ORIGINAL ARTICLE

Mixed-methods study of reported clinical cases of undesirable events, medical errors, and near misses in health care

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Abstract

Rationale, aims, and objectives: Patient safety is recognized as a key indicator of quality of medical care. International experience has shown that all efforts should focus on the delivery of a safer work environment and health care system as a whole in order to reduce or mitigate medical errors and their impact on society. The aim of this study is to investigate and classify the most common incidents regarding patient safety as well as their contributory factors, based on personal real-life experiences and situations in medical care reported by health care professionals.

Methods: A mixed-methods study design was used. Sixty-five respondents participated (aged from 23 to 58 y). Reported cases of undesirable events (UE), medical errors (ME), and near misses (NM) were collected, processed, and analysed based on our original conceptual framework. A qualitative content analysis and descriptive statistics were conducted on the narratives in all 34 reported valid case files. Intercoder reliability was measured through the kappa statistics ($\kappa = .69$). The overall agreement of judgments on all codes was excellent (95%).

Results: A total of 29 MEs in 34 cases were reported. In 85% of them, an average of 1.83 contributory factors were identified. The most common contributory factors were "Incompetence," "Neglect," "Severe work overload," and "Shortage of staff."

Discussion: Important steps to prevent medical errors are their identification and reporting.

Conclusion: Health care professionals appear able to report UEs, MEs, and NMs occurring in medical care practice. They seem more willing to report and distinguish incidents related to MEs than to UEs and NMs.

KEYWORDS

health care professionals, medical error, patient safety, reporting, undesirable event

1 | INTRODUCTION

Patient safety is recognized as a key indicator of quality of medical care by most global health organizations and authorities as well as by many researchers.[1-3] For this reason, over the last couple of decades, efforts have been focused on quality improvement of medical services worldwide. Regardless of the substantial growth in research and health care initiatives in the last decades, medical errors and undesirable events continue to increase globally and present one of the most significant global challenges to modern health care causing huge economic and societal burden.[4-6] The importance of the problem has been acknowledged by the WHO, and they initiated

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the establishment of a World Patient Safety Alliance, aiming to coordinate on a large scale and to encourage improvement of patient safety on a national level.[7] Experts from all over the world focus to develop instruments for measuring patients' safety culture and databases to register adverse events (incidents) and/or errors.[2,8] Thus, the development and implementation of patient safety reporting systems (PSRS) in order to identify and mitigate risks to patients who are harmed by medical care has become a priority and challenge to health care delivery over the last decades. The Institute of Medicine proposed the introduction of systems for registration and evaluation of patients' safety culture. The Institute of Medicine considers patient safety "indistinguishable from the delivery of quality health care" and recommended using PSRS to evaluate why patients are harmed by medical care.[9,10] The implementation of such systems allows analysis of accumulated data and their use for continuous improvement of medical care quality via feedback and learned lessons. The open discussion of patient safety issues without the threat of sanctions and penalty measures in an environment of trust and adverse event and error reporting is the first step to the establishment of patients' safety system.[3,11] International experience has shown that all efforts should focus on the delivery of a safer work environment and health care system as a whole in order to reduce or mitigate medical errors and their impact on society.[1,6,12] So far, Bulgarian health care system lacks PSRS, as well as a legal definition of the term medical error. To our best knowledge, this is the first study in Bulgaria, focused on reporting of undesirable events and medical errors' by health care professionals.

The aim of this study is to investigate and classify the most common incidents regarding patient safety as well as their contributory factors, based on personal real-life experiences and situations in medical care reported by health care professionals.

2 | METHODS AND MATERIAL

2.1 | Study design

A mixed-method study design was used, applying the case method, content analysis with deductive and inductive approaches and descriptive statistics to identify and classify the most common reported undesirable events, medical errors, and near misses.

2.2 | Original conceptual framework

Based on analysis of national and international literature on the subject, the key terms related to patients' safety were defined.[2,6,8,10,13] Our original definitions allowed further content analysis of the reported cases.

