

MEDICAL ERRORS AND PATIENT SAFETY CULTURE – SHIFTING THE HEALTHCARE PARADIGM IN ROMANIAN HOSPITALS

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Abstract: Patient safety (PS) is a global concern of national health systems, defined as the patient's right not to be subjected to unnecessary harm potentially associated with the medical act. Reporting medical errors for learning purpose was deeply encouraged by WHO during the last 10 years, as a mandatory step in preventing future errors and increasing patient safety.

Aim. The paper aims to analyze the level of implementation of Patient safety culture (PSC) and reporting adverse events in Romanian hospitals, during 2011-2019, in the context of this globally shifting paradigm in healthcare.

Materials and methods. The paper is a review of articles published in international databases conducted by the keywords “patient safety” and “medical errors”. A documentation of the statistical data reported by the national health institutions regarding the reports of EA in different national systems was carried out.

Results. Passive reporting of the AEs in the national surveillance systems is on an upward trend, but still low when compared to Western European countries. Several prospective studies, on a limited number of hospitalized patients, showed a prevalence of HAIs 10 times higher than that reported (2,8-5% vs. 0.4%). Similar results were found for reported adverse drug reactions and other adverse events. Missing information about who should report, what should be reported, what are the AEs that are useful for learning purposes, what are the consequences of reporting upon individuals and upon institutions are all important causes of a low rate of reporting.

Conclusions. Changing the culture in healthcare is a longstanding process, but the results in recent years are encouraging. The popularization of “no blame culture” and “learning by reporting AEs”, increasing communication and teamwork by hospital management and national healthcare institutions will improve patient safety in Romanian hospitals.

Key words: medical errors, adverse events, patient safety, malpractice.

INTRODUCTION

Patient safety (PS) is a global concern of national health systems, defined as the patient's right not to be subjected to unnecessary harm potentially associated with the medical act. The adverse event (AE) is defined as unintentional and unwanted impairment of health, injury, illness, temporary or permanent disability or even death of the patient, associated with healthcare, which does not have a direct causal relationship with the disease or treatments applied. Some adverse events are preventable, they represent medical errors of execution or of planning, by omission or by commission, while

other events cannot be attributed to a person, they are due to hazard. An error may or may not cause an adverse event. According to James Reason theory of “swiss cheese model”, most frequently, for a serious AE to happen, a series of minor errors occurs.

A large-scale statistical study of adverse events associated with medical care is difficult, in part due to individual reluctance to report, but also due to the fact that data related to events with potential impact on patient safety are fragmented information found on multiple subsystems: patient electronic file, epidemiological surveillance of nosocomial infections, pharmacovigilance and registry of adverse drug

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reactions, hemovigilance, and other national reporting systems. However, the extent of this phenomenon in health is significant. WHO statistics estimate that 5 people die every minute in the world due to unsafe care [1]. Preventable deaths due to unsafe that are estimated at 200,000 / year in the US, being considered the third leading cause of death in hospital [2].

The publication of the report “To Err is Human - Building a safer health” in 1999 by the IOM Committee on Quality Health Care in America, followed by “Crossing the Quality Chasm - New health system for the 21st Century” in 2000 changed the approach to this phenomenon in the health system, often overlooked. Health professionals have understood that in order to increase patient safety, these errors must be documented, and a change in mentality is mandatory [2, 3]. Thus, there is presently a global transition from the traditional medical and legal approach, which seeks to find the culprit in a person or group of people who did not or did something wrong in a more complex approach to finding the root causes at the level of the system, institution, work flow or practice protocols. It is considered that the most common causes of medical errors are related to stress, exhaustion, poor communication and teamwork or insufficient training for certain staff procedures. In a modern health system, where the patient is considered a partner, honest reporting of errors should be encouraged and used as a means of learning, not sanctioned and repressed [2-4].

