ЭПИДЕМИОЛОГИЧЕСКАЯ БЕЗОПАСНОСТЬ КАК КОМПОНОНТ БЛОКА ОПЕРАТИВНОГО УПРАВЛЕНИЯ ИНФОЦЕНТРА ПРИ ВНЕДРЕНИИ БЕРЕЖЛИВОГО ПРОИЗВОДСТВА В МЕДИЦИНСКУЮ ОРГАНИЗАЦИЮ, ОКАЗЫВАЮЩУЮ ПЕРВИЧНУЮ МЕДИКО-САНІТАРНУЮ ПОМОЩЬ

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В настоящее время первичное звено системы здравоохранения находится в стадии активного реформирования. В деятельность медицинских организаций внедряются технологии бережливого производства, способствующие сокращению потерь медицинских и вспомогательных процессов. Одним из основных методов бережливого производства является визуализация, которая в оперативном менеджменте медицинской организации реализуется в виде создания информационных центров (инфоцентров) с отражением основных показателей деятельности медицинской организации по системе SQDCM: безопасность, качество, исполнение заказа, затраты и комфортная среда. Среди наиболее актуальных для отечественного здравоохранения критериев безопасности медицинской деятельности выделяют показатели эпидемиологической безопасности. Одним из наиболее сложных для индикации, но необходимых для отражения в инфоцентре параметров обеспечения эпидемиологической диагностики выступает показатель аварийности на рабочих местах.

Цель. Обобщение литературных данных по возможности включения параметров эпидемиологической безопасности в оперативную оценку инфоцентра.

Проводимые в нашей стране эпидемиологические исследования в медицинских организациях различных профилей показывают увеличивающуюся частоту различных аварийных ситуаций среди медицинского персонала. При этом, по-прежнему, система индикации и идентификации всех аварийных случаев является несовершенной, а медицинский персонал зачастую скрывает случаи аварийных ситуаций.

Заключение. Внедрение критериев эпидемиологической безопасности как компонента блока оперативного управления инфоцентра медицинской организации в практическую деятельность будет способствовать формированию функционирующей и постоянно совершенствующейся системы анализа деятельности медицинской организации, управления процессами оказания медицинской помощи населению, стандартизации выполнения инвазивных процедур с учетом обеспечения эпидемиологической безопасности. Ключевыми задачами инфоцентра является: фокусировка внимания сотрудников медицинской организации на проблемах, оперативная реакция на возникающие проблемы и риски, а также обеспечение эффективной коммуникации всех участников оперативных совещаний в едином информационном пространстве.

Ключевые слова: бережливое производство; инфоцентр; визуализация; система SQDCM; аварийные ситуации; менеджмент; эпидемиологическая безопасность; новая модель медицинской организации.
EPIDEMIOLOGICAL SAFETY AS A COMPONENT OF THE OPERATIONAL MANAGEMENT UNIT OF THE INFOCENTER IN INTRODUCTION OF LEAN MANUFACTURING IN A MEDICAL ORGANIZATION THAT PROVIDES PRIMARY HEALTH CARE

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Currently, the primary health care system is undergoing active reformation. Lean manufacturing technologies are being introduced into the activities of medical organizations that help reduce the loss of medical and auxiliary processes. One of the main methods of lean production is visualization, which is implemented in the operational management of a medical organization in the form of creating information centers (InfoCenters) that reflect the main parameters of the activity of a medical organization in the SQDCM system: safety, quality, order execution, costs and a comfortable environment. Criteria of safety of medical activity most relevant for the national healthcare system are parameters of epidemiological safety. A parameter most difficult for indication, but necessary for reflection of epidemiological diagnostics in the InfoCenter is the accident rate at work.

Aim. Generalization of literature data on the possibility of including epidemiological safety parameters into the operational assessment of the InfoCenter.

Epidemiological studies conducted in our country in medical organizations of various profiles show an increasing rate of emergency situations among the medical personnel. With this, the system of indication and identification of all emergency cases still remains imperfect, and medical personnel often hide cases of emergency situations.

