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FRAMEWORK FOR RESEARCH OF HUMAN ERROR IN MEDICINE

Bojan Bijelic[1, a], Miroljub Grozdanovic[2,b]

[1,2]University of Nis, Faculty of Occupational Safety in Nis, Carnojevica 10a, Nis, Serbia

[a]bojan.bijelic@znrfak.ni.ac.rs, [b]mirko@junis.ni.ac.rs

Abstract The object of research in this paper is the analysis of human error in medicine. This research is becoming more necessary and important in medical practice and is given more attention by medical staff, professional organizations, and many governments. The methodological approach is aimed at the development and application of methods for recognition, presentation, quantification, and reduction of human error. Results shown in the paper refer to task and error analysis in surgery, human error identification for the application in healthcare, Fault Tree applied in medication error, and application of HFACS method in determination of human error in medical waste management. Since human error is a part of normal human behavior, it is inevitable in medicine as well. Results shown in this paper can stimulate further research in this area, thus reducing human error, which significantly influences poor outcomes in many patients.

Keywords: Human error, medication errors, error analysis, error identification, error quantification, error reduction.

1. INTRODUCTION

During the last two decades, it is becoming more obvious that human error in medicine is neither rare nor unsolvable. The medicine defines human error as a minor factor in medical complications. As the amount of data on human error in medicine increases, including media involvement, medical management is becoming more comprehensive of the issue. The 1999 Institute of medicine report brought larger attention to the public, medical management, and various governments on the subject. This report, published in the 'To Error is Human', introduced the term human error and its role in patient safety [1], and evaluated the nature of human error using classification in medical practice, including medication, procedures, diagnosis, and errors [2].

The report raised awareness on healthcare deficiencies that directly influence patient safety [3]. These findings stimulated a quick institutional intervention to decrease the frequency of medical errors without full comprehension of their causal connection. Individual interventions will probably not give desired results, which is indicative of insignificant influence on the reduction of errors shown thus far [4].

As seen in commercial and military aviation, a further significant decrease in accidents and errors has been achieved by acknowledging the importance of human factors in safety [5]. The same could be expected in medicine.

The term "human error" is a broad category that involves errors that are easy to recognize and diagnose. It is usually defined as an "error in conducting of a required procedure", and involves unwanted actions or activities that deviate from expected standards or norms, thus endangering patients. The concept of human error is defined as human action or lack of action that leads to

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unacceptable system risk with defined limitations of human performance [6]. Errors can occur due to: lack of precision, unprofessional handling, rule recognition oversight, memory oversight, cognitive oversight, attentive oversight, etc.

It is essential to examine errors in the context of a surgeon operating on a patient, which will explore the issue of error and accountability. During an operation, there is a specific action that can be defined as an error e.g. damaging the femoral vein. This is a specific event and is called the coal-face error (active). The importance of this specific definition is that it provides a reference point in defining surgical errors. The other type of error is the systemic error (latent), which is a series of events that leads up to an error, sometimes referred to as the root cause e.g. improper preparation of the patient. These surgical definitions correspond roughly to Reason's terminology of active and latent errors [7].

Clinical errors and malpractice claims are increasingly important aspects of medical practice. There is concern that the risk of acquiring disabling illness due to medical intervention during hospitalization is contributing to the cost of care, adding to the burden of the patient and as a result of malpractice claims, causing mounting and spiraling costs to the health-care system and for society at large [8].

The Institute of Medicine (IOM) report estimated the total cost of medical error as USD 17–29 billion per annum [3]. The relative paucity of data on patient safety in countries other than the USA and in particular in developing and emerging economies has been commented upon [9, 10]. There have been calls for knowledge sharing, arguing for the development of an international knowledge database [11]. There are increasing numbers of reports on clinical errors from other countries [12-15].

