological safety (prevention of infections associated with the provision of medical care – HCRI)" specified in the corresponding "Proposals (practical recommendations)..." [11].

The high risk of developing CAIC in ICU patients is determined by a significant catheterization load due to the wide coverage of central vein catheterization (32.9% per 100 ICU patients), a large number of catheterizations (on average 1384.8 catheters per year), repeated patient catheterizations (on average 1, 3 catheterizations per patient, respectively), the duration of catheterization (the proportion of patients with a

catheterization duration of at least 7 days was 75.4%, the average time the catheter was in the vascular bed was  $16.5 \pm 2.6$  days), as well as the use of insufficiently safe in terms of infectious vascular access (for example, femoral) and types of catheters (non-tunneled CVC) [8].

The system of epidemiological safety during puncture catheterization was assessed through an internal audit of the quality and safety of medical care in accordance with the approved criteria [11]. Out of 16 group indicators for the section "Epidemiological safety" of the above practical recommendations, the following indicators were selected: ensuring the epidemiological safety of medical technologies (during invasive interventions), the availability of fully equipped places for washing and processing hands, compliance with hand hygiene rules by staff, patients and visitors / caregivers, staff adherence to the algorithm for the use of personal protective equipment, organization of a system for ensuring epidemiological safety, a system for active detection, accounting and registration, analysis of CAIC among patients and staff, a system for conducting microbiological studies (including cases of suspected CAIC) and a microbiological monitoring system.

The most common violations of the epidemiological safety of invasive manipulation were: lack of standard operating procedures (SOPs), contradictions between the existing practice of working with CVCs in a medical organization, approved clinical guidelines, manuals, low compliance of medical workers with respect to hand hygiene procedures and the use of personal protective equipment. Epidemiological diagnostics of CAIC, namely the registration and registration of cases of CAIC, the introduction of standard case definitions into clinical practice and the calculation of stratified indicators – these components of the activity were also insufficiently introduced. When organizing microbiological monitoring, the main violations related to the lack of systematic data on the resistance of microorganisms to antimicrobial agents, in particular, to chlorhexidine bigluconate (CGB) as the main drug in the setting of CVC and manipulations for its care.

Quantitative characteristics for each assessed indicator were less than 95–100%. Such results indicate that at all stages of work with a catheterized patient, non-compliance with the rules of epidemiological safety takes place. The overall indicator of ensuring the epidemiological safety of medical activities was 33.9%, which was considered as the functioning of an ineffective system that required significant changes.

The results obtained at this stage of the study became the basis for the development of a new methodological approach – a model of risk-based epidemiological surveillance and control of the CAIC, which was based on two main components as an addition to the existing system of epidemiological surveillance of SOP:

- monitoring the manipulation of central venous catheterization in the patient. Monitoring data will allow you to obtain and analyze information on the risk factors for CAIC associated with the catheterization procedure; to standardize approaches to working with the device and optimize clinical and epidemiological diagnostics of CAIC;

- systematic assessment of the epidemiological support of medical care for catheterized patients.

Manipulation monitoring is a part of the monitoring of the treatment and diagnostic process, aimed at the most critical invasive intervention in terms of the risk of a specific nosological form of HAI, in our case, CAIC. When developing this component of the risk-based epidemiological surveillance model, were held:

- optimization of the system for collecting information on the types of invasive manipulation technologies, cases of CAIC, the number of catheter-days and microbiological monitoring data with the involvement of all officials who work directly with catheterized patients and provide microbiological diagnostics;

- standardization of all stages of the implementation of invasive manipulation, catheter operation.

The standardization of procedures for setting up and caring for CVCs was carried out through the development and implementation of SOPs into clinical practice - documented instructions for performing a working procedure or a formalized algorithm for performing actions, fulfilling the requirements of medical care standards [12, 13]. The following documents were developed: Standard Operating Procedure for Central Venous Catheter (CVC) Placement, Standard Operating Procedure for Central Venous Catheter (CVC) Care.

In addition to the SOP, documents were developed: a SOP algorithm, a block diagram, a manipulation protocol, an observation sheet for a catheterized patient and a control checklist. These documents ensured the process of training, application and control over the implementation of the SOP.

The SOP and the attached package of documents were developed with the involvement of various specialists: surgeon, chief nurse, anesthesiologist-resuscitator, epidemiologist of a medical organization, bacteriologist and procedural nurses of the ICU. Training of medical personnel to conduct a safe procedure for vascular catheterization, familiarization with the SOP, the rules for monitoring the CVC and filling out medical documentation took place at seminars and sections of nurses and doctors, in the process of practical activity. All medical workers (doctors, procedural and guard nurses) involved in setting up and operating the CVC were trained.

