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## STANDARD OPERATING PROCEDURES AS A TREND IN ENSURING HEALTHCARE SAFETY

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*An analysis of healthcare safety indicators has shown that risks associated with providing healthcare which occur in medical organizations lead to additional economic and material losses, lower efficiency of government measures aimed at developing healthcare, and poorer public trust in a healthcare system. One of the basic reasons for this situation is the lack of proper regulation of the activities performed by medical organization personnel whose work is related to healthcare provision.*

*At present there is no scientific justification and procedures required to ensure the needed safety of patients and healthcare professionals are not established. Also, the functions of healthcare personnel related to ensuring healthcare safety have not been formalized and standardized, and also certain methodical ways of ensuring healthcare safety have not been established.*

*The regulation of certain recurring procedures, important for healthcare safety, is most efficiently provided through SOPs. The risk assessment methodology allows to identify the most important elements of the activities performed by the medical organization personnel, to develop and implement standard operating procedures the use of which increases healthcare safety.*

*The authors worked out basic principles (an algorithm) of standard operation procedures (SOP) development used to ensure safety in the field of healthcare which can be considered universal and can be applied at any healthcare organization. According to the mentioned principles and taking the relevance into account, the authors have described certain types of activities performed by healthcare personnel and developed standard operation procedures in the field of healthcare safety.*

*The research of SOP's implementation efficiency at core medical organizations is being performed at the moment.*

**Key words:** *healthcare safety, health risks assessment, standard operating procedures (SOP), healthcare system, regulation of the activities performed by medical organization personnel, risk assessment methodology, healthcare quality, prevention of adverse outcomes.*

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When we assess healthcare quality, we should pay attention not only to how efficient a certain medical intervention has turned out to be, but also to how safe it has been for a patient. Safety related to medical aid provision means that safe medical technologies and treatment procedures are applied; that patients' staying in a medical

organization is safe; and that they enjoy full mental and social comfort there.

Healthcare-related risks for patients, as well as for medical personnel in some cases, are risks of additional substantial economic expenses, material losses, lower efficiency of governmental activities aimed at healthcare development, and lack of

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trust which population have in a public healthcare system. Thus, as per our calculations, additional healthcare expenses related to patients being infected during their staying at in-patient departments amount to about 15% of the overall budget allocation on public healthcare in the RF; these data are quite similar to those obtained in other countries [1]. These are expenses which occur when a clinical course of a primary disease gets worse due to a secondary disease emergence during a patient's staying in a hospital and a consequent longer time which is needed for his or her recovery.

So, healthcare safety is prevention of unfavorable outcomes or harms during treatment or reduction of damage done in case of their occurrence. In order to avoid adverse consequences, we should determine risk factors, perform prevention activities, and assess their results.

It goes well in line with Donabedian's basic elements of healthcare quality provision (a so called Donabedian Model), namely development of structure, process (technology), and result [2]. And here all these elements are interrelated and interdependent.

Of course, we should take into account the fact that there are systematic reasons for insufficient healthcare safety. They are out-of-date regulatory and legal grounds which fix old-fashioned practices of medical activities and education of medical personnel; it is also scientific research which doesn't conform to international standards and is not based on clear and valid evidence; it is narrow specialization, and so on, and so forth [3,4].

A whole set of activities comprising organizational, technical, technological, and preventive ones is aimed at providing safety in medical organizations. And each administrative level in any medical organi-

zation has its own competences and responsibilities.

An up-to-date concept of a risk-oriented approach to analysis of risks which can occur in a medical organization, just as at any object in general, involves detecting threats to people's lives and health as well as those objects which generate risks of damages to life and health [5].

In case of a medical organization threats to life and health can be caused by its personnel as their occupational activities can exert direct, and sometimes even indirect, negative impacts on patients. Most frequently such actions are unintentional as they are caused by lack of knowledge and skills, or by absence of proper conditions for performing job tasks.

One of basic reasons for that is absence of proper regulations on functions which personnel of a medical organization have to perform when they deal with routine medical activities.