Reporting medical errors for learning purpose was deeply encouraged by WHO during the last 10 years, as a mandatory step in preventing future errors and increasing patient safety. In 2015, the EU health commission validated a minimal information model for reporting PS incidents, to allow a comparative analysis and exchange of information between member countries [5].

AIM

The paper aims to analyze the level of implementation of Patient safety culture (PSC) and reporting adverse events in Romanian hospitals, during 2011-2019, in the context of this globally shifting paradigm in healthcare.

MATERIALS AND METHODS

The paper is a review of articles published in international databases conducted by the keywords “patient safety” and “medical errors”. A documentation

of the statistical data reported by the national health institutions regarding the reports of EA in different national systems was carried out.

RESULTS

Romanian hospitals are characterized grossly by large number of beds per 100000 inhabitants (525.3 vs. 372.2 in EU), and one of the highest rate for discharge patients in EU, of more than 35000 at 100000 inhabitants [6], but unequal access to novel investigations and treatment methods among regions, chronic under-financing and loss of human resource in healthcare. On the other hand, there is an increase in development of the private sector, with modern commodities and medical equipment, but with a significantly reduced addressability in comparison to public hospitals partially due to economic reasons.

Reporting HAIs during 2011-2019

Regarding the reporting of different types of AEs, both mandatory and voluntary, the official data is well below the European average. The most analyzed field in the last decade was that of hospital acquired infections (HAIs), whose reporting is mandatory. HAIs is a major public concern; it is an important source of expenses in health budget and it is also a quality indicator of healthcare. HAI prevalence in high-income countries is of 7.5%, although others have reported rates of 5.7%–7.1% in Europe and 4.5% in the US, while in low- and middle-income countries, the prevalence rate ranges between 5.7% and 19.2% The most frequent AEs reported in EU, HAIs are estimated to affect 5% of hospitalized patients, namely about 4.1 million patients/year, with the 4 most common types being: urinary tract infections (27%), lower respiratory tract infections (24%), surgical site infections (17%) and bloodstream infections (10.5%) [7-9]. The burden of treating HAIs on healthcare expenses is estimated to be only in the UK at £ 1 billion per year. In the USA, there are 1.7 million infections occurring each year related to healthcare assistance, and the costs are estimated at \$ 5-50 billion [10].

The level of HAIs reported in the national passive surveillance system was in the period 2008-2010 an extremely low level, of approx. 0.2%, the majority share being that of respiratory infections, to this situation contributing both under-reporting and under-diagnosis of this type of infection in Romanian hospitals. A comparative analysis of hospitals report of HAIs, microbiological lab data and in-hospital

antibiotic prescriptions, performed by Mada [11] (2008) estimates that Romanian hospitals reported less than 10% of the real HAIs, one on the causes being the lack of training and protocols to identify hospital acquired infections, microbiological reports being far more accurate in document the presence of the multi-resistant germs that should be considered hospital related infections. The prevalence study conducted by ECDC in 2012 in ten hospitals in Romania shows a prevalence of HAIs 10 times higher than that actually reported (2.8% -5%). Similar results are found also by Suetens *et al.* [12]. The importance of acknowledge and active screening for HAIs is not only economical, but there are studies that well correlate the rate of mortality and the rate of nosocomial infections in ICU [13].

An important step was the introduction of the National Register of *Clostridium difficile* infections in 2014, followed in 2016 by the National Register of HAIs reporting in sentinel regime for sepsis, pneumonia, urinary tract infections, secondary infections of medical devices and surgical wound infections. Thus, if in 2011 the reported HAIs were 8105 (0.2%), their number doubled in 2016 and continues to grow presently. Another observation is that the structure of HAIs has changed significantly. If in 2011 the most common were respiratory infections, in 2017 digestive infections took the first place (40.89%) [14]. This change clearly supports the fact that the implementation of strict protocols for the diagnosis and reporting of HAIs improves the documentation of this phenomenon in Romanian hospitals (Fig. 1).

