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Research Article

Assessment of Modern Health Care Opportunities in Management of Medical Care Safety

Yuriy Voskanyan[1], Irina Shikina[2,3]*, Fedor Kidalov[4] and David Davidov[2]

[1]*Russian Medical Academy of Continuing Professional Education of the Ministry of Health of Russia, Moscow, Russia*

[2]*Central Research Institute for Organization and Informatization of Medical care at the Ministry of Health of Russia, Moscow, Russia*

[3]*Central State Medical Academy Office of the President of the Russian Federation, Moscow, Russia*

[4]*State Government Institution of Moscow City "Informational-Analytical Center for medical care, Moscow, Russia*

***Corresponding Author:** Irina Shikina, Central Research Institute for Organization and Informatization of Medical care at the Ministry of Health of Russia, Moscow, Russia.

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Yuriy Voskanyan Orcid ID: https://orcid.org/0000-0003-2962-2818

Irina Shikina Orcid ID: http://orcid.org/0000-0003-1744-9528

Fedor Kidalov Orcid ID: http://orcid.org/0000-0003-4914-8164

David Davidov Orcid ID: https://orcid.org/0000-0003-4576-6854

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Abstract

In the article the system reasons of adverse events in modern health care (latent threats) are taken into account, key approaches to management of medical care safety. The authors understand them as the relation of chances of advantage and harm for the patient taking into account risk of adverse events at personnel and risk of adverse changes of the production and external environment are offered are considered. In the developed countries the additional harm connected with health care delivery is registered at 10.6% of the hospitalized patients and less than in 50% of cases belongs to preventable harm category caused by medical mistakes. In other cases its emergence caused by patient behavior, influence of the production environment, imperfection of medical technologies and corporate management systems. In structure of the reasons of hospital lethality the share of the harm connected with health care delivery is 24.9%. Effective management of medical care safety is possible only with interaction of four subjects: government (recognition at the legislative level of the fact of inevitability of medical mistakes taking into account their system reasons, a guarantee of rights and freedoms to medical personnel at registration of adverse events, formalization of the rights, duties and responsibility of the patient, definition of health care as services sectors of high risk, financing of the additional actions connected with safety management), governing bodies of health care (development and implementation of government programs in the field of safety management of medical care), societies (participation in a discussion, adoption of declarations, development of regulations, partnership at delivery of health care) and the most medical organization. The modern strategy of safety management of medical care in the medical organization includes formation of a new safety culture (as element of corporate culture), introduction of accounting system of threats of incidents, and risks, creation of a control system of safety on the basis of risk stratification of incidents.

Keywords: Medical Care Safety; Latent Threats; Medical Mistakes, Adverse Events

Introduction

International studies in the field of medical care safety demonstrate the special role of medical errors and related adverse events, as well as unexpected deaths in the structure of hospital mortality and population mortality in developed countries. The key issues in additional harm risk management include definition of the essence of medical care safety, assessment of the problem severity, identification of systemic reasons for adverse events, formation of a new culture of safety, development, implementation and standardization of effective solutions taking into account the probability of incidents in medicine and the severity of their consequences [1,2].

The authors have formulated a new approach to the definition of the term "medical care safety"; the epidemiology of medical care-related events have been studied and the basic principles of modern strategy of adverse event risk management in medicine have been formulated. Adverse events included unintentional physical or psychological trauma (additional harm), which was most likely related to medical care rather than the course of the main disease or concomitant diseases [3-6]. Information search was carried out by two researchers independently over a period of 1990 - 2017 using medical databases MEDLINE, Cochrane Collaboration; EMBASE, SCOPUS, ISI Web of Science. For the analysis, prospective and retrospective observational studies of high methodological quality were used, which presented data on the frequency and severity of adverse events in multispecialty short-stay hospitals. The frequency of new cases of adverse events (incidence) as well as the percentages of adverse events are shown together with confidence intervals at the 95% probability of accepting the null hypothesis. Published source data pooling was carried out in a meta-analysis, the mathematical model of which was determined depending on the statistical heterogeneity index I^2. In similar studies, the main principles of medical care management were evaluated. The authors necessarily took into account the relation between the principles used and the possibility of managing the systemic causes of additional harm.