2. MAIN PHASES IN HUMAN ERROR EVALUATION

Although many authors suggest different approaches for identification, prediction, and evaluation of human error, analyzing a large number of theories, models, and research in this area, it can be concluded that we can define four main phases of research: recognition of human error, presentation of human error, quantification of human error and reduction of human error [6]. Each of these phases contains activities that define it.

2.1. Human error recognition

The first and basic step in human error recognition is the definition of a problem and the research area of the analyzed system. It enables the definition of system goals and criteria for their realization, and conditions and scenarios that need to be considered before the formation of safety evaluations. The main research areas in human error recognition are task analysis, human error analysis, and human error identification.

2.1.1. Task analysis

Task analysis (TA) is the main analysis providing a detailed description of the operator`s activities in which an error could be recognized. There are many forms of task analysis, and in this paper, we present three most commonly used: task sequence analysis, which evaluates operator`s actions as events in chronological order; hierarchical task analysis (HTA), which considers tasks within a

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hierarchy of aims and work analysis (WA), which studies mutually connected work components: working demands, working environment and working behavior.

2.1.2. Human error analysis and identification

Human error analysis considers the human impact on danger and risk genesis. It is the most important part of the evaluation: if an important error is undetected, it will not be considered and the results can seriously underestimate the effect of human error on the analyzed system. Therefore, during each step of the procedure of activity and task definition and analysis, is necessary to consider the following groups of errors: oversight errors, uncertain activity (when the defined recommendations are not being performed), execution error, inadequate action (when the activities are not performed completely or when an action is performed prematurely or too late) and wrongful execution error (when actives are performed wrongly). Human error identification is the most practical phase in the process of human reliability evaluation, fore if an error is undetected in this phase, it will not be quantified and reduced, but remain as hidden and latent errors within the evaluation itself. The development of methods for human error identification is significant because well-performed identification represents a good foundation for human error quantification.

2.2. Human error representation

Formal methods used in the display of complex tasks and error sequences that can occur in a system are fault tree analysis and event tree analysis.

Fault tree analysis (FTA) is a graphic analytic method, which provides a systematic description of possible conditions of a system resulting in an adverse event or error. These events are undesired systemic conditions, which can occur as a result of functional problems in systemic function but also as a result of human error.

For reliability analysis in systems with possible errors, the application of Event Tree Analysis (ETA) is particularly important. It is an inductive logical method for the identification of various possible outcomes of an initial event.

2.3. Human error quantification

Human error quantification considers human behavior mechanisms in all possible manifestations. Numerous literature data contain analysis of methods used in human error evaluation, based on expert assessment [6]. All human reliability quantification methods are based on human error probability (HEP) calculation, which is a measure of human reliability. HEP is defined as:

$$HEP = \frac{n}{N}$$

Where: n is a number of human error events and N is a number of possibilities (activities) of error.

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In human error analysis, theory of active and latent error suggested by Reason stands out. This theory finds its purpose in a grouping of human errors and classification of mutual influences between humans and technology in various systems.

Reason's model of accident causation provides a theoretical framework that dissects the potential etiology of errors. The theory explains that accidents are caused by active failures (decisions performed by individuals at the delivery end of a system) and latent failures, which are a result of deficiencies in the organizational and management levels of a system. Latent failures predispose a system to error and may result in adverse events if any deficiencies are present within the levels of an organization. Figure 1. Illustrates Reason's "swiss cheese" model of accident causation. This model illustrates that the organizational influence (climate, resource management, and policies) impact supervisory processes (scheduling, training, and oversight), which in turn establish the preconditions (technological and teamwork related) that produce errors [16].

