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Multifactorial model of adverse events and medical safety management

Yury Voskanyan[1[0000-0003-2962-2818]], Irina Shikina[2,3[0000-0003-1744-9528]], Olga Andreeva[2,4[0000-0003-0838-286X]], Fedor Kidalov[5[0000-0003-4914-8164]], David Davidov[2[0000-0003-4576-6854]]

[1] Russian Medical Academy of Continuing Professional Education of the Ministry of Health of Russia, Moscow, Russia, 125993
[2] Central Research Institute for Organization and Informatization of Medical care at the Ministry of Health of Russia, Moscow, Russia, 127254
[3] Central State Medical Academy Office of the President of the Russian Federation, Moscow, Russia, 121359
[4] National Research University Higher School of Economics, Moscow, Russia
[5] State Government Institution of Moscow City «Informational-Analytical Center for medical care», Moscow, Russia, 107078

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Abstract. The article describes a multifactorial model of adverse events related to the provision of medical care. It is shown that their origin is caused by the transformation of systemic causes (latent failures) acting at the level of medical organization, external microenvironment and macro-factors. Four types of global latent failures are described at the level of a medical organization related to: medical technology, work of medical personnel, work environment, and patient behavior. At the external microenvironment level, major latent threats are concentrated at the level of partners, suppliers and outsourcers. Among macro-factors influencing medical care safety especially important are the legal factors defining the status of medical errors and their consequences; economic model of state health care; financial provision of state guarantees and rationing of these volumes in regions and municipalities; availability of state medical care safety management programs; state regulation of medical activity; system of pre- and post-graduate medical education; system of labor regulation and remuneration of medical workers; society's attitude towards medical errors and its participation in the process of medical care safety management. The authors present an algorithm for implementation of a safety management system in a medical organization, including the construction of a new safety culture, an accounting system for recording of threats and incidents, a model for managing medical care safety built into the operational system of the organization.

Keywords: medical care safety, adverse events, incident, medical care safety management system.

1. Introduction

Safety, along with the effectiveness, efficacy and accessibility is an important attribute of the medical care quality. The term safety is directly linked to the risk of harm in medical care provision or development of an adverse event. We defined adverse events as unintentional physical or psychological trauma resulting in temporary

or permanent disability, death, extended hospital stays which is most likely related to medical care rather than the course of the main disease or concomitant diseases [1].

2. Data and Methodology

The work presents a clinical review and its own analytical study. Information was searched independently by three researchers over the period 1990-2019 using medical databases MEDLINE, Cochrane Collaboration, EMBASE, SCOPUS, ISI Web of Science. Prospective and retrospective observation studies of high methodological quality were used for the analysis.

3. Literature review

In Table 1, data on incidence of adverse events in inpatient care in high-income countries over the past 30 years is shown.