Result and Discussion

Safety, along with clinical effectiveness and economic efficacy, is an important attribute of the medical care quality. However, it is necessary to strictly define the limits of this term. The majority of definitions (US Institute of Medicine, US Agency for Healthcare Research and Quality, World Health Organization etc.) connect the term of safety with the lack of unnecessary harm, minimization of its probability, or with the lack of unnecessary risk of adverse events [1]. All such definitions raise new questions related to the need to interpret such concepts as "unnecessary harm", "unnecessary risk", etc. However, most importantly, none of these definitions can quantitatively assess the degree of safety, which makes the management of adverse events difficult to implement. We believe that the medical care safety can be defined as the benefit/risk ratio when providing medical care. The mathematical expression of the harm will be its risk, which is the product of probability of an adverse event by the severity of its consequences. The mathematical expression of the benefit will be the probability of a planned favorable clinical outcome in the absence of the risk of additional harm. Without going into details of mathematical calculations using the values of the probability and rank coefficients of the assessment of the harm severity and the grade of the benefit, we will pay attention only to the fact that, from our point of view, it is not correct to eliminate reasonable risk of the concept "medical care safety". After all, is there any difference for the patient why he/she got hurt rather than benefited from medical interventions in which there was a reasonable risk? It was the disagreement of scientists with this "reasonable risk" that led to the rapid development of medical technologies, including surgery and drug therapy, which significantly reduced the amount of "reasonable risk" and significantly expanded the scope of their application in the target patient cohort. Next, it should be emphasized that the medical care safety is a complex concept that includes four components depending on the object of the potential risk of harm: patient's safety (unintentional physical and/or psychological trauma), staff safety (biological accidents, radiation exposure etc.), internal environment safety (high level of physical factors, pollution, state of the building and engineering systems etc.), safety of the environment (the impact of physical factors, chemical pollution etc.). This is what distinguishes safety in medicine from safety in other areas of economic activity where there are only three components (personnel, internal or external environment). Therefore, we suggest defining the term "medical care safety" as the ratio of the benefit for the patients and the risk of harm to the patient and medical staff, as well as the risk of unfavorable changes in the internal and external environment.

To assess the incidence and severity of additional harm (adverse events) when providing medical care, we selected 14 publications of high methodical quality from 9 countries: USA, Canada, UK, Denmark, New Zealand, Netherlands, Spain, Norway, Brazil. In these articles, the information about the results of inpatient treatment of 124,458 patients in 197 short-stay hospitals was analyzed. The index of statistical heterogeneity I2 of the source data was equal to 0.37, so a fixed effects model based on binary data was chosen for the analysis. The cumulative probability of adverse events in inpatients was 10.6% of the total number of hospitalized patients [3-16] (Table 1).

Author, year of publication	Country	Number of hospitals	Number of observations	Frequency, % (95% CI)
Retrospective studies				
Brennan T., *et al.* 1991 [3]	USA (Harvard)	51	30,195	3.7 (3.5-3.9)
Wilson R., *et al.* 1995 [4]	Australia	28	14,210	16.6 (15.9-17.2)
Thomas E., *et al.* 2000 [5]	USA (Utah, Colorado)	28	14,565	5.4 (5.0-5.8)
Vincent C., *et al.* 2001 [6]	United Kingdom	2	1,014	108 (8.9-12.8)
Schioler T., *et al.* 2001 [7]	Denmark	17	1,097	10.4 (8.6-12.2)
Davis P., *et al.* 2002 [8]	New Zealand	13	6,579	12.9 (12.1-13.7)
Baker G., *et al.* 2004 [9]	Canada	20	3,745	6.8 (6.0-7.6)
Zegers M., *et al.* 2009 [10]	Netherlands	21	7,926	8.4 (7.8-9.0)
Landrigan C., *et al.* 2010 [11]	USA (North Carolina)	10	2,341	18.1 (16.5-19.6)
Classen D., *et al.* 2011 [12]	USA (Massachusetts)	3	795	33.2 (29.9-36.5)
Deilkas E., *et al.* 2015 [13]	Norway	20	40,581	14.5 (14.3-15.0)
Prospective studies				
Andrews L., *et al.* 1997 [14]	Spain	3	1,047	17.7 (15.4-20.0)
Wanzel K., *et al.* 2000 [15]	Canada	1	192	39.1 (32.2-46.0)
Szlief C., *et al.* 2012 [16]	Brazil	1	171	55.0 (47.5-62.4)
Meta-analysis	-	197	124,458	10.6 (10.5-10.8)