Reporting of adverse drug reactions (ADR)

Voluntary reporting of adverse drug reactions (ADRs) in the National Pharmacovigilance reporting system is not a common practice in Romanian hospitals. Several studies pointed out important differences between Romania and Western countries: Farcas *et al.* [15], in 2006, documented that the Romanian staff

reported within the 351 ADRs only (*versus* 20,648 ADRs in France and 20,410 in England). Spontaneous reporting of ADRs, as part of pharmacovigilance, is very little known and used in Romania. In a study conducted by Paveliu [16], 72.93% of surveyed physicians admitted that they have never sent any report, as opposed to 38.7% in Germany, the main cause being the lack of information regarding the mechanism of reporting. In a study performed by active surveillance and voluntary reporting in 2 internal medicine clinics, the overall incidence of ADRs was of 4.7% of hospitalized patients, and 41% of these were considered preventable. The main identified causes were: drug interactions (49.5%), followed by inappropriate dose, inappropriate monitoring, allergic reactions or lack of compliance [17, 18]. ADRs are an important patient safety concern and they are often preventable. A systematic analysis of the most common and repetitive patterns in the clinical setting should be performed regularly in order to propose adequate prevention strategies.

Reporting adverse events (AEs) for learning purpose in national system

In Romania there is a national reporting system of medical errors for learning purpose, created by the National Agency for Quality Management in Health, functioning since 2017, according to European recommendations. All AEs have to be reported, also near-miss and sentinel AEs, for the purpose of learning and creating strategies for improving clinical protocols. Reporting has to be done within first 24 hours or during the first working day. If there were no AEs, this should be reported every trimester. Presently, there are 639 hospitals and unit assimilated to hospitals in Romania that are registered in this electronic platform, yet only 40.3% reported AEs during 2019. The total number of AEs increased from 2324 in 2017 to 5879 in 2019 (Figs 2, 3) [19].

The data analysis shows that the most common AEs reported are HAIs, but their incidence is below the European average. One cause would be the efforts to implement national HAIs reporting programs since 2014, which have made medical staff already aware and educated about reporting this type of AEs, however HAIs reported in this system are only 19.23% of the total HAIs reported in the National Institute of Public Health surveillance system, showing that further efforts are needed to educate medical staff about the importance of reporting for learning purpose.

AEs reporting in Romanian hospitals is on an upward trend, but is still well below the EU average.

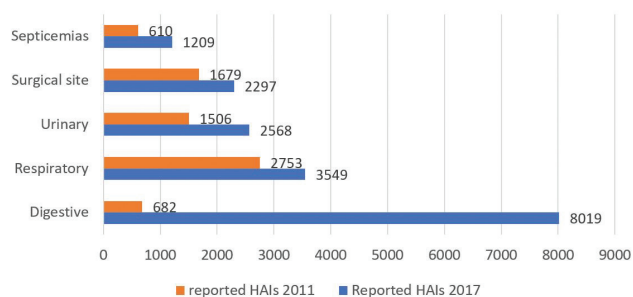


Figure 1. Reported HAIs in 2011 vs. 2017 in Romanian hospitals.

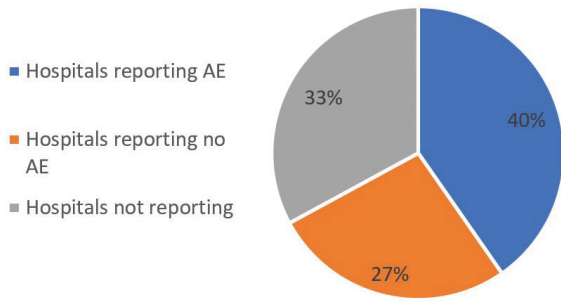


Figure 2. Distribution of hospitals reporting AEs for learning purpose.

This means that this phenomenon cannot yet be known and fought efficiently. Although HAIs remain the most common type of AEs reported, the real burden cannot be known due to the technical difficulties of large-scale data collection, lack of uniformity of diagnostic criteria, the different complexity of treated cases and unequal implementation of safety culture and reporting in Romanian hospitals.