Manipulation monitoring was carried out together with prospective observation of catheterized patients and microbiological monitoring. The main sources of necessary information for monitoring manipulation: documents from the SOP package, observation sheet for the catheterized patient; invasive manipulation protocol; the journal "Recording of the performed vascular catheterizations", containing the personal information about the catheterized patient, type of catheter inserted, anatomical puncture site, dates of staging and removal, developed complication, the medical team that accessed; monthly report form "Report on invasive manipulation of central vein catheterization" required to calculate the total number of catheter-days for the entire cohort of catheterized patients.

The actual effectiveness of the CAIC epidemiological surveillance model was determined by the completeness of the detection of CAIC cases, etiological interpretation, the content of epidemiological diagnostics before the model was introduced (2014–2015) and during the period of its implementation (2016–2017). The effectiveness of risk-based epidemiological control was assessed by the thoroughness of compliance with the SOP requirements, an increase in the compliance of medical workers with the fulfillment of the requirements for ensuring the epidemiological safety of invasive manipulation and an actual decrease in the incidence of CAIC for the time period 2016–2019.

As a result of a comprehensive prospective observation, it was found that the incidence rate of CAIC was 19.4 in 2015 (95% CI 17.5–21.3), in 2016 22.8 (95% CI 21.1–24, 5) per 1000 catheterized patients (mean long-term indicator 21.1 ‰ (95% CI 20.3–21.9), which was assessed as a statistically significant increase in the detection of cases of CAIC. Thus, according to the average long-term data, the incidence rate of CAIC increased by 6.2 times compared with the official registration – 21.1 ‰ (95% CI 20.3–21.9) vs 3.4 ‰ (95% CI 2.8–4.0) in catheterized patients and 1.6 times in retrospective in-depth analysis – 21.1 ‰ (95% CI 20.3–21.9) vs 13.3 ‰ (95% CI 12.6–14.0) catheterized patients. Thanks to the

organized monitoring of the invasive procedure in combination with prospective observation, the stratified incidence rate of CAIC in the ICU was calculated for the first time and its regular determination was introduced, while the average long-term indicator was 14.7 ‰ (95% CI 13.9–15.5). Now it is possible to compare these indicators with the levels of the incidence density of CAIC, determined by the WHO based on the results of multicenter studies and used as conditional comparison levels [14].

Thus, the incidence density of CAIC among ICU patients of a multidisciplinary hospital for adults (according to average long-term data), calculated in catheter days, turned out to be statistically significantly higher than the average WHO indicator – 1.2 times (14.7 ‰ (95% CI 13.9 – 15.5) vs 12.2 ‰ (95% CI 11.4–13.1)) for high-income countries and 3.5 times (14.7 ‰ (95% CI 13.9–15, 5) vs 3.5 ‰ (95% CI 2.9–4.1) – for countries with middle and low income, which indicates a high intensity of the epidemic process of CAIC in the hospital.

Gram-positive flora (84.1%) prevailed in the etiological structure of CAIC, the largest proportion were microorganisms of the genus *Staphylococcus* (*S. aureus* — 42,1%, *S. epidermidis* — 28,9%, *S. saprophyticus* — 2,6%).

Three intensive care units used different protocols for the procedure or did not use them at all, and there were also cases of non-standardized approaches to the care of the catheter and the puncture site of the CVC. Differences in care related to the technique and frequency of flushing the CVC, the use of antimicrobial agents (ointments, powders, skin antiseptics) at the puncture site and under the dressing, frequency and indications for changing the dressing. With regard to the antiseptic agents (AA) used to treat the puncture site, it was found that during the placement of the catheter, 0.5% alcohol CGB solution was used to treat the surgical field, while during the operation of the catheter in some ICUs, the puncture site was treated with a 0.02% aqueous solution of CGB. It was also determined that there is no unified standard of microbiological diagnostic measures in case of suspicion of a case of CAIC, namely, the rules and frequency of blood sampling from a peripheral vein for bacteriological culture were not followed, indications for removal and direction for culture of the distal CVC segment were not determined. Such violations contributed to the inadequate collection of information about the characteristics of the treatment and diagnostic process, cases of CAIC, etc. Taking into account the fact that the risk of developing CAIC is determined by the number and invasiveness of medical and diagnostic procedures [2, 10], it is necessary to objectively assess the high risk of infectious complications in the case of a non-standard and unsafe from an epidemiological point of view, the process of using an invasive device – a vascular catheter.