Table 1: Probability of adverse events.

Most of them (41.3%) were related to surgery, 14.4% - with drug therapy, 9.8% - with late or incorrect diagnosis, 9.1% - manipulations; 8.4% - incorrect treatment plan [3-5, 9-10, 15] (Table 2).

Types of medical interventions	Source						Meta analysis: Percentage % (95% CI)
	Brennan T., *et al.* 1991 [3] (n = 1,117)	Wilson R., *et al.* 1995 [4] (n = 2,952)	Thomas E., *et al.* 2000 [5] (n = 787)	Wanzel M., *et al.* 2000 [15] (n = 32)	Baker G., et al. 2004 [9] (n = 360)	Zegers M., *et al.* 2009 [10] (n = 744)	
	Percentage %						
Surgery	47.7	39.3	44.9	31.2	34.2	54.2	41.3 (40.1-42.6)
Manipulation	7.0	6.7	13.5	9.4	7.2	17.0	9.1 (8.4-9.8)
Drug therapy	19.4	8.4	19.3	15.6	23.6	15.3	14.4 (13.5-15.3)
Incorrect treatment plan	7.5	9.3	4.3	15.6	11.9	5.1	8.4 (7.7-9.1)
Late or incorrect diagnosis	8.1	10.6	6.9	28.1	10.6	6.3	9.8 (9.0-10.5)
Other interventions	10.3	25.7	11.1	-	12.5	2.1	17.0 (16.1-18.0)
Total	100.0	100.0	100.0	100.0	100.0	100.0	-

Table 2: Types of medical interventions and percentages of adverse events.

Only 45.5% of adverse events were considered preventable [3-4,610,15,17-20], and in 27.7% of cases additional harm was caused by negligence in the actions of the personnel [3,5,21] (Table 3 and 4).

Author, year of publication	Total number of events	Number of preventable events	Percentage % (95% CI)
Hospital			
Brennan T., *et al.*1991 [3]	1,117	308	27.6 (25.0-30.2)
McGuire H. et al.,1992 [17]	2,409	1,180	49.0 (47.0-51.0)
O'Neil A., *et al.*1993 [18]	133	83	62.4 (54.2-70.6)
Wilson R., *et al.*1995 [4]	2,302	1,178	51.2 (49.1-53.2)
Wanzel K., *et al.*2000 [15]	192	88	45.8 (38.8-52.9)
Vincent C., *et al.*2001 [6]	119	57	47.9 (38.9-56.9)
Schioler T., *et al.*2001 [7]	114	46	40.3 (31.3-49.4)
Davis P., *et al.*2002 [8]	850	315	37.1 (33.8-40.3)
Baker G., *et al.*2004 [9]	289	106	36.7 (31.1-42.2)
Zegers M., *et al.*2009 [10]	663	283	42.7 (38.9-46.4)
Outpatient clinic			
Singh H., *et al.*2004 [19]	308	108	35.1 (29.7-40.4)
Woods D., *et al.*2007 [20]	2,608	1,296	49.7 (47.8-51.6)
Meta-analysis	11,104	5,048	45.5 (44.5-46.4)

Table 3: Preventable dverse events.

