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Review Article

Medical Safety Management System from the Perspective of a Multifactorial Model of Adverse Events in Medicine -

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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 labour 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. It has been convincingly demonstrated that the effectiveness of the described model will be low if threats of external microenvironment and macro factors levels remain out of control. At the same time, a medical organization should be able to choose partners and suppliers based on open information about quality and safety of goods and offered services. The results of the article strongly recommends embedding all outsourcing processes into the operating system of a medical organization with full control of outsourcing activities, its intermediate and final results. To change macro factors, the state and society must be vigilant with regards to health care quality and safety. The systemic causes of adverse events must be recognized at the federal level, the rights and freedoms of medical workers must be guaranteed in case of registration of medical errors and incidents, and health care itself must be classified as a high-risk service. At the same time, declared state guarantees must be financed, the economic model of state health care must be adapted to market conditions, state regulation of medical activity must be revised in terms of its impact on the final value and safety. At the same time, there is a need for an in-depth reform of pre- and postgraduate medical education in many countries; taking into account the need for a qualified and independent doctor being assigned to a patient. In addition, working hours and wages of medical professionals should be aligned with the existing norms of risky industries and services. Another important condition for achieving a high level of medical care safety is an open dialogue with society and the formation of cooperative relationships on safety issues between medical professionals, patients and their families.

Keywords: Medical care safety; Adverse events; Incident; Medical care safety management system

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 stay which is most likely related to medical care rather than the course of the main disease or concomitant diseases [1].

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

Over the last three decades, the incident trend line of adverse events has remained horizontal (Figure 1).

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

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 (Table 3).

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].

And 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. From our point of view, 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 favorable targeted clinical outcome. As an example, let's imagine two departments of vascular surgery, which perform the same operation on patients with critical lower limbs ischemia - femoral popliteal bypass with distal anastomosis below the knee joint. Fifty patients were operated on in both wards. Positive outcome (limb salvage) was achieved in 40 patients in the

first department, in the second department in 45 patients. One complication related to medical care, amputated limb infection developed in one patient in the first ward. In the second department, one patient developed one complication related to medical care

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)

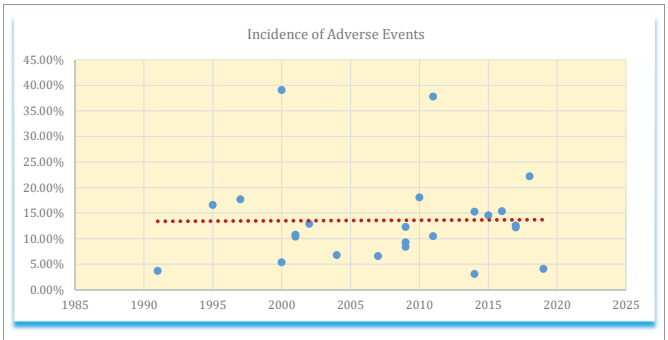

Figure 1: Incidence of adverse events over the last 30 years (based on data from table 1).

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)

Table 3: Cause of death in the U.S. population [26].

Cause of death (2013 г.)	Number of deaths	Percentage % (95%CI)
Cardiovascular diseases	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

provision, bilateral lower lobe pneumonia. Complications are comparable in severity and lethality. The complication rate is 2% in both departments. But let's consider it from the perspective of the gained benefit: the ratio of benefit to harm in the first case is 196, and in the second one is 441. Safety is undoubtedly higher in the latter case. 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 unfavorable 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 [31-33]. Under certain conditions, latent failures become an actual (real) failure - 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 threat s 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) [34-36].

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, 38-42]. Tables 4-7 provide an example of latent failures at various levels.

In the process of transforming a root latent failure, its level may not match the level of the active threat that leads to the incident. Thus, for example, the latent failures "coincidence of personal data" is at the level of patient, but in the process of transformation we can see an active threat on the level of medical personnel (the choice for intervention of the wrong patient). This approach to systematization of latent failures reflects the essence of medical care itself, which includes not only processes related to medical activity, but also processes related to the actions of medical personnel and processes related to patient behavior. All three groups of processes take place in a certain environment, which itself contributes to the intermediate and final outcomes.

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 [31,35-38]. A new safety culture is based on the following seven assumptions:

1. In the complex systems to which medical organizations belong, it is impossible to foresee and prevent all deviations and resulting incidents, making the latter an inevitable companion of medical care processes.

Table 4: Examples of global latent failures at the level of medical technology (authors' classification).

Medical Products	Pharmaceutical Products	Manual	Source of Knowledge or Rule
1. Trauma (side-effect)	1. Toxicity (side-effect)	1. Trauma (side-effect)	1. Staff analysts
2. Constructive and functional imperfections	2. Allergic reactions (side-effect)	2. Difficulty	2. Author's personal experience
3. Difficulty		3. Uselessness	3. Organization experience
4. Fault tolerance		4. Redundancy	4. Low-quality publications

Table 5: Examples of global latent failures at the staff level (authors' classification).

Personnel Management	Staffing	Competence	Mental state and Physical Condition
1. Failures in general management (decision making, planning, organization, coordination, control);	1. Staff shortages failures	1. Baseline lack or excess of competencies	1. Industrial overload
2. Failures in special management (social, operational, project, strategic);	2. External part-timers' failures	2. Freedom in the implementation of official duties	2. Personal problems and disease
3. Logistics failures	3. Outsourcing of services failures	3. Acquired competence deficiency or excess	3. Low level of commitment to the organization
4. Quality management model in the organization (no process approach, no participatory management and no continuous system improvement)			4. Distrust in leadership
	Communication	**Teamwork**	
1. Failures in staff communication	1. Failures in implementation		
2. Failures in staff communication with patient and family members	2. Failures to ensure continuity in patient treatment in transfer between doctors		
3. Failures in identification			

Table 6: Examples of global latent failures at the environmental level (authors' classification).