Conclusion. Introduction of criteria of epidemiological safety into the practical activity of a medical organization as a component of the operational management unit of the InfoCenter will contribute to the formation of functioning and constantly improving system of analysis of the activity of medical organizations, to the control of provision of medical care, and to standardization of invasive procedures to ensure epidemiological safety. The key tasks of the InfoCenter are: focusing the attention of medical organization employees on problems, prompt response to emerging problems and risks, and also ensuring effective communication of all participants of operational meetings in a single information space.

Keywords: lean manufacturing; InfoCenter; visualization; SQDCM system; emergency situations; management; epidemiological safety; new model of medical organization.

The federal project «Development of the system of primary medical care» within the National «Healthcare» Project implies completion of formation of a network of medical organizations (MO) based on new principles of providing medical care to the population [1]. In its turn, as the basic paradigm of New model of MO providing primary medical care (PMC), the managerial concept of lean production (LP) is used that has been actively introduced into the system of Russian healthcare since 2016 [2,3].

In 2018 Federal Center of organization of PMC of Healthcare Ministry (HM) of the Russian Federation (RF) submitted medical recommendations «New model of medical
organization providing primary medical care» where for the first time 9 blocks of criteria (21 criteria) of New model of MO providing PMC were published: management of streams of patients, the quality of space, standardization of processes, quality of medical care, availability of medical care, involvement of personnel to improvement of processes, and effective use of equipment [4]. Formation of the management system (Block 8) implies visualization of management of processes through arrangement of information centers (InfoCenters) in MO. The aim of this work was generalization of literature data on the possibility of inclusion of parameters of epidemiological safety into the operative evaluation of InfoCenter.

**Lean Production Visualization Method**

Visualization is one of the methods of lean production, which consists in presenting information in a visual form for the best visual perception and making the right decision [5]. In the methodology of introduction of visualization, one of the fundamental provisions is the principle of management from the place of value creation – *Shop Floor Management* (SFM) [6,7]. Each management system differently sets priorities, organizes planning, focuses on various aspects of the activities of municipalities, forms various groups of parameters, and, in general, differently achieves results [8]. The main objective of SFM is to continuously provide effectiveness of processes by identification and elimination of losses, achievement of the proper state of the main processes in the MO through decomposition of aims into standardized parameters: safety, quality, order execution, finances, corporate culture, involvement of personnel, etc. [9].

Classic methods and tools of visualization are considered to be marking, contouring, color coding and information boards. Some researchers distinguish the road sign method, the «was-has become» method and paint marking, as separate elements [10]. A.V. Sazonova, et al. adds graphical operating instructions to this list [11].

Aim decomposition tools are used to operationalize the strategy and manage the achievement of strategic aims and objectives by focusing of MO management system on continuous improvement of the activities in the points of greatest influence on key parameters of the activity. To apply a systematic approach to strategy deployment and aim-setting, various technologies and tools for aim decomposition can be used (aim tree, Hoshin Kanri X-matrices, information centers, etc.), each having both strengths and weaknesses [12]. In the lean production methodology, the most popular tool for visualization of the SFM principle is InfoCenter [7,13].

**InfoCenter as a Tool for Visualization of Lean Production Method**

InfoCenter is a classic aim decomposition tool used for visual management of the main and auxiliary processes, which allows to identify problems and accelerate making managerial decisions through effective meetings and fast communications, and also forms effective channels of constant feedback for managers of various levels of MO (doctor in-chief, head nurse, heads of departments, etc.).