Severe harm and disability in patients with adverse events were observed in 11.8% cases, and unexpected death - in 5.3% of cases [4-6,8-11,15,22] (Table 5).

The analysis of cumulative frequency of hospital mortality rate in a number of countries showed quite a large percentage of unexpected death caused by adverse events - 24.9% [4;6;9;10; 22-29] (Table 6).

Source	Number of adverse events	Severity of harm			
		Severe harm and disability		Death	
		Absolute number	Percentage % (95% CI*)	Absolute number	Percentage % (95% CI)
Wilson R., *et al.* 1995 [4]	2,324	315	13.7 (12.3-15.1)	112	4.9 (4.0-5.8)
Thomas E., *et al.*2000 [5]	787	130	16.6 (13.9-19.1)	52	6.6 (4.9-8.3)
Wanzel K., *et al.* 2000 [15]	144	10	6.9 (2.8-11.1)	2	1.4 (0.5-3.3)
Vincent C., *et al.* 2001 [6]	110	7	6.4 (1.8-10.9)	9	8.2 (3.1-13.3)
Davis P., *et al.*2003 [8]	850	87	10.2 (8.2-12.3)	38	4.5 (3.1-5.9)
Baker G., *et al.*2004 [9]	289	14	4.8 (2.4-7.3)	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 [10]	663	33	5.0 (3.3-6.6)	52	7.8 (5.8-9.9)
Landrigan C., *et al.*2010 [11]	588	67	11.4 (8.8-14.0)	14	2.4 (1.1-3.6)
Meta-analysis	6,388	753	11.8 (11.0-12.6)	340	5.3 (4.8-5.9)

Table 5: Severe harm, disability and unexpected death in case of an adverse event.

Source	Country	Percentage of unexpected deaths % (proportion)	Hospital mortality rate % (proportion)	Percentage of unexpected deaths of hospital mortality rate % (95% CI*)
Wilson R., *et al.*1995 [4]	Australia	0.79 (112/14210)	1.90 (270/14210)	41.5 (35.6-47.4)
Vincent C., *et al.*2001 [6]	United Kingdom	0.89 (9/1014)	-	26.6 (21.8-31.3)
Campbell M., *et al.*2011 [23]		-	3.35 (1581358/47172030)	
Baker G., *et al.*2004 [9]	Canada	1.23 (46/3745)	-	34.2(30.0-38.3)
Canad. Inst. of Health Inf., 2005 [25]		-	3.60 (109989/3058901)	
Andrews J., *et al.*2006 [22]	Spain	0.27 (15/5624)	-	20.8 (14.9-26.6)
Aiken L., *et al.* 2014 [26]		-	1.3 (283/21520)	
Zegers M., *et al.* 2009 [10]	Netherlands	0.66 (52/7926)	-	17.2 (14.0-20.4)
Jarman B., *et al.*2010 [27]		-	3.84 (90873/2363332)	
Makary M., *et al.*2016 [28]	USA	0.71 (251454/35416020)	-	34.8 (29.3-40.3)
Hall M., *et al.*2013 [29]	USA	-	2.04 (715000/35049019)	
Meta-analysis	-	0.71 (251688/35448539)	2.85 (2497773/87679012)	24.9 (24.9-24.9)

Table 6: Hospital mortality rate and unexpected deaths.

The authors from the Johns Hopkins Hospital [28] showed that adverse events form the third cause of mortality in the USA accounting for every tenth death in the country (Table 7).

Cause of death (2013)	Number of deaths	Percentage % (95% CI)
Cardiovascular disorders	614,348	23.6 (23.6-23.7)
Neoplasms	591,699	22.8 (22.7-22.8)
Harm related to provision of medical care	251,454	9.7 (9.7-9.7)
Chronic respiratory diseases	147,101	5.7 (5.6-5.7)
Unintentional damage	136,053	5.2 (5.2-5.3)
Cerebrovascular accident	133,103	5.1 (5.1-5.1)
Alzheimer's disease-related complications	93,541	3.6 (3.6-3.6)
Diabetes-related complications	76,488	2.9 (2.9-3.0)
Influenza and pneumonia	55,227	2.1 (2.0-2.0)
Kidney diseases	48,146	1.8 (1.8-1.9)
Suicide	42,773	1.6 (1.6-1.7)
Other causes	407,060	15.7 (15.6-15.7)
TOTAL	2,596,993	100.0

Table 7: Mortality rate structure in the US population (Makary M. *et al.*, 2016).