Technological Environment		Social Environment Level
Failures Associated with the Workplace	**Failures Associated with the Building**	1. Access to building by a third party with unfavorable intentions
		2. Unfavorable intentions on the part of staff
1.Tools (equipment, instruments)	1. Construction	3. Unfavorable intentions on the part of patients and their family members
2. Labour objects (consumable medical devices, drugs, reagents, disinfectants)	2. Engineering system	
3. Working space (area, volume, physical and chemical factors, ergonomics)	3. Organization of the architectural space	

Table 7: Examples of global latent failures at the patient level (authors' classification).

Failures Associated with Mental State and Physiological Condition	Failures Associated with Personal Characteristics	Failures Associated with Personal data Features
1. Pain	1. Low general educational level	1. Coincidence of personal data
2. Mental and physical disorders related to the disease and its concomitant conditions	2. Insufficient level of medical literacy	
	3. Patient's dissatisfaction	

Table 8: Coding of failures, threats and incidents.

Code	Event type	Comments
A	Latent failure and vulnerability	Circumstances or events that have the capacity to cause error
B	Active threat	An error that did not reach the patient
C	Incident without harm (near miss)	An error that reached the patient but did not cause harm
D	Incident without harm (near miss)	An error that reached the patient and required monitoring or diagnostic procedure to confirm that it resulted in no harm to the patient
E	Harm (accident or adverse event)	Temporary dysfunction that required intervention without increasing the duration of inpatient treatment
F	Harm (accident or adverse event)	Temporary dysfunction that required intervention and initial or prolonged hospitalization
G	Harm (accident or adverse event)	Permanent function impairment (disability)
H	Harm (accident or adverse event)	Life-threatening disorders that required intervention to sustain life (cardiopulmonary resuscitation, intensive care and/or major interventions)
I	Critical incident	Patient death

2. The main causes of adverse events are latent failures, which initially turn into vulnerabilities, and then, interacting with medical personnel and security systems, into active threats: human errors and violation, unsafe processes in the environment where medical care is provided and unsafe patient behavior.

3. Management of incidents risk arising in medical care provision is aimed at the reduction of the probability and severity of harm and should be based on preventing the transformation of latent failures.
4. The guarantee of safety is not the individual skill of the care providers but a proactive medical care safety management system integrated into the overall management system and quality management system.
5. Successful implementation of medical care safety management system requires the commitment and responsibility of the top management of the medical organization, an open and transparent corporate climate, the involvement of all personnel, patients and their family members in the management process, continuous improvement of the processes that make up the system and learning from their own and global collective negative experiences.
6. Medical care safety management system requires additional resources in terms of time, funding, supplies and personnel.
7. Medical care safety management suggests that under certain circumstances safety issues may be more important than production tasks.

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 (Table 8) 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, 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 9).

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].

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;

Table 9: 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	Auditor	• Direct control of staff actions and medical records
	• Voluntary reporting		• Analysis of ratio incidents of various severity
Medical records	• Retrospective analysis	Patient	• Interview with family
	• Prospective analysis		• Complaints from patients and their families
Colleague	• Cross-Control	Automated control systems	• Automation of error accounting
			• Automation of complaint recording
Official	• Analysis of integral indicators (lethality, complications, etc.)	Official	• Cross-analysis of integral indicators dynamics (mortality and complications dynamics)
(mandatory) reporting		(mandatory) reporting	
		Global Trigger Tool	• Atypical event analysis
			• Atypical death analysis
			• Atypical complications analysis
			• Atypical patient behavior analysis

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.

Global Trigger Tool is a retrospective review of a random sample of patient records using clues (triggers). The presence of a trigger requires an additional search for an adverse event that quite often accompanies the trigger. The trigger concept was first introduced to monitor drug therapy side effects by Jick H. in 1974 and was subsequently improved and automated by Classen D.C. in 1992. In the late 90s, it was adapted for all areas of hospital care and became the Global Trigger Tool. Trigger Tool are quite "strict" indicators, i.e. their registration is usually mandatory regardless of the performer's will. They significantly reduce the search for medical incidents related to medical care provision, thereby increasing the efficiency and effectiveness of accounting system. The presence of a global instrumental trigger does not mean in 100% cases that it is an adverse event or accompanying it. It is a reason for a mandatory and thorough audit [1,47-49]. More than fifty triggers are described in the literature. They are divided into 6 groups where each explores a specific area of health care: Cares; Medication; Surgical; Intensive Care; Perinatal; Emergency Department [49]. There is no upper limit for number of used triggers, each medical organization selects and systematizes them for itself.

The Global Trigger Tool methodology includes 5 stages [49]:

- **Creating a Review Team**, which usually consists of two reviewers (review records) and an expert doctor (confirms or refutes the reviewer's evaluation)
- **Sampling Patient Records** (not less than 10 closed and completed records every two weeks; each record is viewed independently by each reviewer.)
- **Review Process** (viewing records with identification of all 6 modules Triggers; not all records are used for analysis, but first of all: discharge codes, particularly infections, complications, or certain diagnoses, discharge summary, medications administration record, laboratory results, prescriber orders, operative record, nursing notes, physician progress notes; if time permits, any other areas of the record (such as History & Physical, Consult notes, or Emergency Department notes).
- **Determination of an Adverse Event** (verification of an adverse event if a positive trigger is detected; only Adverse Events belonging to category E-I on the NCC MERP scale are recorded);
- **Data collection** (adverse events per 1,000 patient days; adverse events per 100 admissions patients with adverse events per 100 admissions.