The use of information boards in InfoCenters, uniform in content, ensures equal access of all employees to information not only in form, but also in content. Creation of information centers allows solution of six main tasks: 1) visualization and increase in transparency of all processes; 2) operational identification of losses; 3) consideration of the activity of a separate structural unit or of MO in whole in terms of key performance indicators (KPI); 4) increase in the speed of making managerial decisions; 5) increase in cross-functional communication between staff and management; 6) reduction of transaction costs.
SQDCM System of InfoCenter of Medical Organization

In a classic variant, visual presentation of InfoCenters suggests realization of SFM principle through certain basic elements, a specific set of which depends on the MO, its aims and tasks, and also on the current condition of the operative activity. In lean management, a special system of basic elements of InfoCenters is used that was primarily developed for British auto industry. Given the name by the first letters of basic elements (a mnemonic rule widely used in the world scientific community), the system has several variants of arrangement of the elements and, accordingly, names: QCDF (quality, cost, delivery, flexibility), QDIP (quality, delivery, inventory, productivity), SQDCIPE (safety, quality, delivery, cost, inventory, productivity, environment), SQDC (safety, quality, delivery, customer) etc. The most common variant in our country that was at first used in the production companies (PAO KAMAZ, GK ROSATOM, GAS group) and then in the system of healthcare, was SQDCM (safety, quality, delivery, cost, morale) standard [14,15]. Because of impossibility to translate some components of SQDCM to Russian, different versions can be encountered in the works of different authors [16]. Thus, the term «morale» in some sources is translated as «corporate culture», and in others – «comfortable environment»; the term «delivery» has several interpretations: «on-time fulfilment», «fulfilment of the order», «volume», «order», etc.

Each component of SQDCM system may be correlated with certain criteria of New model of MO providing PMC. However, a strategic task of Russian healthcare at present is, undoubtedly, to ensure the quality and safety of medical care. Introduction of new medical technologies into practice, increase in the number of invasive procedures and interventions determine the urgency of ensuring the epidemiological safety of medical activities, which, in turn, dictates the necessity to form an operational department for monitoring and assessing compliance with safety requirements within the framework of the MO information center [17].

Epidemiological Safety

Epidemiological safety of medical care is a complex of conditions characterized by absence of unacceptable risk of initiation in patents and medical personnel of infectious diseases associated with rendering of medical assistance, of carriage state, intoxication, sensitization of an organism, traumas induced by micro- and macroorganisms and by products of their vital activity and also by cultures of cells and tissues [18].

The main documents that determine measures to ensure epidemiological safety in realization of medical activities in the Russian Federation are: SanPiN 2.1.3.2630-10 «Sanitary and epidemiological requirements to organizations engaged in medical activities» (approved by the Decree of the Chief State Sanitary Doctor of the Russian Federation of May 8, 2010 №58); the National Concept of prevention of infections associated with rendering of medical care (approved by the Chief State Sanitary Doctor of the Russian Federation on November 6, 2011); Federal clinical recommendations on ensuring epidemiological safety, approved by the National Association of Specialists on Control of Infections Associated with the Provision of Medical Assistance (NP «NASKI») and agreed with the Profile Commission of the Ministry of Health of the Russian Federation on Epidemiology.

Among the methods of evaluation of the criteria of epidemiological safety, of highest interest is classification developed by the working group of the Profile Commission on Epidemiology of HM RF that was further incorporated into the basis of the general system of parameters of quality and safety of
medical care, also through Practical recommendations of Roszdravnadzor on organization of the internal control of quality and safety of medical activity in a medical organization (outpatient clinic) [19]. The whole variety of factors providing epidemiological safety, can be reduced to six key components: 1) epidemiological safety of medical technologies; 2) epidemiological safety of medical environment, 3) effective biological monitoring, 4) epidemiological diagnostics, 5) epidemiological safety of medical personnel, 6) staff resourcing of epidemiological safety [18]. Each component may be broken down to constituents and may be evaluated by criteria of epidemiological safety.