The causes and the mechanism of development of adverse events were studied in 20 publications of high methodological quality. The main reasons for additional harm were latent threats. These threats are not directly related to the source of the adverse event, are constant and do not carry any danger if they are inactive [21,30,31]. Under certain conditions, a latent threat is activated and turns into a dangerous situation (active threat 1), which, in its turn, lead to the development of dangerous processes (active threats 2) - unsafe actions (errors) of the personnel, unsafe patient behavior, unsafe processes in the environment in which medical care is provided. The result of a dangerous situation are dangerous events (incidents), which in the international literature are called incidents. The incident might cause harm to the patient (an incident without sequelae) or end with harm (an incident with sequelae) or might lead to the patient's death (a critical incident) [30-32].

Latent threats exist and transform into adverse events at three levels: at the level of the staff, at the level of the patient and at the level of the environment. At each of these levels, global latent threats (that are present regardless of the site of medical care provision and its profile) and specific latent threats (caused by the specific site of medical care provision and its profile) have been described. Quite often, a transformation of a latent threat moves

from one level to the other [32-34]. In most cases, the incidents and resulting adverse events are the result of the transformation of several latent threats followed by a series of active threats that coincide in time and space [32].

So far, four groups of global latent threats have been studied at the staff level: related to personnel management (management system, procedural rules, communication (including identification and verification), team work); associated with personnel selection (staff positions, staff turnover, employment of part-time employees) associated with personnel competence (low baseline competence, freedom in the implementation of official duties, acquired competence deficiency) related to mental state and physiological condition of the personnel (personal problems and disease, a distrust in leadership and procedural rules, low level of commitment to procedural norms) [30,33-35]. These threats turn into a dangerous situation during the provision of medical care and lead to dangerous events – staff errors (blunder, miscalculation, omission, violation) [36,37].

Global threats at the patient level can be divided into three groups: caused by mental state and physiological condition of the patient (pain, physical and mental disorders), caused by the personal characteristics of the patient (low general educational status, insufficient level of medical literacy, low level of motivation to fulfill medical prescriptions), caused by the personal data features (coincidence of personal data). The described threats turn into a dangerous situation at the time of the patient's movement, his/her communication with the staff, the implementation of medical prescriptions and in the process of self-monitoring of the patient's condition. As a result, dangerous events develop - incorrect actions (lack of actions) of the patient, or staff errors in the process of staff-patient interactions [33,38-41].

At the level of the environment in which medical care is provided, two groups of global latent threats have been studied: those related to the social environment and those related to the technological environment. In the technological environment, there are threats associated with the workplace (tools and objects of labor, workspace) and threats associated with the building (constructions, engineering and logistics systems). The environmental threats turn into a dangerous situation during the provision of medical care [30-32,35,38]. As a result, unsafe processes occur in the environment itself (accidents, failures, failures in the building, equipment, engineering systems, direct harmful effects of physical, chemical or biological factors). Other variants of transformation of the latent threats of the environment include unsafe patient's behavior (e.g., stumbling) or a staff error that occurred in the process of its interaction with the tools (items) of labor and workspace [33,38,40,41].