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 [50-52]. Risk management includes 6 steps:

1. Incident analysis
2. Incident risk assessment
3. Developing a risk response plan
4. Plan execution, performance and efficiency assessment
5. Standardization of plan's activities
6. 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 2).

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 (Table 10,11).

*NHS Foundation Trust. Risk Management Procedure. January 2013.

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].

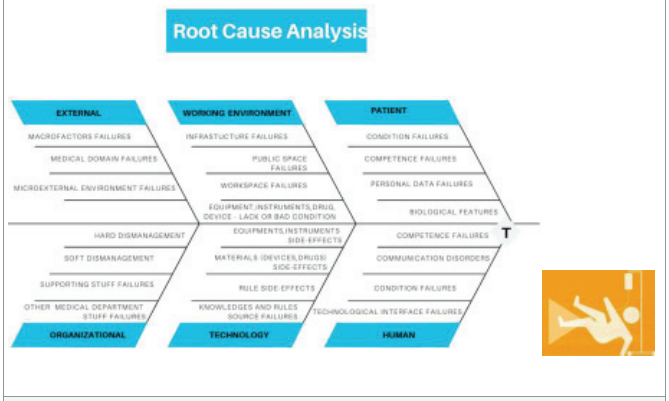

Figure 2: Incidence analysis, (WHO patient safety curriculum guide: multi-professional edition. World Health Organization 2011)

Table 10: Incidents stratification according to severity of harm*.

Score	Name	Severity of Harm (scale equivalent NCC MERP)	Number of Personnel Involved	Additional Treatment Period	Additional Treatment Costs (pound sterling)
5	Catastrophic (critical)	I	> 50	-	> 1 million
4	Major	G,H	16-50	>15 days in hospital	500 thousand - 1 million
3	Moderate	F	3-15	8-15 days in hospital and 1-7 days outpatient	250 -500 thousand
2	Minor	E	1-2	1-7 days in hospital and 1-7 days outpatient	10-25 thousand
1	Insignificant	C,D	0-1	not required	< 10 thousand

Thermal risk scale is used to assess the amount of risk. Risks entering the red zone are classified as extremely dangerous, those entering the orange zone as dangerous, those entering the yellow zone as moderately dangerous and those entering the green zone as non-dangerous (Figure 3).

The risk response plan includes 5 key sections (Table 12).

Features of response plan depending on the risk value are given in table 13.

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.

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 threats. 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.

Table 11: Stratification of incidents based on frequency and probability [50].

Score	Development Probability	Frequency of Occurrence 1 Case	Incident Probability Over Period %
1	Almost certain	1 time a week or more	81-100
2	Likely	1 time in 8-30 days	61-80
3	Possible	1 time in 31-60 days	41-60
4	Unlikely	1 time in 61 days – 12 months	21-40
5	Rare	Not if there are latent threats	20 and less

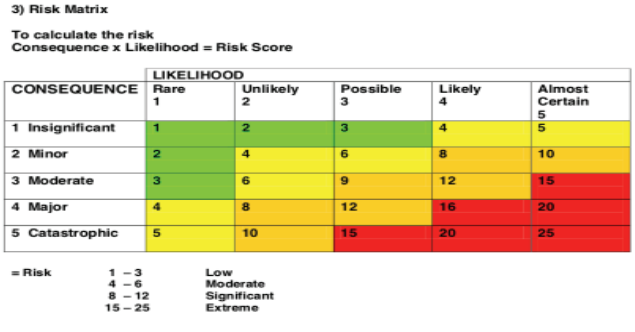

Figure 3: Thermal risk scale (NHS Foundation Trust. Risk Management Procedure. January 2013).

Table 12: Risk response plan [50].

Medical Care Provided by the Risk Owner	Response Method	Risk Management Area	Resources for Risk Management	Residual Risk Level
• continues	• risk accepted	• risk owner	• people	Risk value determined by the risk management committee in a medical organization
• ends	• risk minimized	• other departments	• finance	
	• risk eliminated	• medical organization	• material inventories	
	• risk is avoided	• health care authority	• info	

Table 13: Risk Response Plan for different sizes [50].

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

Implementation of safety management system is a project and should be carried out by the project team based on project management principles and taking into account ten areas of project management. Given the limited resources of the organization, it is recommended that the implementation of the security management system be carried out in two phases. In the first stage, only those failures that have already led to incidents (e.g. a fall) are affected by the pilot conversion method. In the second stage, solutions are implemented to prevent the transformation of failures with potentially dangerous consequences (for example, limiting access of patients and third parties outside the building perimeter (in windows, on balconies) to prevent fallout).

In order to measure the safety level in the entire medical organization (as well as in any of its unit), the authors proposed an integral patient safety index – IPSI. The IPSI represents the sum of the benefit/harm ratio based on the category of treatment complexity. The chances of benefit are calculated by multiplying the chances of positive outcomes (target result defined by the treatment plan) by weighting the treatment complexity category: $a_1{*}x_1 \ldots\ldots a_5{*}x_5$.

The harm chances are calculated by multiplying the chances of incidents by weighting their severity: b1*y1 .... b5*y5.

The integrated safety factor will look like:

IPSI = Σ ($a_1 * x_1 / b_1 * y_1$ + …… $a_1 * x_1 / b_i * y_i$ …….. $a_{1i} * x_{1i} / b_i * y_i$)

With the highest possible safety, the IPSI strives for infinity. With IPSI < 1, the harm chance exceeds the benefit chance.