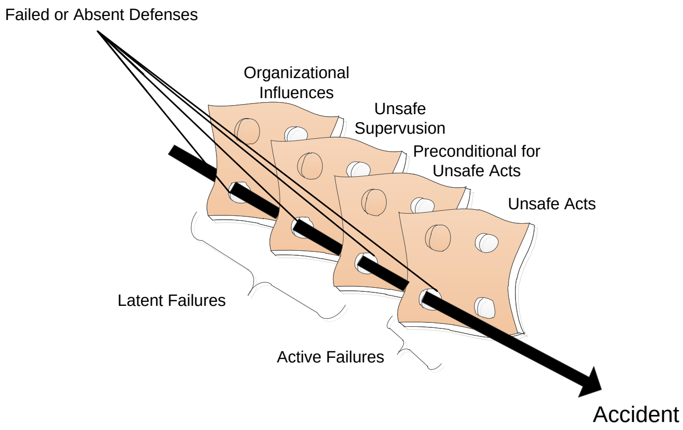

Figure 1. The "Swiss cheese" model of human error causation.

2.3.1. Human error databases

Human error databases formation had three phases. The first phase lasted from 1970 to 1980, during which a significant number of data was collected. In the second phase (1980-1990) this approach was neglected due to the collection of a small amount of data. The third phase lasted from 1990-2000, and after NUCLARR project and numerous studies by Kirwan, interest in data collection on human error was revived. Identification of human error represents the main difficulty occurring during a gathering of operational empirical data which leads to the formation of quantitative HEP. To gain relevant data, human error identification should be performed without determining guilt and in an anonymous manner, to avoid punishment for the perpetrator. However, the main precondition for the correct implementation of human error databases is a determination of individual responsibility for specific accidents. This requires an unbiased judgment, which is not always easy to provide. Despite these difficulties, a certain number of data on human error was formed based on a collection of operational empiric data and can be used adequately. Ideally, all data should be collected from operational experiences, experiments, or relevant simulations. However, very small number of data is collected

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from these resources and most databases are comprised of data from other resources such as expert evaluation.

Most commonly known human error databases are CORE-DATA (Computerized Operator Reliability and Error Database), HERA (Human Event Repository Analysis), HPES (Human Performance Evaluation System), HFIS (Human Factors Information System), CAHR (Connectionism Assessment of Human Reliability), SACADA (Scenario Authoring, Characterization, and Debriefing Application), etc [17].

2.4. Human error reduction

In cases of a significant impact of human error, there is a notable destabilization of an analyzed system. In these cases, the need for human error reduction increases and can be accomplished with workplace design, activity procedure formation, or the development of staff training methods. If human error reduction becomes necessary, the influence and frequency of an analytically identified error can be reduced with the development of a general strategy for error reduction (e.g. Human Reliability Management System – HRMS) to enhance overall system performance.

There are various modes for the reduction of error influence on an analyzed system. These are predictability enhancement (enhancement of operator`s skills in anticipation of a problem), cognitive enhancement (enhancement of the ability to precisely determine abnormalities and enhancement of abnormality diagnostics), enhancement of skills and jurisdiction of an operator (accomplished with training), and formation of strategies for error reduction (formation of strategies and various scenarios for various types of errors).

3. RESULTS

3.1. Surgical Task and Error Analysis

Task analysis has been used in surgery to identify and quantify errors executed during an operation. In this paper, we present methods (M) and conclusions (C) on task & error analysis papers from 1995 to 2005.: M - Task analysis of specific tasks & motion analysis of generic movements & C - Novices performed specific tasks and generic movements slower than expert surgeon [18]; M - Task & error analysis of specific & generic aspects of laparoscopic cholecystectomy data capture can study human error in laparoscopic surgery & C - Categorization of interstep (procedural) & intrastep (execution) errors [19]; M - Hierarchical task analysis of laparoscopic cholecystectomy, inguinal hernia repair, fundoplication & C- HTA can be used to study the relationship between goals 7 actions at various levels of the hierarchy [20]; M - Error checklist scoring of procedural tasks in laparoscopic cholecystectomy & C - Error checklist scoring was reliable, valid & practical [21]; M - Generic sub-task analysis of instruments used in various laparoscopic operations & C - Laparoscopic instruments used to perform a variety of maneuvers in addition to primary function [22]; M - Consequential & inconsequential errors derived from task analysis of laparoscopic cholecystectomy & C- OCHRA provides objective & comprehensive assessment of surgical performance [23]; M - Error event definitions of generic & specific aspects of laparoscopic cholecystectomy & C-Reliability of defined procedural errors [24].