This reason has been mentioned by the WHO when its experts stated that inefficiency of medical activity was mostly determined by poor knowledge or improper application of clinical standards and protocols; by absence of guidelines and recommendations; by inadequate surveillance [6].

Nowadays, a great deal of work in healthcare is dedicated to development and implementation of standards on medical aid which are to be applied in case of certain diseases. More than 680 standards are in force now; they contain standard requirements to lists of diagnostic and treatment services, medications and medical appliances, blood preparations, and other components which are necessary for providing qualitative medical aid [7].

However, these documents don't include any requirements to activities aimed

at providing safety for patients who have to stay in a medical organization. In general, these documents, just as many other regulatory and legal acts which are related to medical organizations functioning, contain requirements to a way in which work of a medical institution is organized and medical activities are performed; these requirements can't be directly applied to a specific medical worker. Regulation of activities performed by personnel which is aimed at providing greater safety for patients calls for development of a specific document.

A discussion on this necessity to work out regulations (standardization) for certain routine procedures which are important for achieving a target result started some decades ago; it resulted in creation of a specific document, or Standard Operating Procedure (SOP). The term was first introduced in the middle of the 20th century [8].

A Standard Operating Procedure is a document which regulates activities performed by a specific worker and contains specific consequence of actions which are necessary to complete a specific task. A SOP is usually created in such cases when a routine (repeating) procedure should lead to a certain (known) result which is important for overall functioning of an organization.

SOPs became widely spread in various spheres such as industry, business, public administration, education, healthcare, etc. Of course, there are differences caused by a specific sphere where they are applied, but still, all the SOPs have a common structure, common chain

of actions which is necessary for completing a routine (repeating) procedure; this procedure, in its turn, is a component of the overall quality system [8].

SOPs fix a goal, outline a task, and determine who should do what, when and how. They contain the clearest possible description of action chains which should be completed. In order to achieve greater visualization and better understanding of actions described by a SOP it can contain figures, diagrams, tables, or photos.

SOPs are usually developed taking into account standard regulations which exist in a specific sphere and envisage procedures of objective control, both intermediate and final.

SOPs have the following advantages: they minimize probability of personnel not fully understanding their responsibilities, provide comparability and conformity with standard requirements.

SOPs were first developed and applied in healthcare less than 10 years ago. First of all, they were applied in pharmacy, where they became an integral part of quality management system as well as activities performed at laboratories and clinical departments [9–13].

In particular, the Order issued by the RF Public Healthcare Ministry on April 01, 2016 No. 199H "On Approval of Rules for Good Laboratory Practice"<sup>1</sup> states that proper quality of work is provided due to fixing standard operating procedures which contain detailed, profound, and consistent regulations on how to perform a preclinical examination or how to implement proce-

<sup>1</sup> Ob utverzhdenii Pravil nadlezhshchei laboratornoi praktiki: Prikaz Minzdrava Rossii №199n ot 01.04.2016 g. [On Approval of Rules for Good Laboratory Practice: The Order by the RF Public Healthcare Ministry issued on April 01, 2016. No. 199H]. Available at: <https://minjust.consultant.ru/documents/20332> (20.03.2018).

<sup>2</sup> MG 64-04-003-2002. Proizvodstvo lekarstvennykh sredstv. Dokumentatsiya. Obshchie trebovaniya. Primernye formy i rekomendatsii po ikh zapolneniyu: Rasporiazhenie Minpromnauki Rossii № R-16 ot 15.04.2003 g. [Manufacture of medications. Documents. Basic requirements. Model forms and recommendations on filling them in: the Order issued by the RF Ministry for Industry and Science on April 15, 2003 No. P-16]. Available at: <http://base.garant.ru/6147324/> (20.03.2018).

dures which are not described in detail in an examination report. Standard operating procedures regulate a) samples arrival, identification, marking, processing, and taking, application, storage, destruction, and utilization of examined substances, medications, and reference samples; b) maintenance and calibration of measurement instruments and equipment; c) preparation of reagents, nutrient media, and feedstuffs; d) maintenance of rooms where research is performed; e) receipt, transportation, storage, description, and identification of examined substances and test-systems; f) filling in a research report [14].