Weighting factors for harm are distributed proportionally to the distribution of its rank values scores in a range from 0 to 1 (Table 14).

Calculation of weighting factor for treatment complexity category is linked to two matrices: severity of the patient's condition and type of medical care; main intervention complexity and potential side-effect severity of the medical technology (Tables 15,16).

We build an integral thermal matrix taking into account the last two matrices (Figure 4). The red area is a very high complexity category of treatment, brown - high complexity category, orange - moderate complexity, yellow - small complexity, green - minor complexity.

We define weighting factors for different categories of treatment complexity by using the proportions of the matrix in the figure 4 (Table 17).

As an example of this model in use, let's look at a 400-bed multidisciplinary hospital where 25,000 patients were admitted for treatment during the calendar year. The distribution of patients by treatment complexity categories and their chances of benefit are given in table 18.

Chances of harm for each treatment complexity categories are shown in table 19.

The Integral Patient Safety Index is 411,473.625 (Table 20). Its absolute value makes no sense, but if uniformity in measuring this indicator is followed, its dynamics over the period has great importance in the objective assessment of changes in safety level in the medical organization as a whole, and in each of its units.

The above approach to safety measurement using the Integral Patient Safety Index is based on the expert evaluation method that was tested by our research group in 2004 in the Stavropol Regional Clinical Hospital [54].

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

Table 14: Weighting factors for different types of harm severity.

Incident Type	Harm Severity (scores)	Weighting Factor
Catastrophic	5	0,333
Major	4	0,267
Moderate	3	0,200
Minor	2	0,133
Insignificant	1	0,067
TOTAL	15	1,000

Table 15: Severity of the patient's condition and medical care type.

Severity of the Patient's Condition (scores)		Urgency of Medical Care (scores)				
		Outpatient Care	*Routine Inpatient Care*	*Emergency Inpatient (during 24 hours)*	*Emergency Inpatient (1 hour)*	*Urgent Inpatient (immediately)*
		1	2	3	4	5
Satisfactory	1	1	2	3	4	5
Moderate	2	2	4	6	8	10
Severe	3	3	6	9	12	15
Extremely Severe	4	4	8	12	16	20
Critical (shock)	5	5	10	15	20	25

Table 16: Complexity and invasiveness of the main intervention.

Potential Side-Effect Severity (score)	Complexity (score)				
	1	2	3	4	5
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15
4	4	8	12	16	20
5	5	10	15	20	25

Side-effect severity and complexity (score)	Severity of the condition and the type of medical care (score)													
	1	2	3	4	5	6	8	9	10	12	15	16	20	25
1	1	2	3	4	5	6	8	9	10	12	15	16	20	25
2	2	4	6	8	10	12	16	18	20	24	30	32	40	50
3	3	6	9	12	15	18	24	27	30	36	45	48	60	75
4	4	8	12	16	20	24	32	36	40	48	60	64	80	100
5	5	10	15	20	25	30	40	45	50	60	75	90	100	125
6	6	12	18	24	30	36	48	54	60	72	90	96	120	150
8	8	16	24	32	40	48	64	72	80	96	120	128	160	200
9	9	18	27	36	45	54	72	81	90	108	135	144	180	225
10	10	20	30	40	50	60	80	90	100	120	150	160	200	250
12	12	24	36	48	60	72	96	108	120	144	180	192	240	300
15	15	30	45	60	75	90	120	135	150	180	225	240	320	375
16	16	32	48	64	90	96	128	144	160	192	240	256	320	400
20	20	40	60	80	100	120	160	180	200	240	320	320	400	500
25	25	50	75	100	125	150	200	225	250	300	375	400	500	625

Figure 4: Matrix of treatment complexity category (cumulative Matrix based on data from tables 15 and 16).

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. At the state level must be adopted regulations that recognize the possibility and inevitability of medical errors, incidents and adverse events in health care, guarantee the rights and freedoms of health personnel who report them openly, determine the leading role of systemic causes in the origin of incidents, classify health system as high-risk service, formalize the rights, duties, and responsibilities of the patient itself. An example of such document is the Danish Patient Safety Act [55], analogous of which are adopted in many developed countries. We would like to draw your attention to a short extract from the act: "a medical error report by a health care worker will not result in any disciplinary investigation or punishment, either by the employer or by the National Health Department's supervisory body or a prosecution". The second important area is the formalization of State guarantees with regard to types and volumes of medical care. Excessive populism, resulting in state declaration that almost all types of medical services are accessible to entire population in any quantity in conditions of unsecured funding, lack of safe infrastructure and the necessary number of specialists can turn into a disaster for population. And here it is very important to distribute responsibility between the state, insurance funds and population in terms of receiving quality and safe outcome of medical care. The third important decision will concern medical organizations founded by the state. It is a profound misconception that state health organizations should have different economic model from privately owned health organizations. For example, in some post-Soviet countries, the tariff structure of medical services in state hospitals does not include depreciation of buildings, equipment and other fixed assets, profit and almost all indirect costs. Direct costs are calculated on the basis of available funding and are not related to market conditions. Budgeting in such organizations is linked only to historical costs, does not take into account real costs, changing needs for medical services, gross domestic product inflation, exchange rate differences and uncertainty risks. It is quite obvious that future of such model is rather sad: irreversible wear and tear of infrastructure up to destruction of buildings, lack of safe industrial environment, lack of modern equipment, necessary medicines and medical products, high turnover, dissatisfaction and professional burnout of personnel, reduction of collective intellectual potential of medical organization. Tied to subsidies from the federal and regional budgets, state medical organizations are in fact deprived of independence in decisions making on major economic operations. All decisions on capital expenditures are made by the chief administrator of budget funds or insurance funds. It even reaches level of centralization procurement of pharmaceuticals, medical products and food products to state hospitals, which is accompanied by catastrophic interruptions in supply, gross violations of quality and assortment of centralized inventory. The legal and regulatory framework governing public procurement should ensure the ability to quickly meet the need for inventory regardless of procurement cost and volume. Otherwise, especially in situation where the population's need for medical services is rather unstable, the state guaranteed access to medical care will remain an empty declaration. The new economic model of state health care should provide for a full tariff for any medical service, including absolutely all direct and indirect costs taking into account their market cost, as well as the cost of medical care safety management and treatment of related complications. The tariff for medical service should include profit, which cannot be withdrawn by the founder, but should be used for personnel training and development, strategic changes, proactive modernization of infrastructure. It is necessary to review the existing practice of financial sanctions by medical insurance organizations for identified adverse events. These sanctions further reduce the medical care safety due to unpredictable funding gaps. In our opinion, with regard to incidents verification the relationship between medical and insurance organizations should be based on cooperation rather than antagonism, as both sides are interested in expanding the scope of quality and safe medical services. The planned medical care volumes (regulations) should be calculated based on real need in the region, or better, in the municipality. Size and share of state support should be determined based on this need (rather than average norms).