The AE rate is estimated between 8-12% of hospitalizations in EU countries, and of these 50% are preventable and 30% can lead to patient death [20]. According to WHO data from 2017, out of the 421 million hospitalizations that take place annually, 42.7 million have adverse events, of which the most common causes are: surgery (27%), medication errors (18.3%) and in-hospital infections (12.2%), generating additional costs of up to 15% for national health systems and being an important cause for the lack of trust of the population in health systems and staff medical. It is estimated that approx. 7 million patients have complications each year, of which one million are fatal [20].

On the other hand, when questioning the patients, the common perception is that AE are even more frequent. 23% of European Union citizens claim to have been directly affected by medical error and 18% declared to have experienced a serious AE during hospitalization [21]. Evidence on medical errors shows that 50% to 70.2% of such harm can be prevented through comprehensive systematic approaches to patient safety [20].

The causes of underreporting AEs

The road to improving patient safety is long and complicated, and remains an ongoing concern. Under the influence of international trends of shifting healthcare paradigm and encouraging recognizing errors, the public perception upon doctors and medical systems passed from the traditional infallibility and respect to over mediatize the negative aspects - from

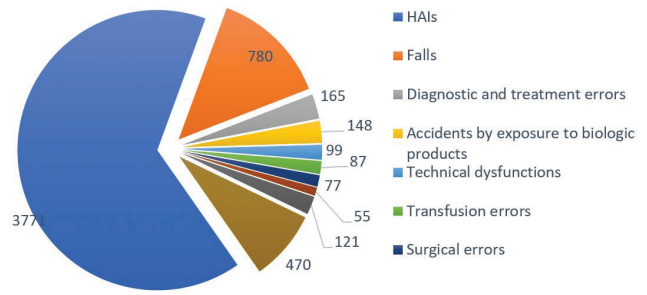


Figure 3. Types of AEs reported by Romanian hospitals in 2019.

the discontinuity in supplies, poor hotel conditions to real or supposed medical errors that were more over discussed in a non-academic way, in social media than in scientific meetings [22]. This changed the healthcare consumers mentality, who became more aware of their rights of safety and satisfaction in medical assistance.

The terms medical malpractice and error are separated by a fine delimitation, often not fully understood even by specialists in the field. Malpractice presupposes, according to the national legislation, the existence of an error of which someone is guilty, through negligence, recklessness or insufficient medical knowledge for the exercise of the profession. Malpractice defines that state of conflict between the consumer and the medical system, a failure to ensure patient satisfaction and safety and is often treated as a taboo subject in the medical world.

A vicious circle is going on, on one hand there is an increased awareness of the healthcare professionals that safety must be improved in hospital care, but on the other hand there are still psychological barriers in reporting AEs, though the logistics are created. Studies have identified as possible factors: ignorance of the differences between medical error and malpractice, fear of public exposure, the feeling that reporting is punitive, misunderstanding the importance of reporting, little information about AEs with learning potential, whose reporting would be useful, the medical staff's tendency to formally comply with the patient safety protocols [23-26].

In a comparative study analysing reporting of the AEs in hospitals of Romania and Italy, one of the differences observed is the fact that, in Romania, the full responsibility for a case is considered to be that of the attending physician, which makes the errors generally reported by doctors, but not by nurses [27]. Another reason for the low reporting in national systems is the perception of physicians that the discussion of EAs should be limited in the specialties, where there is the best environment for them to understand and practice

protocols to change if necessary, to avoid repetition. On the other hand, the increased flow of patients and the pressure of the time factor on the medical staff means that in fact no time is allocated for reporting AE without consequences or with minor consequences on the patient. Another study notes a resistance to reporting in groups that believe they have already implemented the safety culture [23, 24].

The dangers arising from these are that unknown errors cannot be sanctioned by effective prevention measures. Even minor AEs must be reported and documented, because, in the current conception, the patient's suffering related to the production of a sentinel AE, is rather the consequence of the unfavourable association of several minor incidents of various causes, such as lack of monitoring, insufficient training, poor communication, inadequate training or technique.