Table 1. Incidence of adverse events in inpatient care

Author, year of publication	Country	Number of hospitals	Number of observations	Incidence % (95%CI)
Retrospective studies				
Brennan T. et al., 1991[2]	USA (Harvard)	51	30 195	3,7 (3,5-3,9)
Wilson R. et al., 1995 [3]	Australia	28	14 210	16,6 (15,9-17,2)
Thomas E. et al., 2000 [4]	USA (Utah, Colorado)	28	14 565	5,4 (5,0-5,8)
Vincent C. et al., 2001 [5]	United Kingdom	2	1 014	10,8 (8,9-12,8)
Schioler T. et al., 2001 [6]	Denmark	17	1 097	10,4 (8,6-12,2)
Davis P. et al., 2002 [7]	New Zealand	13	6 579	12,9 (12,1-13,7)
Baker G. et al., 2004 [8]	Canada	20	3 745	6,8 (6,0-7,6)
Michel Ph., 2007 [9]	France	71	8 754	6,6 (6,1-7,1)
Zegers M. et al., 2009 [1]	Netherlands	21	7 926	8,4 (7,8-9,0)
Aranaz-Andres J. et al.,2009 [10]	Spain	24	5 624	9,3 (8,6-10,1)
Shoop M. et al., 2009 [11]	Sweden	28	1 967	12,3(10,8-13,8)
Landrigan C. et al., 2010 [12]	USA (North Carolina)	10	2 341	18,1 (16,5-19,6)
Aranaz-Andres J. et al., 2011 [13]	Argentina,Mexico, Colombia, Peru, Costa Rica	58	11 379	10,5 (9,9-11,0)
D'Amour D. et al., 2014 [14]	Canada	11	2 699	15,3 (13,9-16,7)
Somaella L. et al., 2014 [15]	Italy	1	1 380	3,3 (2,5-4,4)
Deilkas E. et al., 2015 [16]	Norway	20	40 581	14,6 (14,3-15,0)
Nilson L. et al., 2016 [17]	Sweden	7	3 301	15,4 (14,1-16,6)
Halfon P. et al., 2017 [18]	Switzerland	1	1 007	12,6 (10,6-14,8)
Rafter N. et al., 2017 [19]	Ireland	8	1 574	12,2 (10,6-13,9)
Prospective studies				
Andrews L. et al., 1997 [20]	Spain	3	1 047	17,7 (15,4-20,0)
Wanzel K. et al., 2000 [21]	Canada	1	192	39,1 (32,2-46,0)
Rebasa P. et al., 2011 [22]	Spain	1	13 950	37,8 (37,0-38,7)
Forster A. et al., 2019 [23]	Canada	5	1 159	22,2 (19,8-24,7)
Atkinson M. et al., 2019 [24]	USA (California)	1	1 423	4,1 (3,1-5,2)
Meta-analysis	-	430	177 709	12,7 (12,6-12,9)

More than 15% of adverse events are severe or fatal (Table 2).

Table 2. Severity of harm in case of an adverse event

Source	Number of adverse events	Severity of harm			
		Severe harm and disability		Death	
		Number	Percentage % (95% CI*)	Number	Percentage % (95% CI)
Wilson R.et al., 1995 [3]	2 324	315	13,7 (12,3-15,1)	112	4,9 (4,0-5,8)
Thomas E. et al., 2000[4]	787	130	16,6 (13,9-19,1)	52	6,6 (4,9-8,3)
Wanzel K.et al., 2000 [21]	144	10	6,9 (2,8-11,1)	2	1,4 (0,5-3,3)
Vincent C.et al, 2001[5]	110	7	6,4 (1,8-10,9)	9	8,2 (3,1-13,3)
Davis P. et al., 2003 [7]	850	87	10,2 (8,2-12,3)	38	4,5 (3,1-5,9)
Baker G. et al., 2004 [8]	289	15	5,2 (2,9-8,4)	46	15,9 (11,7-20,1)
Andrews J. et al., 2006 [22]	655	90	13,7 (11,1-16,4)	15	2,3 (1,1-3,4)
Zegers M. et al., 2009 [1]	663	33	5,0 (3,3-6,6)	52	7,8 (5,8-9,9)
Landrigan C. et al., 2010[25]	588	67	11,4 (8,8-14,0)	14	2,4 (1,1-3,6)
Meta-analysis	6 388	754	11,8 (11,0-12,6)	340	5, 3 (4,8-5,9)

The scientists at the Johns Hopkins Clinic [26] showed that adverse events related to medical care provision account for every tenth death in population, ranking at third place for causes of mortality amongst the causes of death in the U.S. population, after cardiovascular disease and neoplasms.

Additional direct and indirect costs associated with the diagnosis and treatment of one patient with an adverse event are on average USD 13,019 [27,28]. Thus, adverse events in medicine are not casuistic and represent one of the main problems in health care systems today. When comparing the probability of death in air travel (1 death per 5 million passengers transported) and the probability of death from medical complications (1 death per 140 hospitalized), it is easy to see that civil aviation safety is more than 30,000 times greater than that of health care. All of the above confirms the fact that modern health care should be classified as an unsafe area of services, and the management of health care safety should be integrated into the management systems of the entire medical industry, as well as into the management systems of each medical organization [29].