State health authorities must do four important things to ensure

Table 17: Weighting factors for different categories of treatment complexity.

Categories of Treatment Complexity	Maximum Score	Weighting Factor
Minor complexity	20	0,019
Small complexity	60	0,056
Moderate complexity	125	0,116
High complexity	250	0,231
Very high complexity	625	0,579
TOTAL	1080	1,000

Table 18: Chances of benefit.

Category of Treatment Complexity	Number of Patients	Positive Outcome	Chances of Positive Outcome	Weighting Factor	Chances of Benefit, Adjusted by the Factor
Minor complexity	1 000	999	999,000	0,019	18,981
Small complexity	4 000	3 913	44,977	0,056	2,519
Moderate complexity	12 000	11 656	33,884	0,116	3,931
High complexity	6 000	5 764	24,424	0,231	5,642
Very high complexity	2 000	1 903	19,619	0,579	11,359
TOTAL	25 000	23 236			

Table 19: Chances of harm.

Category of Treatment Complexity	Incident				
	Insignificant	Minor	Moderate	Major	Critical
Minor complexity	76	10	5	0	0
Small complexity	100	29	10	1	0
Moderate complexity	120	90	15	2	1
High complexity	300	200	70	7	3
Very high complexity	1 500	500	113	15	8
TOTAL	2 096	829	213	25	12
Weighting factor of incident	0,067	0,133	0,200	0,267	0,333
	Chances of harm				
Minor complexity	0,00551	0,00134	0,00101	0,00000	0,00000
Small complexity	0,00172	0,00097	0,00050	0,00007	0,00000
Moderate complexity	0,00068	0,00101	0,00025	0,00004	0,00003
High complexity	0,00353	0,00459	0,00236	0,00031	0,00017
Very high complexity	0,20100	0,04433	0,01198	0,00202	0,00134

Table 20: Benefit/ harm ratio and Integral Patient Safety Index.

Category of Treatment Complexity	Insignificant Incident	Minor Incident	Moderate Incident	Major Incident	Critical Incident	TOTAL
	3444,31443	14128,7143	18886,095	0,0000	0,0000	36459,1227
Minor complexity	1466,28358	2593,4532	5025,405	37728,3933	0,0000	46813,535
Small complexity	5808,49254	3911,29574	15704,345	88322,3558	141645,853	255392,342
Moderate complexity	1599,97015	1230,21053	2389,79	18091,2285	33868,9429	57180,1421
High complexity	57,4079602	260,278195	963,455442	5719,0799	8628,26126	15628,4828
IPSI	12376,4677	22123,9519	42969,0904	149861,057	184143,057	**411473,625**