The introduction of a risk-based epidemiological surveillance model made it possible to more fully identify and analyze the risks associated with the manipulation of vascular catheterization and the period of operation of the CVC device. In connection with the updated data, epidemiological control was optimized, aimed at minimizing the identified risks. In addition to the generally accepted measures of preventive and anti-epidemic protection, a set of measures (bundle) for the prevention of CAIC was developed and implemented simultaneously, which included:

- standardization of the procedure for staging and caring for the catheter in three ICUs, as well as in those departments where the patient was treated after CVC staging;
- standardization of the use of CGB-based antiseptics when working with CVC and puncture site;
- standardization of diagnostic measures for suspected cases of CAIC using the standard definition of a case of HCRI;
- systematic internal audits of the system for ensuring the epidemiological safety of medical care for catheterized patients according to approved criteria with the adoption of management decisions.

The standardization of procedures for setting, caring for CVCs, using AA and diagnostic measures was carried out through the development and implementation of SOPs and related documents into clinical practice, which is described in more detail above.

The stage of monitoring the fulfillment of the requirements of SOPs for setting and caring for a vascular catheter was carried out by the method of visual observation, filling out and further analysis of the corresponding checklist. As part of the internal audit, in three ICUs and two departments of the hospital (neurological department and dialysis department), in which certain contingents of patients were treated, 315 observations were carried out (total for ICU – 234, dialysis department – 45, neurological department – 36). The analysis of the checklists filled out by the auditors made it possible to compare the implementation of the standardized rules for staging (Fig. 1) and caring for the vascular catheter (Fig. 2) before the introduction of the SOP and after the training and implementation cycle of the SOP.

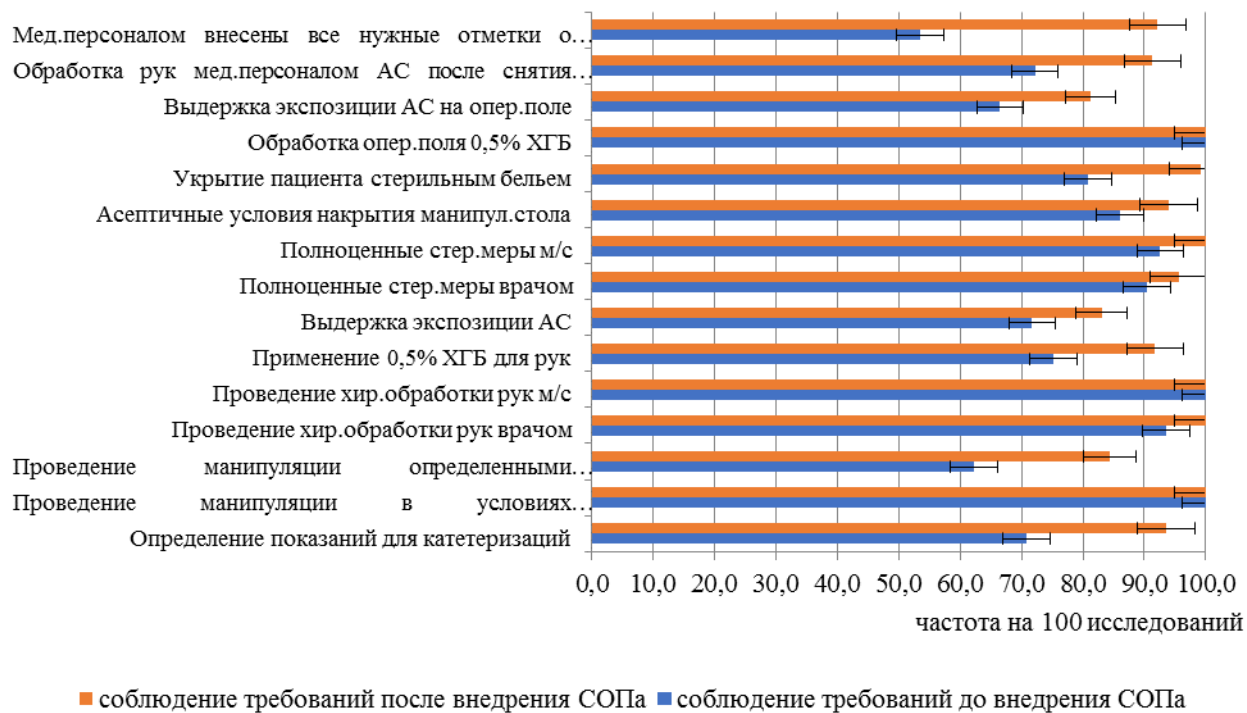


Fig. 1. Monitoring the implementation of the stages of an epidemiologically safe procedure for setting up the CVC before and after the introduction of the SOP (average data for the hospital)