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3.2. Task analysis of laparoscopic and robotic surgery

Task analysis (TA) is often represented by tables or flow charts, which reflect the chronological nature of this method of analysis. To construct a surgeon's view of a TA of an operation/procedure, the process is followed in 7 phases [25].

A series of consensus conferences have convened to compile the outcome measures to form the basis for an FRS (Fundamentals of Robotic Surgery) program. In 2012, Dulan et al. [26] identified the cognitive and procedural skills needed for robotic surgery using a list of 23 tasks. The same year, this list was discussed at the SLS (Society of Laparoendoscopic Surgery) consensus meeting in Boston, resulting in the definition of 25 specific outcome measures [27], categorized into preoperative (System settings, Ergonomic positioning, Docking Robotic trocars, Operating Room set up, Situation awareness, Closed loops communications, Respond to system errors); intraoperative (Energy sources, Camera control, Clutching Instrument exchange, Foreign body management, Multiarm control, Eye-hand instrument coordination, Wrist articulation, A traumatic tissue handling, Dissection—fine blunt, Cutting Needle driving, Suture handling, Knot tying, Safety, and operative field), and postoperative (Transition to bedside assistant, Undocking tasks). These tasks can now become the accepted standard for training and certification [28].

3.3. Human error identification and analysis techniques

Human error identification and analysis techniques for application in healthcare are Barrier analysis [29], Change analysis [30], Failure Modes Effects Analysis (FMEA) [31], Influence diagrams, and Systematic Human Error Reduction and Prediction (SHERPA) [32].

3.4. A Fault and Event Tress applied to medication error

An example of a fault tree is shown in Figure 2. While the numbers in the example are entirely fictitious, the diagram shows how physical and human error probabilities can be combined using logical OR gates to provide an overall estimation of an adverse outcome. These use Boolean logic where probabilities are assigned to events. These are inputted to a gate and result in the calculation of the overall probability for the top event. An event tree is a tree-like diagram that splits according to escalation and recovery events as well as an operator's choices between responses at each stage. Usually, the probability of given branches is calculated thus providing the expected probability of each outcome. In addition, the concept of Cognitive Event Trees has been developed to examine the effects of decisions made regarding ambulance treatment of patients [33]. A fault tree is a tree diagram using AND/OR logic which is used to examine how an incident occurred or could occur due to contributing factors and events. It can be used for safety risk modeling in healthcare [34], medication applications [35], and analysis of nuclear medicine [36].