effective functioning of safety management systems in medical organizations. The first is the preparation and coordination of state programs in medical care, including creation of national registers, single national security module as part of medical information systems, and national guides to medical care safety. The second is optimization of government regulation. First of all, norms concerning medical organizations infrastructure and their personnel should be systematized and bound to reality. These norms must be complied with and implemented in 100% of medical organizations, taking into account the profile of provided medical care. The norms and quality criteria governing medical activity, must be linked to value generated by the activity (patient health and targeted clinical outcome). Thus, the criterion of screening quality should be the proportion of people with newly detected malignancies, rather than proportion of people covered by screening. Activities regulation should not be redundant, but should contain only those requirements that allow to influence the result or make executable decisions to manage the result. Excessive standards hinder medical care provision by diverting staff to useless activities and vice versa, reducing care safety. The same applies to reports and direct monitoring activities. The report, which does not lead to a decision, is not only useless but also harmful as valuable time of a medical worker has been spent on its preparation. Excessive inspection control disrupts normal rhythm of a medical organization, significantly increasing the likelihood of all types of medical errors (mistake, miscalculation, omission and violation). It should be stressed that a medical organization is not a conveyor production. Its personnel is based on people with a heuristic type of activity, and organizational structure of this type belongs to adhocracy where the key mechanisms for activities coordination are not processes standardization but qualifications standardization and mutual agreement, including in form of clinical guidelines and treatment protocols [56]. Processes standards are necessary but they should have local character, consider specificity of infrastructure and competence of concrete organization, be plastic and have the main purpose to prevent such error type of personnel as an omission, taking into account presence of initial high qualification of personnel. No standard or even clinical recommendation can replace the lack of competence resulting from a low level of medical education, which is the third area to be regulated by the health or education authorities (varies from country to country). Medical education reform should be based on two key paradigms. The first paradigm: after obtaining a diploma and accreditation certificate (or an individual medical license), a patient should be admitted to an independent doctor who has full knowledge, skills and abilities defined by the professional educational standard. The second paradigm: from a global perspective, health care value formation does not begin when a patient crosses the doorstep of a medical organization, but when a student crosses the doorstep of a medical college or university. Taking into account the described paradigms, training of medical workers is possible only in the system of university medical clusters, including the university and associated medical college, multidisciplinary expert class hospital, multi-disciplinary expert class polyclinic, medical transport organization, simulation center, research complex, scientific and production complex, library with information resources, hotel, dormitory, sports complex, catering and leisure network. It is important that education, science and medical production should be integrated into the university cluster. It will allow to achieve maximum efficiency and effectiveness in generation of new knowledge, new technologies generation and materialization. The whole learning process should be divided into three stages: fundamental education (3 years), clinical education (3-4 years) and step residency (from 3 to 8 years depending on the final specialty). In the last two stages, the education system should include sections on health care safety management both in general and within each clinical discipline. The share of state funding (or state support for education) should be at least 80%. Only in this case final competitive selection of specialists can be supported. The residency itself should have a step nature (for example, that it is impossible to pass the residency in cardiothoracic surgery without having completed the residency in ambulance and emergency care, anesthesiologists and intensive care, general surgery, etc. - the modules may vary depending on the final specialization). At any stage, training can be completed by the resident's request with an appropriate accreditation certificate. The residency process should include a mentoring institute where residents are trained by the most experienced professionals with pedagogical skills. The mentors selection should be done on a competitive basis, provide for separate decent funding and have no more than 2 residents per one mentor. The mentor should have the primary responsibility for residents graduation. The decision to award a diploma and an accreditation certificate should be made by a team of experts, in which the university clinic plays a crucial role. The final examination must include three steps: entrance test, manual skills assessment and a final interview with a team of experts. Usually it takes about 25-30 years to build such medical education system. There are three things to consider for the system of postgraduate education. Firstly is the high rate of knowledge renewal (today the half-life of knowledge is 1-3 years). Secondly is the existing need for the doctor to perform basic work function (providing medical care). Thirdly is the constantly changing in need for medical care volumes and types. Fourthly is the intensive updating of medical technologies with increasing penetration of cognitive information systems. By virtue of mentioned above it becomes clear that the knowledge and skills received as a result of training should be immediately introduced (training for the future is deprived of any sense); training cannot be only discrete as there is a constant updating of knowledge and technologies; discrete training itself cannot be long (as the medical worker cannot be distracted from performance of labour function for a long time as it worsens medical care safety and reduces qualification of the medical worker). That is why at the

postgraduate level medical organization itself should provide possibility of unhindered access to quality medical information, free round the clock access to the best info-medical resources. Offline training should be minimized and left only for new areas where new manual skills are required. But even in this case it should not take more than a week (except for the initial mastery of new complex technologies) and provide for off-line training for all team members. University clinics should become hubs for generating new knowledge and technologies and replicating them within the country during online and offline training courses. Medical organizations should be interested in the continuous learning and development of their staff, so the cost of education should either be included in the tariff of medical service or covered from profits. Re-accreditation should take place once every 3 years taking into account the half-life of knowledge. The decision to renew the accreditation certificate should be made by the same team of experts and with key staff from the university clinic. This decision should be based on an in-depth interview with the applicant and the report analysis on the applicant's previous activity, signed by the head of the medical organization. The postgraduate education process should not be bureaucratic. There should be no reports on studied literature, taken courses and attended educational cycles and received points for this. Neither a doctor nor a nurse has time for this. But the most importantly it does not make any sense, because the actual level of qualification of a medical worker, which is assessed by experts is important. And finally, the last direction of state regulation in health care should be rationing of working hours and wage system. Taking into account the fact that work overload significantly increases the probability of medical error, it should be prohibited at the state level for a medical worker to perform work for more than 8 hours. The second important direction is to control the minimum wage of a medical worker that should not be lower than the social norm for people with a heuristic type of activity. It is not a consumer basket cost, but a large social package that includes a adequate nutrition, comfortable accommodation, use of transport and internet, vacation and recreation, access to Internet and digital telephony, access to professional public resources, opportunity to buy modern clothes, goods for everyday life and recreation, availability of necessary services, access to quality and safe medical care. Otherwise, the health worker will have a constant psychological noise that is a serious latent failure in origin of the incidents [57].

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 [58-60].

CONCLUSIONS

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.

REFERENCES

1. Zegers M, Bruijne M.C, Wagner C, Hoonhout LH, Waaijman R, Smits M, et al. Adverse events and potentially preventable deaths in Dutch hospitals: Results of a retrospective patient record review study. Qual Saf Health Care. 2009; 18: 297-302. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/19651935

2. Brennan TA, Leap LL, Larid NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study. I N Engl J Med. 1991; 324: 370-376. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/1987460

3. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The quality in Australian health care study. Med J Aust. 1995; 163: 458-471. **PubMed: PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/7476634

4. Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, Williams EJ, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. Med Care. 2000; 38: 261-271. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/10718351

5. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: Preliminary retrospective record review. BMJ. 2001; 322: 517-519. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/11230064

6. Schiøler T, Lipczak H, Pedersen B.L, Mogensen TS, Bech KB, Stockmarr A, et al. Incidence of adverse events in hospitals. A retrospective study of medical records. Ugeskr Laeger. 2001; 163: 5370-5378. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/11590953