From the point of view of operational management, it is not reasonable to reflect all the criteria for epidemiological safety within the framework of the information center of MO or of a separate structural unit. In component 1 (epidemiological safety of medical technologies) it is possible to visualize parameters of aseptic implementation of manipulations: 1) correspondence of the hand hygiene technology of medical personnel to the standard (in at least 95% of cases); 2) observance of epidemiologically safe algorithms of invasive manipulations and operations (in at least 95% of cases); 3) provision of each medical technology with sterile materials according to the standard (algorithm) for epidemiologically safe medical technology, manipulation and surgery (in 100% of cases). In component 2 (epidemiological safety of the hospital environment) in the case of hospitals and day hospitals, it is advisable to: record the coverage of bedding with chamber disinfection (100% of the number of patients discharged) and, to a lesser extent, correspondence of the quality of the current preventive disinfection to the requirements of sanitary legislation. In component 3 (effective microbiological monitoring), for some structural units of the MO it is important to use parameter of provision of clinical material from patients having infectious diseases and suspected of their presence, with microbiological examination (in 100% of cases). In component 4 (epidemiological diagnosis), one of the most important parameters is the completeness of identification of infectious diseases associated with rendering of medical care (100%). Forming the information center, the medical personnel in component 5 (epidemiological safety of medical personnel) in the operational management unit should consider the need to reflect: coverage with immunization regulated by sanitary legislation (at least 95%) and timely medical examinations (100%). Parameters of component 6 (staff resourcing of epidemiological safety) does not imply operational management within the information center.

Epidemiological safety of medical care is a complex of conditions characterized by absence of unacceptable risk of initiation in patients and medical personnel of infectious diseases associated with rendering of medical assistance. Today, one of important problems of observance of epidemiological safety is insufficient diagnostics of cases of infections in patients and in medical personnel associated with rendering of medical care. Causative factors of such a situation include the absence of standard definitions of cases of infections associated with rendering of medical care, for the aims of epidemiological diagnosis; absence of software for epidemiological diagnostics; non-correspondence of the technology of the real epidemiological diagnostics to the standards developed in MO; understatement of the rate of incidents at the workplaces. The latter is one of the most serious problems of epidemiological safety in Russian healthcare requiring restructure of the current system through introduction of incidence rate into the operational management block of the InfoCenter.
Incident Rate at Workplaces

Medical personnel of any institution of healthcare system is exposed to increased risk of infections associated with rendering of medical care which many-fold rises in medical incidents. To predict the risk of professional infection of the personnel, it is necessary to take into account the situation with spread of infections in MO, the rate of incidents, their character and severity, the amount of the causative agent getting into the wound in case of injury, a probability of being infected with a particular infection [20,21].

In conditions of growing morbidity of the population with various blood-borne infections, primarily with HIV infection and viral hepatitis B and C, special attention is required to organization of measures to record all medical emergencies and off-nominal situations resulting from the activities of medical personnel under a high risk of infection [22,23]. In accordance with the requirements of SanPiN 2.1.3.2630-10 «Sanitary and epidemiological requirements to organizations engaged in medical activities», any patient, regardless of the history of infection, is considered a potential source of infection, which may result in infection of medical personnel [24].

According to various authors, the risk of professional infection with viral hepatitis of MO specialists is from 3 to 30% [24]. In the period between 2015 and 2017, cases of professional HIV infection of medical workers and suspicions of them were recorded in 21 constituent entities of the Russian Federation [24]. In conditions of MO, the probability of contracting HIV infection is highest in injuries with contaminated medical instruments, in particular, with hollow medical needles (the probability of infection is about 0.3% and depends on the time passed after the blood got on the instrument). When biological material containing a pathogen comes into contact with mucous membranes and damaged skin, the probability of infection is not more than 0.09%. That is why infection with HIV among medical workers, primarily nurses, most often occurs as a result of incidents [23].