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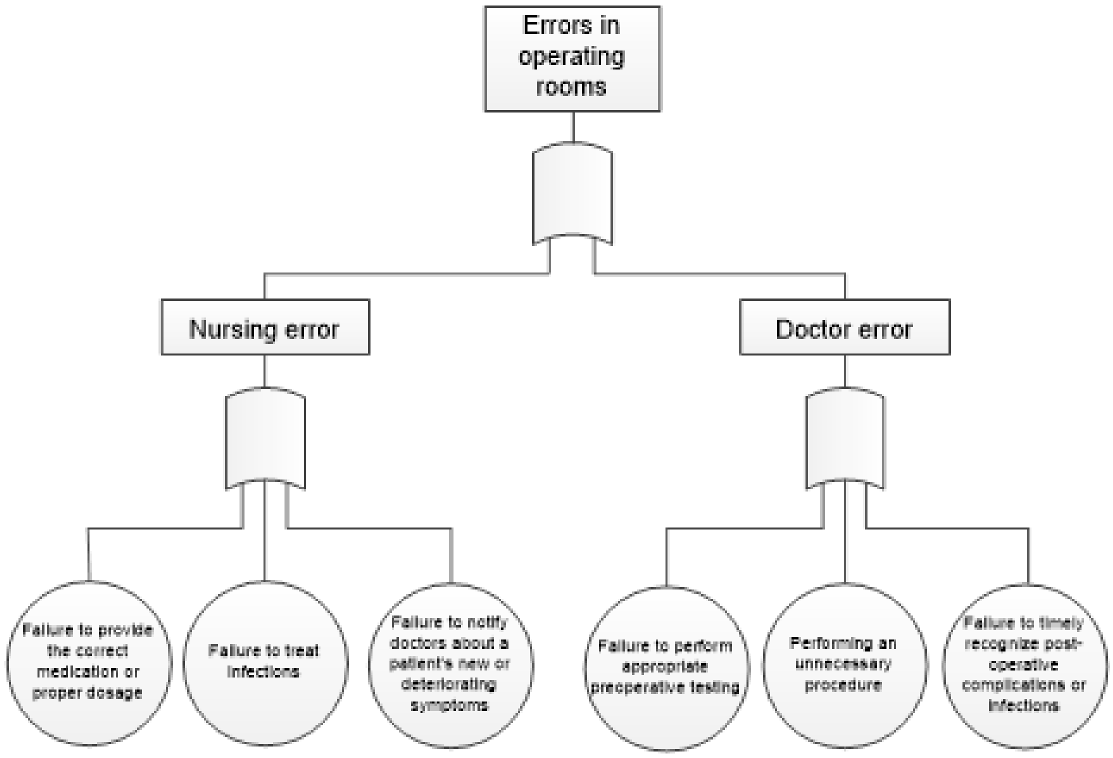

Figure 2. A Fault Tree applied to medication error.

3.5. Improvement of Reason`s model using HFACS method

Improvement of Reason`s model is accomplished using models, Human Factors Analysis and Classification System – HFACS, that overcome its shortcomings and add a precise definition of active and latent failures. HFACS describes four types of failure levels (unsafe activity, preconditions for unsafe activity, unsafe supervision, and organizational influences), each corresponding to one of the four layers within Reason`s model. These are:

- unsafe activity, with active failures of the operational staff;
- preconditions for unsafe acts, it is consist of environmental factors, operational staff condition, and additional staff factors;
- unsafe supervision, which represents latent additional staff failures and
- organizational influences, which refer to latent failure by staff on the highest executive level, whose decisions directly influence control, conditions, and actions of operational staff.

Application of the HFACS method regarding the determination of causes of human errors in the management of medical waste in a tertiary medical institution in the Republic of Serbia is shown in the paper Makajic-Nikolic et al. [37]. Medical waste is defined as „all waste, dangerous or not, which is generated while providing medical care". Analysis of human error causes is performed for infective waste because it is waste with the longest life cycle which carries a large risk of infection. The infective waste consists of: cultures and material from laboratories that contain infective agents;

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equipment, material, and tools in contact with blood, blood derivatives, and bodily fluids; excretions from clinically verified infective patients; waste from medical wards for pathology and isolation of infective patients; waste from dialysis or infusion, etc. A high-risk event that was analyzed for possible causes of human error in this system was a probability of infection as a result of human error in medical waste management. It was noted which errors could occur and on which of the four levels (Figure 3).