7. Davis P, Lay-Yee R, Briant R, Ali W, Scott A, Schug S. Adverse events in New Zealand public hospitals I: Occurrence and impact. NZMJ. 2002; 115: U271. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/12552260

8. Baker G.R, Norton P.G, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian adverse events study: The incidence of adverse events among hospital patients in Canada. CMAJ. 2004; 170: 1678-1686. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/15159366

9. Michel Ph, Quenon JL, Djihoud A, Tricaud-Vialle S, de Sarasqueta AM. French National survey of inpatient adverse events prospectively assessed with ward staff. Qual Saf Health Care. 2007; 16: 369-377. **PubMed: PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/17913779

10. Aranaz-Andres JM, Aibar-Remon C, Vitaller-Burillo J, Requena-Puche J, Terol- Garcia E, Kelley E, et al. Impact and preventability of adverse events in Spanish public hospitals: Results of the Spanish National Study of adverse events (ENEAS). Int J Qual Health Care. 2009; 21: 408-414. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/19841027

11. Soop M, Fryksmark U, Koster M, Haglund B. The incidence of adverse events in Swedish hospitals: A retrospective medical record review study. Int J Qual Health Care. 2009; 21: 285-291. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/19556405

12. Landrigan CP, Parry GJ, Bones CP, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med. 2010; 363: 2124-2134. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/21105794

13. Aranaz-Andrés JM, Aibar-Remón C, Limón-Ramírez R, Amarilla A, Restrepo F.R, Urroz O, et al. Prevalence of adverse events in the hospitals of five Latin American countries: Results of the 'Iberoamerican Study of Adverse Events' (IBEAS). BMJ Qual Saf. 2011; 20: 1043-1051. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/21712370

14. D'Amour D, Dubois CA, Tchouaket E, Clarke S, Blais R. The occurrence of adverse events potentially attributable to nursing care in medical units: cross sectional record review. Int J Nurs Stud. 2014; 51: 882-891. **PubMed:** **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/24238893

15. Sommella L, de Waure C, Ferriero AM, Biasco A, Mainelli MT, Pinnarelli L, et al. The incidence of adverse events in an Italian acute care hospital: Findings of a two-stage method in a retrospective cohort study. BMC Health Serv Res. 2014; 14: 358. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/25164708

16. Deilkas ET, Bukholm G, Lindstrøm JC, Haugen M. Monitoring adverse events in Norwegian hospitals from 2010 to 2013. BMJ Open. 2015; 5: e008576. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/26719311

17. Nilsson L, Risberg MB, Montgomery A, Sjo¨dahl R, Schildmeijer K, Rutberg H. Preventable adverse events in surgical care in Sweden. A nationwide review of patient notes. Medicine. 2016; 95: e3047. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/26986126

18. Halfon P, Staines A, Burnand B. Adverse events related to hospital care: A retrospective medical records review in a Swiss hospital. Int J Qual Health Care. 2017; 29: 527-533. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/28586414

19. Rafter N, Hickey A, Conroy RM, Condell S, O'Connor P, Vaughan D, et al. The Irish National Adverse Events Study (INAES): The frequency and nature of adverse events in Irish hospitals-a retrospective record review study. BMJ Qual Saf. 2017; 26: 111-119. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/26862223

20. Andrews LB, Stocking C, Krizek T, Gottlieb L, Krizek C, Vargish T, et al. An alternative strategy for studying adverse events in medical care. Lancet. 1997; 349: 309-313. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/9024373

21. Wanzel KR, Jamieson CG, Bohnen JMA. Complications on a general surgery service: Incidence and reporting. Can J Surg. 2000; 43: 113-117. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/10812345

22. Rebasa P, Mora L, Vallverdu´ H, Luna A, Montmany S, Romaguera A, et al. Adverse events in general surgery. A prospective analysis of 13 950 consecutive patients. Cir Esp. 2011; 89: 599-605. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/21871615

23. Forster AJ, Huang A, Lee TC, Jennings A, Choudhri O, Backman C. Study of a multisite prospective adverse event surveillance system. BMJ Qual Saf. 2020; 29: 277-285. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/31270254

24. Atkinson M.K, Schuster M. A, Feng J.Y, Akinola T, Clark K.L, Sommers B.D. Adverse events and patient outcomes among hospitalized children cared for by general pediatricians *vs* hospitalists. JAMA Network Open. 2018; 1: e185658. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/30646280

25. Andrews JM, Remon CA, Burillo JV, Lopez PR. National Study on Hospitalisation-Related Adverse Events (ENEAS) 2005. Quality plan of national health system. Report February 2006. https://bit.ly/34D0GlS

26. Makary MA, Daniel M. Medical error-the third leading cause of death in the US. BMJ. 2016; 353: i2139. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/27143499

27. Andel C, Davidow SL, Hollander M, Moreno DA. The economics of health care quality and medical errors. J Health Care Finance. 2012; 39: 39-50. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/23155743

28. Mello MM, Studdert DM, Thomas EJ, Yoon CS, Brennan TA. Who pays for medical errors? An analysis of adverse event costs, the medical liability system, and incentives for patient safety improvement. Journal of Empirical Legal Studies. 2007; 4: 835-860. https://tinyurl.com/sclv3vx

29. Tokyo Declaration on Patient Safety. Tokyo. April 20, 2018. Third Global Ministerial Summit on Patient Safety.

30. Thiels CA, Lal TM, Nienow JM, Pasupathy KS, Blocker RC, Aho JM, et al. Surgical never events and contributing human factors. Surgery. 2015; 158: 515-521. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/26032826

31. Macchi L, Pietikäinen E, Reiman T, Heikkilä J, Ruuhilehto K. Patient safety management. Available models and systems. Finland, 2011. https://tinyurl.com/ubm5ps5