E.V. Dubel, et al. (2017) give the results of analysis of 104 medical incidents in hospitals according to the record in the journals of incidents for 5 years [25]. The most part of incidents were associated with punctures (75.0%) or cuts (14.4%) of skin of hands with sharp medical instruments contaminated with patient’s blood. Here, each 5th case (22.1%) of incidents happened in injections and taking of blood. The cause of most part of incidents (65.4%, 95% confidence interval 56.1–74.6%) was neglect of safety rules by medical personnel in fulfilment of professional duties. A part of medical personnel (14.4%) did not use individual protection means, in particular, gloves and face screens protecting against sputtering of biological fluids in invasive interventions. Especially alarming is the fact identified during investigations of medical incidents that in many cases patients that were potential sources of infection were infected with viral hepatitis B (7.7%) and C (26.0%), HIV-infection (2.9%). Only 59% of patients had no infectious pathology. Here, incidence of viral hepatitis B among patients of a hospital in the studied period of time was 7.0 per 1000 patients, hepatitis C – 18.5 per 1000 patients, HIV-infection – 3.4 per 1000 patients. This evidences the fact that medical personnel concealed cases of medical incidents when the involved patients had no blood-borne infections in the history.

L.A. Dementyeva, et al. (2017) come to similar conclusions focusing on the absence of the actual control by managers of MO and epidemiological services of observance of the requirements of the normative documents including those on registration of the incidents, and of timely postcontact chemoprophylaxis of professional infection [23]. Besides, in
result of testing medical personnel, the author found unawareness of the personnel of regulatory protocol measures on registration of medical cases.

Z.P. Kalinina, et al. (2014), studying the question of blood-borne hepatitis in medical workers in hospitals of Saint-Petersburg found that from 2009 to 2013, the record of the rate of microtraumas of medical personnel with instruments containing biological materials of patients with viral hepatitis, increased by 11.4% and made 5.77 per 1000 of personnel [25]. The most common kinds of traumas were those received during removal of dropper bottles, opening of ampules (4.96 per 1000 personnel) which is associated, on one hand, with a large workload on the personnel and hurriedness in performing medical manipulations, on the other hand – with non-observance of safety rules and algorithms of manipulations.

It should be noted that in our country there exist a number of regulatory documents that strictly regulate the behavior of a medical worker in the event of an incident: sanitary and epidemiological rules SP 3.1.5.2826-10 «Prevention of HIV infection»; Sanitary and epidemiological rules and regulations SanPiN 2.1.3.2630-10 «Sanitary and epidemiological requirements to organizations engaged in medical activities»; sanitary and epidemiological rules SP 1.3.2322-08 «Safety of work with microorganisms of III-IV pathogenicity (danger) groups and pathogens of parasitic diseases»; Order of the Ministry of Health and Medical Industry of RF of August 16, 1994 №170 «On measures to improve prevention and treatment of HIV infection in the Russian Federation»; guidelines MI 3.1.3342-16 «Epidemiological surveillance of HIV infection». The examples and other numerous literature data mentioned in this review show that MO managers and responsible persons should organize an effective system for checking and maintaining competencies of all medical personnel in this issue. And the results of periodic inspections of the competencies of MO personnel should become one of the parameters of the operational management of the epidemiological safety of the information center.

According to position of WHO, not a single healthcare organization in any country can claim to be absolutely free from the risks of infringements of epidemiological safety [27]. At the same time, reduction of the total risk of infection of both patients and medical personnel is impossible without creation of clear, understandable and objective system of registration of incidents and of any other actions of increased risk of infringement of epidemiological safety. At present, both in the world practice and in our country, there exist practical recommendations with indication of criteria and parameters of epidemiological safety. However, in formation of the operational management block of the InfoCenter, each MO must take into account its own actual issues, problems and possibilities on the basis of the principles of lean production.

Conclusion

Introduction of criteria of epidemiological safety as a component of operating management block of InfoCenter of MO into practical activity forms functional, viable and constantly improving system of analysis of the activity of MO, of management of the processes of rendering of medical care to the population, standardization of invasive procedures taking into consideration epidemiological safety. InfoCenter as an instrument of lean production provides medical care to the population of the proper safety, and, on the other hand, visualizes problems, increases transparency and operational efficiency of making managerial decisions. For MO management, control of processes through SQDCM system permits timely prediction and control of different risks associated with epidemiological safety.
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