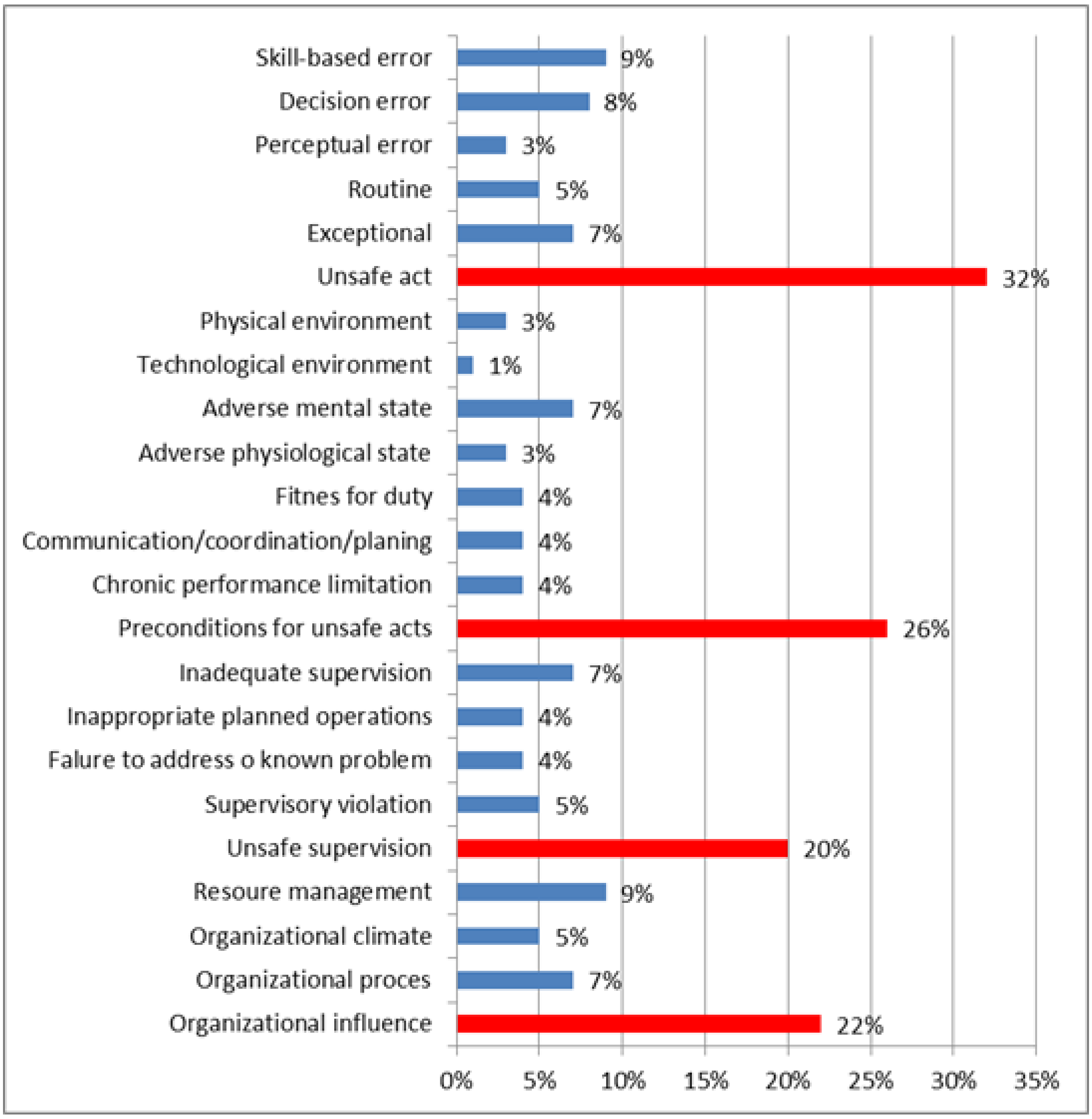

Figure 3. Human errors in the management of medical waste [37].

The largest number of various human error causes occurs within the category of unsafe activity (32%). Among them, the most common errors are skill errors (inadequate filling technique or inadequate binding of the packaging to the infective material, poor judgment of packaging fullness, putting gloves on uncarefully), decision-making errors (use of inadequate packaging due to lack of adequate packaging, inadequate reaction to packaging damage, etc.) extraordinary errors. Errors in resource management within organizational influences occur with a significant percentage (9%).