Notes: AA – antiseptic agents; CB – chlorhexidine bigluconate; CVC – central venous catheter; ICU – Intensive Care Unit; SOP – Standard Operating Procedures

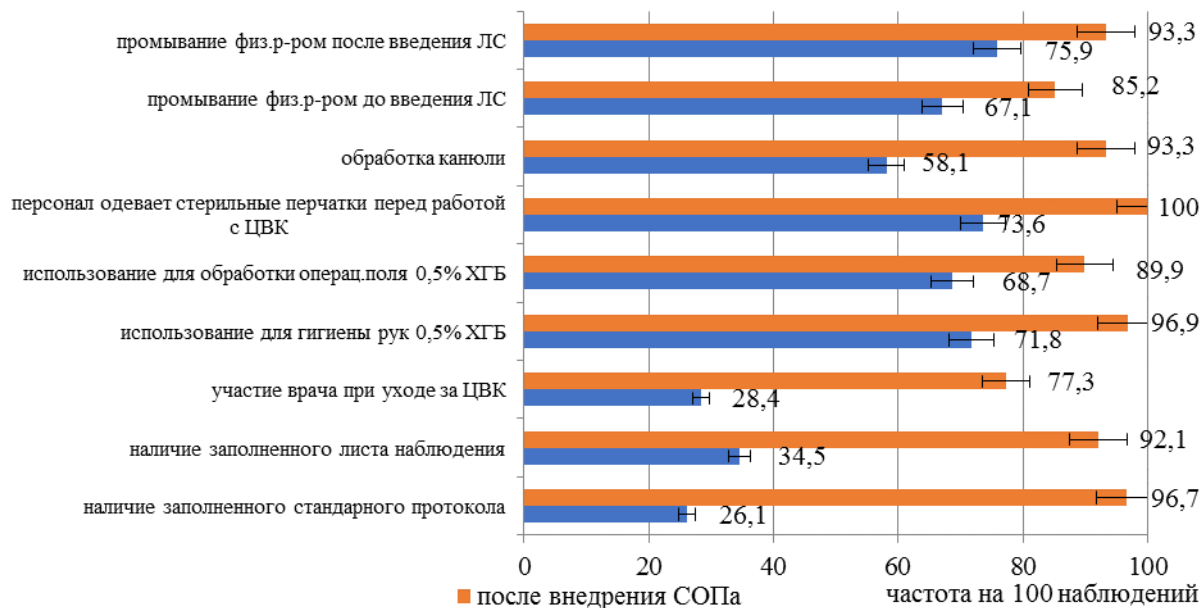


Fig. 2. Monitoring the implementation of the stages of an epidemiologically safe CVC care procedure before and after the introduction of the SOP (average data for the hospital)

Notes: CB – chlorhexidine bigluconate; CVC – central venous catheter; SOP – Standard Operating Procedures

After the standardization of all stages of work with the catheter, an improvement in compliance with the epidemiologically safe principles of insertion of vascular catheters in 12 indicators was recorded by 5.2–38.7%.

The adherence of medical personnel to the requirements of the SOP when performing venous catheter care procedures increased in all 9 control indicators by 17.4–70.6%.

Thus, the system of epidemiological support for the safe procedure of puncture catheterization and subsequent manipulations on the operation of the CVC reached 92.5% of compliance with the SOP requirements.

An indicator of the effectiveness of the changes made (introduction of a model of risk-based epidemiological surveillance and control) was a statistically significant decrease in the incidence rate of CAIC by 1.8 times compared to the initially determined real level: 12.5 ‰ (95% CI 11.8–13.2) vs 22.8 ‰ (95% CI 21.1–24.5) catheterized patients,  $p=0.0001$ .

## CONCLUSION

The conducted epidemiological study made it possible to reveal the real incidence rate of catheter-associated bloodstream infections in catheterized patients, to determine the leading infectious agents, and to identify risk factors. The drawbacks of the organization of epidemiological support of the epidemiological safety of invasive manipulation have been established. The actual epidemiological effectiveness of the model of risk-based epidemiological surveillance and control of catheter-associated bloodstream infections has been proven.

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