Understanding of the medical care safety concept and how the global causes of adverse events develop should form the basis for building health care safety management systems. From our point of view, most definitions of health care safety are not specific and sometimes even based on the assumption that it is possible to completely exclude the possibility of adverse events. In our opinion, this is wrong, because even in the best clinics in the world, including those with sufficiently effective safety management systems, adverse events continue to occur, even in the form of the most incredible accidents. In 2015 scientists from Mayo Clinic [30] showed that of the 1.5 million operations and interventions performed between 2009 and 2014, there were 69 incidents that were attributed to unlikely events (no events), of which 24 (34,8%) - wrong procedure, 21 (30,4%) - wrong side/site surgery, 19 (27,5%) - forgotten instruments and materials (foreign object post procedure), 5 (7,2%) - wrong implant/prosthesis.

In addition harm may be caused not only to the patient but also to the personnel of the medical organization itself (e.g. a biological accident), to the work environment (e.g. chemical contamination, delocalization of medical waste), and to the environment (e.g. chemical and biological contamination) during provision medical care provision. Finally, medical care safety assessment makes sense only in terms of obtained benefits or favourable targeted clinical outcome.

Interaction of the medical organization with the external microenvironment (suppliers, partners, outsourcers) and macro-factors (political, legal, economic, social, technological, environmental) is another important issue to ensure medical care

safety. Political factors (volume of state guarantees), legal factors (quality of state regulation of the industry and legal consequences of medical errors), economic factors (economic model of health care), technological factors (system of pre- and post-graduate medical education, quality of research and development, total technological infrastructure, including information technologies) have the greatest influence on medical care safety. Based on the above, in our opinion, the most correct way to define "medical care safety" is the ratio of benefit and harm to the patient, taking into account the risk of adverse events in the personnel and the risk of unfavourable changes in production and environment. This balance is created by optimal interaction of the safety management systems of the medical organization, the external microenvironment and macro factors.

Construction of a safety management system in a medical organization, apart from precise definition, requires adherence to a model that describes the mechanism of adverse event development, which is called a safety model. The modern safety model is based on two assumptions [31]:

existence of multiple non-linear relationships between probability of incident and severity of harm in the organization;

high proportion of uncertainty in prediction of adverse events development and the consequences of the interventions to prevent these events.

The basic or systematic causes (main causes) are the so-called latent (hidden) failures or latent conditions. These failures are not directly related to an adverse event, are characterized by relative constancy and do not carry any danger if they are dormant [31,32,33]. Under certain conditions, latent failures become an vulnerability. As an example, let's consider such latent failure as coincidence of two patients with the same personal data (first and last names). It will only become a vulnerability if these patients are hospitalized in the same ward, or if they are together in front of the same outpatient doctor's office. Vulnerability further develops into active threat (by interacting with medical personnel, patients, and defense systems): personnel errors and violation (e.g. choice of the wrong patient for intervention), unsafe patient behaviour (e.g. tripping and slipping) or unsafe processes in the environment where medical care is provided (e.g. non-sealed container with aggressive acids). The outcome of the active threat is a dangerous event or incident (e.g. a medical intervention performed on the wrong patient; crash, fall). The incident that does not end with harm is called an incident without sequelae – near miss (e.g. a fall without injury). The incident that caused harm is referred to as an accident or an adverse event (e.g. a threatening rhythm disturbance following amiodarone injection to the wrong patient). The incident that ended in death is called a critical incident. The multiple non-linear safety model assumes that the vast majority of the incidents are the result of a transformation of many latent failures, among which two groups should be distinguished: root and contextual. Root latent failures transformation ends in an incident, and context latent failures transformation removes barriers to root failures transformation. The model's non-linearity also implies that the magnitude (strength) of the active threats not proportional to the severity of the resulting incident (e.g. a high degree of patient's walking impairment at risk of falling may be accompanied by minor injury, and vice versa) [34,35,36].