The experience of other EU countries shows the effectiveness of these feedback mechanisms of EA's voluntary reporting systems. Thus, in Germany, CIRS selects AE with learning potential and presents on the site under the heading "case of the month", anonymously, the most interesting AE, an important issue to prevent errors is communication among medical staff [28]. In Spain, SINAPS regularly organizes meetings, regional workshops on AE, encouraging reporting and presenting AE with learning potential [29]. In France, reporting is blame free, but non-reporting, if the existence of an AE is demonstrated leads to the initiation of monitoring visits.

DISCUSSIONS

Changing culture and mentalities in healthcare is a complex and uninformed process around the world. There are many social, cultural, institutional and economic factors with a big impact upon implementing PSC and reporting AEs. It is well established that errors in healthcare cannot be completely eliminated due to the complexity of healthcare systems. However, they can be greatly reduced by means of an efficient management of clinical risk, through the best possible documentation and identification of the mechanisms that predispose to their occurrence [30, 31]. Systems are targets that need to be changed to reduce medical errors, rather than the old traditional approach of blaming an individual/group of individuals for not doing the right thing/when they should/how they should. The "blame free" reporting of all AEs, even without consequences on the patient is encouraged because it is the most valuable data source for increasing patient safety.

Studies show that the real safety level of an institution for its clients is most correctly estimated by its employees. Employees' sense of security is directly connected to the quality of teamwork, interpersonal communication, mutual respect at work and the ability to speak openly and gain support in the event of a problem [32-34]. An American study shows that nurses and doctors who are dissatisfied with the quality of teamwork are more exposed to faster emotional exhaustion, in emergency reception units about 1/3 being affected. Emergency surgery is particularly vulnerable to patient safety issues, due to short time of planning and difficulties related to preoperative investigations and risk assessment. In recent years, research has shown that emergency surgical patients carry unique perioperative risk factors and have increased risk of postoperative morbidity and mortality when compared to their non-EGS counterparts [35-37]. In geriatric surgery, coexisting associated diseases and possible ADRs secondary to drugs interaction are important factors to consider. Experienced surgical teams, good communication between ICU and surgical departments, proactive management of co-morbidities and hydro-electrolytic imbalance, implementing clinical protocols are key elements to increase patient safety [38-40].

The most exposed to the risk of errors are the resident doctors and in general the staff on the learning curve [41]. Thus, the regulation of the supervision by the guiding doctor, the improvement of the communication, theoretical and practical training courses are measures to control the clinical risks and increase the patient's safety.

In the conditions of a permanent pressure on the medical staff due to the increased workload, lack of time, deficient staff, numerous procedures to be performed, communication with the patient often takes a back seat. However, studies show that poor communication is the main reason for dissatisfaction of consumers of health services [42]. Good communication gives the patient a sense of safety and satisfaction, but also helps to minimize the risk of adverse events: correct collection of medical history, risk of allergies, chronic medication, strongly associated, understanding the patient with his overall health problems and making the best therapeutic decisions.

In conclusion, improving patient safety is a multi-faceted task and requires individual responsibility, and multi-disciplinary and organizational commitment. Reporting medical errors national system creates logistical permits for the development of safety culture

in hospitals. Under the auspices of the international trend of development of the national reporting systems of AE for learning purpose, “blame free” and patient safety culture, the healthcare paradigm is shifting in Romanian hospitals. Only by well documenting the phenomenon, by sending feedback to those reporting, by choosing the most useful cases for learning and presenting them anonymously to the whole healthcare community, those errors might have a decreased chance of happening again. Changing mentalities is a long-standing process, but the results in recent years are encouraging. The popularization of “no blame culture” and “learning by reporting AEs”, increasing communication and teamwork by hospital management and national healthcare institutions will improve patient safety culture in Romanian hospitals.

Conflict of interest

The authors declare that they have no conflict of interest.

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