Methodical guidelines MG 64-04-003-2002 "Manufacture of medications. Documents. Basic requirements. Model forms and recommendations on filling them in"<sup>2</sup>, approved by the Order issued by the RF Ministry for Industry and Science on April 15, 2003 No. P-16 enlist SOPs among basic documents necessary for enterprises which manufacture medications.

All medical organizations, regardless of their departmental subordination and legal form, are to implement SOPs in their activities. These SOPs should describe quality management systems, production processes, packing and receipt of primary raw materials, auxiliary, packaging and printing materials, sampling procedures, and quality control performance. And here a SOP is a unified detailed printed instruction related to standard actions or operations performed at an enterprise [15].

Importance of SOPs development is also highlighted in documents which set forth requirements to GCP or Good Clinical Practice. It is determined by a desire to achieve greatest possible validity of obtained information via its unification and formalization.

Thus, in December 2004 experts from the RF Ministry for Public Healthcare

and Social Development introduced a program for additional pharmaceutical provision for specific population categories (so called cash-for-benefits welfare reform) and stated that SOPs would be applied together with orders and methodical guidelines to fix procedures for distribution of medications, responses to conflict situations, and other rules of additional pharmaceutical provision. Unfortunately, it was absence of clear and precise mechanisms of implementation, SOPs included, which caused a lot of problems when the program was implemented in Russia [16].

SOPs are not so widely spread either in domestic or foreign clinical practices as they really should be.

Foreign literature contains data on certain examples of SOPs implementation and application in clinical practices. It is shown that when they are applied, it allows to decrease a number of medical errors in diagnostics, to reveal risk factors for patients, to detect patients who are prone to suicide etc. However, these examples are only isolated cases, and there is no systemic work in the sphere [9,11,13,17–19].

"Practical recommendations on how to organize internal quality control and safety of medical activities in a medical organization" developed by Rospotrebnadzor's Center for Monitoring and Clinical-Economic Examinations is a good step towards determining methodical approaches to creation and assessment of parameters within a system of internal control over healthcare safety. This document spots out basic tasks which are to be solved if we want to provide quality and safety of medical activities; it also determined what parameters should be assessed (for example, if there are algorithms which describe how to take sample materials for microbiological examination), how they should be assessed (whether there are algorithms in all

divisions, personnel are aware of them and follow them properly etc.). However, the document doesn't determine a methodological procedure for creation of such algorithms and it makes development of regulations (SOPs) more difficult. The only hint is that they are assumed to be created by personnel employed at medical organizations in full conformity with peculiarities of this or that institution [20].

So, up to now, procedures which can provide proper safety of patients and personnel at medical organizations haven't been scientifically grounded and developed; functions performed by personnel at medical organizations and aimed at providing healthcare safety haven't been formalized and standardized; specific methodical techniques for providing healthcare safety haven't been determined.

We developed basic principles (algorithms) for creating standard operating procedures (SOPs) which regulate provision of healthcare safety; these SOPs are basic and universal and can be applied in any medical organization. Thus, any SOP should contain the following:

- ◆ purpose: what specific activities (procedures, manipulations) are regulated by this SOP;

- ◆ application sphere: what enterprises (organizations) or structural departments this SOP should be applied at;

- ◆ regulatory references: a list of documents which regulate activities in the sphere this SOP is related to;

- ◆ terms and symbols: a conceptual apparatus and expansion of abbreviations which are used in this SOP;

- ◆ responsibilities assignment: a list of workers who are responsible for control over conforming to SOP requirements and for medical personnel training aimed at creating awareness about rules fixed in this SOP;

- ◆ logistics and technical support: a list of equipment and materials which are necessary to conform to SOP requirements;