All latent failures are divided into two large groups: global (that are present regardless of the site of medical care provision and its profile) and specific (caused by the specific site of medical care provision and its profile). There are four levels of latent failures within each of these groups; each of them could be a source of an incident: level of medical technology, level of personnel, level of environment in which medical care is provided and the level of the patient. [33,36, 38,39,40,41,42].

The safety medical care management system in a medical organization should include a new safety culture, an accounting system for recording failures, threats and

incidents, a model of medical care safety management embedded in the main operational function and a mandatory part of the technological process.

A new safety culture, as part of the corporate culture, implies a change in the key paradigm and is based on the main assumption that harm caused in the process of medical care provision is not related to the final care providers, but to a multitude of systematic threats, without management of which it is impossible to significantly influence the frequency and severity of adverse events [31,35,36,37,38]. Several questionnaires with certain limitations and disadvantages have been proposed to assess the safety culture in a medical organization [43,44].

The accounting system of recording failures, threats and incidents includes 5 directions: continuous data and information collection; processing and verification of failures, threats and incidents (based on a higher probability of connection with medical care processes); registration of failures, threats and incidents (on a material carrier); measurement of failures, threats and incidents (analysis of frequency and severity of 100% of incidents during a certain period) monitoring of failures, threats and incidents (repeated measurements at specified intervals). In the process of health care system registration in many countries the letter coding of threats and incidents is used, as proposed by the U.S. National Coordinating Council for Registration and Prevention of Medical Errors - NCC MERP, 1998-2001 [34,36,45,46]. Qualitative and objective reporting and accounting of failures, vulnerabilities, threats and incidents is one of the main elements of the health care safety management system, without which all follow-up activities are meaningless. The most frequent problems in failures, threats and incidents report and account are reception of poor-quality data and the information, masking of incidents (ignoring their connection with process of rendering of medical care provision), concealment of incidents (absence of registration of verified incidents), false optimization of measurement (analysis and estimation with exception of critical and severe incidents). We want to underline that in countries with practice of prosecution for medical errors, and also in the organizations where there is no transparent climate in relation to incidents originator, overcoming the described problems is impossible; therefore, construction of a control system of safety will have exclusively declarative character. Reliable sources should be used to obtain quality data and information in other cases. From this point of view, we would like to distinguish two groups of sources: with high and low dependence on care provider (Table 3).

It is quite obvious that at the first stage the main role in obtaining reliable data and reliable information will belong to sources with low dependence on the performer. When a high level of safety culture is achieved, sources with high dependency on the performer begin to prevail. Rather important direction to improve quality of received information is the use of encouragement procedure of personnel for verification and registration of threats and incidents at first stages [33,34,36,38,41].

Table 3. Sources of Data and Information

With high dependency on care provider		**With low dependency on care providers**	
Source	Method of obtaining data and information	Source	Method of obtaining data and information
Personnel	Voluntary communication Voluntary reporting	Auditor	Direct control of staff actions and medical records Analysis of ratio incidents of various severity
Medical records	Retrospective analysis Prospective analysis	Patient	Interview with family Complaints from patients and their families
Colleague	Cross-Control	Automated control systems	Automation of error accounting Automation of complaint recording
Official (mandatory) reporting	Analysis of integral indicators (lethality, complications, etc.)	Official (mandatory) reporting	Cross-analysis of integral indicators dynamics (mortality and complications dynamics)

		Global Trigger Tool	Atypical event analysis Atypical death analysis Atypical complications analysis Atypical patient behavior analysis

In recent years, an increasing number of medical organizations have begun using the methodology for evaluating Global Trigger Tool include atypical treatment abnormalities, atypical deaths, atypical complications given the nature of the disease and used medical technology, and atypical behaviors. For example, unplanned return of a patient to the operating room within 30 days of surgery is usually associated with development of a postoperative complication; prolonged antibiotic treatment after a planned abdominal surgery is usually associated with medication-associated infections; neurological deficits in a patient after a planned cholecystectomy followed by transportation home in a wheelchair are usually associated with medication-associated complications [1,47,48,49].