32. Leap LL, Brennan TA, Nan Laird MPH, Lawthers AG, Localio AR, Barnes BA, et al. The Nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice study II. N Engl J Med. 1991; 324: 377-384. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/1824793

33. Beuzekom M, Boer F, Akerboom S, Hudson P. Patient safety: Latent risk factors. Br J Anaesth. 2010; 105: 52-59. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/20551026

34. Lawton R, Carruthers S, Gardner P, Wright J, McEachan RR, et al. Identifying the latent failures underpinning medication administration errors: An exploratory study. Health Serv Res. 2012; 47: 1437-1459. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/22375850

35. Reason J. Human error: Models and management. BMJ. 2000; 320: 768-770. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/10720363/

36. Hoffmann B, Rohe J. Patient safety and error management. Dtsch. Arztebl. Int. 2010; 107: 92-99. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/20204120/

37. Mitchell R, Williamson A, Molesworth B, Chung A. A review of the use of human factors classification frameworks that identify causal factors for adverse events in the hospital setting. Ergonomics. 2014; 57: 1443-1472. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/24992815

38. Carayon P, Schoofs Hundt A, Karsh B, Gurses AP, Alvarado CJ, Smith M, et al. Work system design for patient safety: The SEIPS model. Qual Saf Health Care. 2006; 15: 150-158. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/17142610

39. Clancy C, Tornberg D. TeamSTEPPS: Assuring optimal teamwork in clinical settings. Am J Med Qual. 2007; 22: 214-217. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/17485563

40. Edmondson A. Learning from failure in health care: Frequent opportunities, pervasive barriers. Qual Saf Health Care. 2004; 13: 113-119. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/15576689

41. Lyons M. Should patients have a role in patient safety? A safety engineering view. Qual Saf Health Care. 2007; 16: 140-142. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/17403763

42. Verstappen W, Gaal S, Esmail A, Wensing M. Patient safety improvement programmes for primary care. Review of a Delphi procedure and pilot studies by the LINNEAUS collaboration on patient safety in primary care. Eur J Gen Pract. 2015; 21: 50-55. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/26339837

43. Haugen AS, Søfteland E, Eide GE, Nortvedt MW, Karina Aase K, Harthug S. Patient safety in surgical environments: Cross-countries comparison of psychometric properties and results of the Norwegian version of the hospital survey on patient safety. BMC Health Serv. Res. 2010; 10: 279. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/20860787

44. Profit J, Etchegaray J, Petersen L.A, Sexton J.B, Hysong S.J, Mei M, et al. The safety attitudes questionnaire as a tool for benchmarking safety culture in the NICU. Arch Dis Child Fetal Neonat Ed. 2012; 97: 127-132. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/22337935

45. Pronovost P, Weast B, Holzmueller C, Rosenstein BJ, Kidwell RP, Haller KB, et al. Evaluation of the culture of safety: Survey of clinicians and managers in an academic medical center. Qual Saf Health Care. 2003; 12: 405-410. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/14645754

46. Lilford R, Mohammed M, Braunholtz D, Hofer T. The measurement of active errors: Methodological issues. Qual Saf Health Care. 2003; 12: 8-12. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/14645889

47. Hibbert P, Williams H. The use of a global trigger tool to inform quality and safety in Australian general practice: A pilot study. Aust Fam Physician. 2014; 43: 723-726. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/25286432

48. Michel PH, Quenon J, de Sarasqueta A, Scemama O. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. BMJ. 2004 January; 328:199. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/14739187

49. Griffin FA, Resar RK. IHI global trigger tool for measuring adverse events (Second Edition). Institute for Healthcare Improvement. Cambridge, 2009. https://tinyurl.com/w8hedgq

50. SH NCP 25 Risk Management Strategy and Policy (Version: 6). December 2018.

51. Pietra L, Calligaris L, Molendini L, Quattrin R, Brusaferro S. Medical errors and clinical risk management: state of the art . Acta Otorhinolaryngol Ital. 2005; 25: 339-346. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/16749601

52. Shaw R, Drever F, Hughes H, Osborn S, Williams S. Adverse events and nearmiss reporting in the NHS. Qual Saf Health Care. 2005; 14: 279-283. **PubMed:** https://www.ncbi.nlm.nih.gov/pubmed/16076793

53. National Quality Forum (NQF), Serious Reportable Events in Healthcare-2011 Update: A Consensus Report, Washington, DC: NQF; 2011. **PubMed:** https://bit.ly/2XHuLPJ

54. Shikina IB, Vardosanidze SL, Voskanyan Yu E, Sorokina NV. Problems of patients' safety assurance in modern medical care. Moscow, Publishing House Glossarium LL; 2006. p. 336.

55. Act on Patient Safety in the Danish Health Care System ACT No. 429 of 10/06/20037

56. Mintsberg H. The structure of organization. Prentice Hall. 1st ed. 1978. **PubMed:** https://bit.ly/2Vvuahh

57. Zadvornaya OL, Voskanyan Y.E, Shikina IB, Borisov KN. Socio-economic aspects of medical errors and their consequences in medical organizations. MIR (Modernization Innovation Research). 2019; 10: 99-113. **PubMed:** https://bit.ly/34I11E2

58. World Alliance for Patient Safety. Forward Programme 2008-2009.

59. Voskanyan Y, Shikina I, Kidalov F, Davidov D. Medical care safety-problems and perspectives. 2020; 78: 291-304. **PubMed:** https://bit.ly/2Vcp8aL

60. WHO patient safety curriculum guide: multi-professional edition. World Health Organization 2011.