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3.6. Use of human error reduction in medicine

To reduce human errors in cardiac surgery, the Flawless Operative Cardiovascular Unified Systems initiative (FOCUS) was formed, which was developed in conjunction with the Johns University Quality and Safety Research Group using an approach focused on locating errors through network surveillance (LENC). LENC process has three main areas: interactions (communication) between the operating room and cardiac team members; clinical performance of knowledge quality and safety dependent processes and ergonomics/safety or human-machine interfaces [38].

The purpose of the research was to develop an algorithm to permanently reduce human errors in healthcare. The research involved analysis of methods of error reduction. The Failure Modes and Effect Analysis (FMEA) started the distancing from reacting to errors and moved toward the beginning of prevention of errors from occurring.

A popular choice among hospitals has been to use a methodology called Root Cause Analysis (RCA) [39, 40]. RCA is a systematic approach aimed at discovering the causes of close calls and adverse events to identify preventative measures. RCA teams look beyond human error to identify system issues that contributed to or resulted in the close call or adverse event. The goal is to answer what happened, why it happened, and what can be done to prevent it from happening again. RCA has been used by many hospitals to investigate their adverse events or adverse drug events (ADE).

In the Human Simulation Center (HSC), which dealt with training for interaction between medical teams with the aim of human error reduction, a “MevidIO” program was formed with a live-monitoring and debriefing framework. Developed for a full-scale simulation center designed to model error transduction in medical emergency care process chains, the framework integrates educational and scientific aspects [41].

To improve human error source identification and develop preventive methods for their reduction, research in four broad areas of medical activity was conducted: use of medical devices, use of drugs, teamwork, and diagnostic/decision support [42].

4. DISCUSSION

Every year, people die due to medical errors and the problem is larger than most people realize. Between fifty and one hundred thousand people die yearly due to medical errors. This total is greater than all the people that died due to motor vehicle accidents, breast cancer, and AIDS combined.

There are claims that medical errors are a problem for cognitive scientists. However, the majority of researchers emphasize the importance of human error studies performed by medical workers, using practical examples, to prevent these errors [43].

Some medical human errors show a tendency toward repetition, due to unsolved perceptive, cognitive, and behavioral problems, which occur during contact between medical staff and patients [44].

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The belief that we would not have medical safety problems if people would stop making errors, if taken to its logical conclusion, suggest that to improve safety, one needs to get rid of errors. People, though, make errors. Therefore, as long as there are people (patients and providers) in medical units, there will be errors. Efforts to improve patient safety that depend on requiring people to be faultless are misguided and wasteful. The reason goes beyond simply that “people make errors” – research demonstrates that errors often are caused by poorly designed systems, which some have referred to as “design-induced” errors. See also the report, for an excellent example of how poor design leads experienced emergency medical technicians to error [45]. Therefore, if an error occurs, one should not ask: “why did the person make the mistake”, but rather: “what caused the mistake to occur?” [46].

Health care practitioners must learn the underlying reasons for their mistakes and appreciate appropriately designed countermeasures because learning about errors in medicine is necessary, effective, and relatively easy.

If national authorities find a way to harmonize and formalize critical aspects, such as the severity of standard events, it is possible to estimate risk and define auditing needs, well before the occurrence of serious incidents, and to indicate practical ways toward the improvement of safety standards.

5. CONCLUSIONS

American Institute of Medicine report and numerous literature data show that medical errors often lead to the death of a patient. These errors could have been lessened by correct analyses which lead to defined professional recommendations. However, recognition of the importance of medical human errors occurs only in the last few years. Although various medical areas have a large number of employees, there is no significant interest in research on human resources and human work-related errors. There are even suggestions to young researchers in this area not to show significant interest in the subject. However, a number of scientists that are proposing a different approach increases. Human error in medicine should be studied professionally to fully contribute to their reduction. Therefore, we think that the contribution of results shown in this paper is significant because it influences error reduction in medicine, which increases patient safety.

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