The health care safety management model provides for management of latent failures transformation in order to reduce the probability of an incident and severity of harm. The tool of this model is risk management in medicine. By risk we will mean multiplying the probability of an incident by the severity of its consequences [50,51,52]. Risk management includes incident analysis; incident risk assessment; developing a risk response plan; plan execution, performance and efficiency assessment; standardization of plan's activities; monitoring residual and emerging risks.

Incident analysis involves identifying latent failures and constructing a root latent failures transformation route. For this purpose, it is most convenient to use the Ishikawa chart at all levels (technology, personnel, environment, and patient) described above, which easily identifies root and contextual latent threats.

Confidence that the final failure latent rather than active threat is usually given by the 5-6 level of fork (Figure 1).

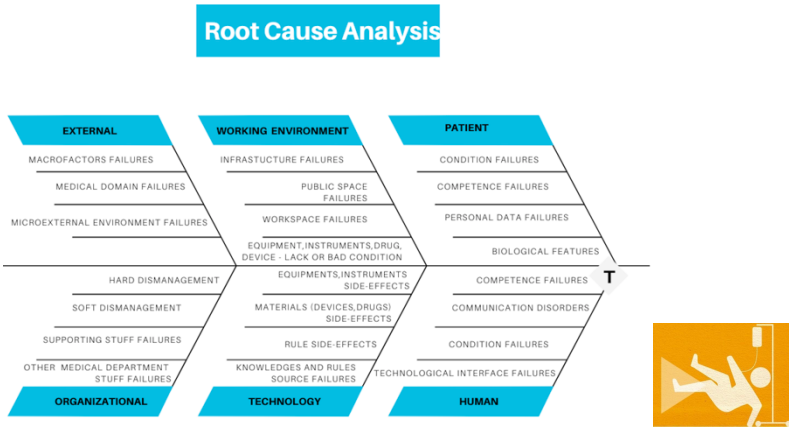

Fig. 1. Incidence analysis (World Health Organization (WHO) patient safety curriculum guide: WHO multi-professional edition. 2011)

In order to assess magnitude of incident risk, we need to bring the severity and likelihood of the incident to the expert grade scale. For this purpose, scales proposed by experts from the UK National Health System (NHS Commissioning Board Authority) are usually used. To estimate severity and probability, 5-point scales are used [50]. It should be noted that all incidents listed on the NQF list (No events) should be classified as large incidents, regardless of the severity of caused harm [53]. Thermal

risk scale is used to assess the amount of risk. Risks entering the red zone are classified as extremely dangerous (Score 15-25), those entering the orange zone as dangerous (Score 8-12), those entering the yellow zone as moderately dangerous (Score 4-6) and those entering the green zone as non-dangerous (Score 1-3). The risk response plan includes 5 key sections (Table 4).

Table 4. Risk response plan (based on [50])

Medical care provided by the riskowner	Response method	Risk management area	Resources for risk management	Residual risk level
-continues -ends	-risk accepted -risk minimized -risk eliminated -risk is avoided	-risk owner -other departments -medical organization -health care authority	-people -finance -material -inventories -info	Risk value determined by the risk management committee in a medical organization

Features of response plan depending on the risk value are given in Table 5.