- ◆ procedure: a SOP should explain what purposes regulated procedures have and what conditions are necessary to provide their successful implementation and achievement of target results;

- ◆ training for personnel: a SOP should regulate staff training and practical skills development in relevant spheres and determine a person who is responsible for this training and certification of personnel (assessment of their knowledge and skills);

- ◆ assessment of efficiency: parameters which characterize aspects a SOP is concentrated on should be monitored;

- ◆ visual information: relevant instructions, posters, and methodical materials are to be created;

- ◆ statistical forms and supplements: there should be a list of obligatory relevant statistical forms which are included into a SOP and applied when monitoring is performed, records on personnel certification, and supplements which explain how to conform to proper consequence of relevant manipulations.

So, this developed algorithm for SOP creation includes all the necessary aspects which can give answers to the most important questions related to providing qualitative healthcare: How to do it right? When? Where? and Who should do it? If a SOP is implemented, what will be the results?

With all the above-mentioned principles taken into account and bearing healthcare safety in mind, we selected certain activities performed by medical personnel and developed standard operating procedures for them [21–30].

A SOP named "Receipt and distribution of disinfectants to departments at a medical organization in order to support

their activities" was created in the sphere of providing overall structural safety.

A SOP named "Disinfection-related activities. Training for medical personnel" was created in the sphere of providing healthcare technological safety.

A SOP named "A procedure regulating hygienic treatment of hands and application of medical gloves to prevent infections related to medical aid provision" was created to ensure safety of treatment results.

All the above-mentioned SOPs are now being implemented in several clinical centers in Moscow.

To assess whether the SOP "A procedure regulating hygienic treatment of hands and application of medical gloves to prevent infections related to medical aid provision" was implemented efficiently, we performed a comparative analysis with its purpose being to reveal how requirements to hygienic treatment of hands and application of medical gloves were met in our core medical organizations before the SOP was implemented and after its implementation.

Knowledge and skills which medical personnel had were evaluated by experts in real time mode; we then performed a comparative analysis of the evaluation results.

We processed 875 questionnaires for personnel which were specially designed for this research; 492 questionnaires for patients; we also conducted 104 interviews with medical organizations supervisors and heads of various departments and then processed the results.

Efficiency of SOP implementation was assessed by experts, senior nurses at various departments; they assessed efficiency of their activities before it was implemented and after it. Overall, we had 600 inspections, 300 in 2016 before the SOP

was implemented, and 300 in 2017 after its implementation in the core medical organizations.

Results of the comparative analysis revealed that after the SOP was implemented there was a substantial increase in an integral parameter which characterized average level of medical personnel conforming to the rules for hygienic treatment of hands and application of medical gloves in all the structural departments at the core medical organizations. Overall average level also grew from 42.0% before SOP implementation to 57.3% after it.

We intend to continue our research on how efficiently SOPs are being implemented in the core medical organizations.

But at the same time our experience proves that successful implementation of SOPs and, consequently, expected positive results to a great extent depend on how well supervisors and personnel at medical organizations realize the necessity to apply SOPs. Preliminary work is required here, both workshops for personnel and individual conversations with supervisors.

Therefore, the results of the performed comparative analysis allow us to state that SOP implementation undoubtedly had a positive effect on medical personnel compliance with requirements for hygienic treatment of hands and application of medical gloves. Consequently, SOP is an efficient tool for improving quality and providing greater healthcare safety and its implementation into routine practices at other medical organizations is appropriate and meets up-to-date requirements.

Standard operating procedures should be revised taking into account the latest requirements, technical possibilities, and technological and scientific achievements.

We think that SOPs creation and implementation aimed at providing

healthcare safety should be systematic as only systematic work can ensure achievement of target results at all management levels.

SOPs should be created for all the organizations in the healthcare system: starting from federal and regional management authorities and up to a specific medical organization and its personnel. If standards operating procedures are clear, unambiguous, and meet all the require-

ments of up-to-date medical theory and practices, then their creation and all-round application can truly become an effective instrument in the system of healthcare quality management.

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