Conclusion

Successful experience of safety management in developed countries has shown that the solution to this problem can not be implemented only at the level of one medical organization. A comprehensive approach at the level of the public authorities, medical care system and society is needed. In the first case, it is necessary to make significant changes in the regulatory framework. These changes should define medical care as a high-risk service, admit the fact of existence of medical errors and adverse events, guarantee medical personnel the rights and freedoms in case of detection and recording of cases of additional harm to the patient, to formalize the powers and responsibilities of the patient, to provide additional funding to ensure the target level of the patient's safety, staff and the environment. The medical care system should adopt a new safety culture taking into account the existing high probability of adverse events and systemic causes of additional harm, provide management for the development and standardization of effective solutions to prevent the risk of additional harm, justify additional funding for activities and the necessary infrastructure to ensure the target level of safety in medical organizations. At the society level, it is necessary to arrange a discussion on the issues of medical care safety, the result of which should be an understanding of the need to form a single team of healthcare providers, patients and their relatives in the process of providing medical care - a team that will provide comprehensive management control of the feasibility, timeliness, occupancy and quality of implementation of the chosen treatment plan.

The modern strategy of medical care safety management in a medical organization includes the development of a new safety culture, arrangement of the incidents and threat accounting, incident stratification, the definition of the scope of incident management and the scope of activities, the introduction of the incident investigation algorithm, the standardization of the process of preventing the transformation of a latent threat into an adverse event. The in-

troduction of this strategy usually includes two stages. At the first stage, the described events relate to latent threats, which ended in the development of incidents and adverse events. At the second stage, all latent threats at the clinic are identified and managed including those which did not end in the development of incidents [1,32,34,35].

The new safety culture, which is part of the corporate culture, is based on the following provisions: incidents and adverse events are inevitable parts of medical care, they are based on permanent systemic causes - latent threats; safety is ensured by eliminating systemic causes and guaranteed not only by individual skills of the performer, but an integrated system that provides for the creation of conditions that prevent the transformation of a latent threat into an adverse event; prevention of harm associated with the provision of medical care is proactive, which implies the management of all latent threats identified in the clinic. The level of safety culture is assessed by means of special questionnaires, taking into account the orientation to the listed values of the top management, staff awareness of safety issues, staff perception of the general level of safety, staff commitment to procedural standards and their trust in management, as well as the quality of team management and the quality of communication [1,30,32,34].

The accounting system includes obtaining information about the threats and incidents, their identification, registration, monitoring and measurement. For accounting, most countries use character encoding of threats and incidents suggested by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP, 1998 - 2001) [1,31,33,42,43]. A big problem related to objective accounting is concealment and (or) masking of incidents and adverse events. In case of concealment, the incidents are simply not reported, in case of masking, they are interpreted as complications related to the course of the primary or concomitant diseases. The most common object of concealment and masking is an infection related to provision of medical care. Several effective solutions have been suggested in order to prevent concealment and masking of incidents: collection of information not only from medical records but also from colleagues, patients and independent auditors as well as accounting automation [30,31,33,35,38]. Another quite effective solution is a system of registration of procedure-related incidents and their consequences. An example is a system Global Trigger Tool used for this purpose in Europe and the USA. Procedure-related events include "rigid" (independent of a subjective factor) process indicators, non-typical complications, abnormal behavior and non-typical patient's condition as well as all cases of unexpected deaths. Information about a procedure-related event is the reason for a thorough audit, as a result of which it is usually possible to reveal medical care-related incidents [10,44,45].

Incidents' stratification determines the grade of their risk (a hazard class). For stratification, two main criteria measured in rank coefficients are used. They include the severity of the harm and repeatability (incidence) of the incident. The hazard class of the incident is determined in accordance with the classification proposed by experts of the UK National Healthcare System - NHS Commissioning Board Authority, which distinguishes four risk groups, each of which regulates the scope of activities, the scope of management and the possibility of further medical care provision. While investigating the incident, active and latent threats are identified and the adverse event route map is formed [32,33,35,46,47].

Prevention of transformation of the latent threat into an adverse event is achieved by the development and implementation of a management standard that envisages the elimination of preventable and minimization of the impact of unpreventable latent threats. For this purpose, a multilevel protection system envisaging the block of each stage of the latent threat transformation is normally created [21,32,33,35,48-50].

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