Table 5. Risk Response Plan for different sizes (based on [50])

Risk value	Medical care	Risk management area	Monitoring	Risk response
Low	continues	Risk owner	every six months	accepted
Moderate	continues	Risk owner	quarterly	minimize, eliminated
Significant	continues	risk owner other departments organisation management	monthly (if they score 10 or more); bi-monthly (if they score below 10)	minimized, eliminated
Extreme	continues	-risk owner -other departments -organizational management -health care authority	monthly	avoided, minimized

Risk minimization or elimination is determined by the possibility to influence the root latent failures. If the root latent failures are completely eliminated, the residual risk value is 0. The majority of latent failures cannot be completely eliminated, therefore, in this case, it is possible to speak only about minimization of risk influence by formation of procedural and physical barriers to transformation of root and all contextual latent failures. The Risk Management Committee of a medical organization determines a target indicator - an acceptable residual risk level that in most cases corresponds to green or yellow risk level areas [54,55,56]. Residual risk will never be acceptable in the case of a law violation, or if there is a probability of death or disability more than 80%, in case of damages resulting in a critical decrease of the medical organization assets.

Implementation of the plan envisages practical application of influence methods on transformation of latent failures. The sequence of actions used in the plan is standardized and becomes the procedural norm for the risk owner and other units after efficiency and effectiveness evaluation.

Reaching the residual risk level takes risk management to the next stage - monitoring residual and new risks. New risks always appear when new medical technologies are introduced, new medical devices (including equipment) and new pharmaceuticals appear, new employees are hired, large changes in the work environment where medical care is provided (repair, reconstruction, redevelopment), changes in legislation, organizational changes are made.

4. Results

The changes described above can be considered organizational changes that involve a deep transformation of strategy, corporate culture, and operating model. It is a movement to safety from the inside. Unfortunately, outside movement is also needed, transformation of the microenvironment and macro factors that allow for the successful implementation of internal changes. As for the microenvironment (suppliers, partners, and outsourcers), an alliance of the right relationships can and should be built by the medical organization itself. Above all, it is a choice of partners who could ensure continuous quality and safe medical cycle for the patient. It is better if these partners make a similar transformation in their organization. Secondly, they are suppliers of equipment, consumable medical devices, pharmaceuticals, and disinfectants. An uninterrupted supply chain of inventories and services should be created and automated to ensure uninterrupted supply, as well as a system of transparent control by the medical organization of legality, goods quality and transportation conditions. The second group of suppliers is suppliers of network resources (water, heat, electricity, sewerage, water supply, low-power resources) with whom contractual relations and any other interaction should have a long-term nature and provide for minimization of risks of network failures (maximum protection, duplication of networks, etc.). Outsourcing activities (cleaning, laundry washing, catering, waste disposal, security, etc.) should be built into the operating system of the medical organization, comply with established safety requirements. Outsourcing process itself, its intermediate and final results should be controlled by responsible persons from the medical organization.

It is much more complicated in terms of macro factors. The main condition for success is state and society obsession with quality and safe health care [57,58,59,61,62]. Relationship between patient, his or her family members and health care workers must be transformed from antagonism into a cooperative relationship at the society level. Society must be aware of high risk of complications associated with medical care, understand the root cause and negative consequences of sanctions by the patient's relatives against medical professionals. By gaining access to their medical history, the patient and their family members should become partners in medical care safety management system, taking part in the control of processes involving the patient, in discussions on the development of effective solutions concerning the identification of errors, incidents, and management of latent failures, especially in terms of failures related to patient behavior [63,64,65,66].

5. Conclusion

The concept of medical care safety is much broader than the absence or minimization of unintentional harm to the patient. Medical care safety should be considered as a dynamic property of a medical organization in the process of interaction of its internal environment with external microenvironment and macro-factors. One the one hand, a medical organization can be a source of adverse events for both patient and staff, as well as for the environment. On the other hand, safety within a medical organization is affected to an equal extent by the state and changes of external environment. This explains the fact that medical care safety management solely at the hospital level (even an expert hospital - a referral center) often fails to deliver the expected success that would have seemed to be guaranteed by a new culture, new solutions and practices, impeccable infrastructure and state-of-the-art technological approaches. Unfortunately, the organic dependence such of a complex system as a medical organization on external and internal disturbances necessitates a vertically integrated approach to managing the risks of adverse events at the level of the state, society and entire health care system.

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Aims and Objectives
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Contact information

Website: https://ics.events

Email: conf@ics.events