Undesirable event (UE) (complication)	any harm, complications, or even lethal events that require further follow-up, treatment, or hospitalization and are attributable to the patients' individual differences with her/his unique physiology (age, gender, and pregnancy) and pathology (as disease course, the presence of co-morbidity, allergic states, multiple underlying medical conditions, and genetic predisposition),

or are related to other external circumstances or factors (polypragmasie, food and alcohol interactions, drug additions, high risk invasive procedures, etc). They occur regardless of the adherence to the established standards and guidelines of good medical practice.

Near miss (NM)	is any taking action or failure to take action (adverse event) that has the potential to harm the patient and cause complications or even death, but have not resulted in real harm or adverse event due to either early detection or sheer luck.
Medical error (ME)	potentially preventable actions or failures to act or both that deviate from the established standards, protocols, rules, or good medical practice codes (personal errors) or are due to system defects (system error). Medical errors are potentially harmful to patients, which might cause complications or even death. It should be noted that not all errors result in patient harm.

In our opinion, the terms ME and UE could be classified as preventable and not preventable.

On the basis of these definitions, we propose the following conceptual framework model related to patient safety in health care practice (Figure 1). The relationship between UE, ME, and NM, based on their preventability and reasons to occur, is presented in Figure 1.

2.3 | Participants and assignment's description

Students from Masters in Public Health and Healthcare Management Programme at the Plovdiv Medical University were recruited in the study. It took place during the 2017 to 2018 school year. We asked the participants to describe voluntary an UE, ME, or NM from their own medical experience. The assignment included a description of the most significant real UE, ME, or NM from their practice in the last 5 years where the respondents were directly or indirectly involved in the event that was related to patient safety. Within 60 minutes, the students had to outline the problem and reflect on the contributing factors as well as to share their own professional
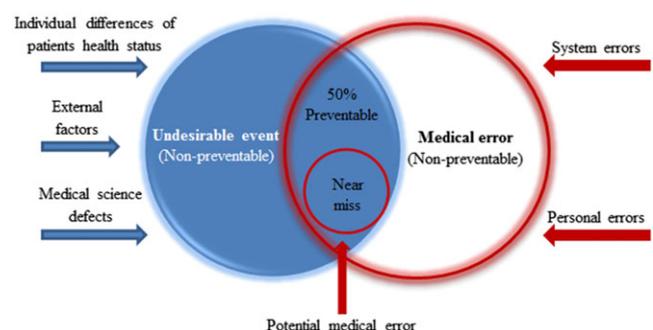

FIGURE 1 Relationship between medical error, undesirable event, and near miss based on the preventability of the event

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attitude and their own thoughts and beliefs on the issue. Earlier in the study, the respondents were made familiar with the authors' conceptual model of patient safety. The conceptual model was developed within the frame of the university project No. 11/2017 named "Development and implementation of web-based platform for registration and evaluation of the level of patient safety culture in the healthcare and performance of a representative national survey on patient safety."

Recruited respondents had to meet the following criteria:

- Completed Masters' programme of Medicine, Dental Medicine, and Pharmacy as well as Bachelor and Master of Health Care Management for nurses, midwives, and other health care professionals.

- They had to work in health care.

After describing of the cases, the respondents were asked to mark if any actions were carried out in order to prevent future occurrences.

2.3.1 | Coding of case report events

Content analysis was used for data processing. The technique requires researchers objectively and systematically to record and interpret the described text data in order to provide qualitative and quantitative description of the text content.[14,15] The case study approach is best used to investigate complex issues of interest to the researcher in their real-life settings.[16] On the basis of the methodology of directed content analysis, the authors used a combination of deductively and inductively determined codes. Two coders participated to ensure the credibility of the collected data and to secure the trustworthiness of the case study.

The first (R.D.) and the third (I.D.) authors thoroughly investigated all reported cases. All validly completed cases were carefully checked to ensure that collected data, study findings, and the created theoretical model are consistent with the students' knowledge. Subsequently, the main categories and the contributing factors of the proposed conceptual model were coded independently. Using axial coding, the coding framework of the study was developed. The reliability of the codes within each category was determined in 2 phases. Firstly, 2 coders trained in qualitative data analysis coded 34 empirical cases. Intercoder reliability was measured through the kappa statistics, and disagreements between the 2 coders were discussed during a peer debriefing session and were consensusly solved. After revision of the codes, the kappa value was .69, indicating a moderate level of agreement.[17] Finally, the primary coder (R.D.) processed all of the data using the revised coding scheme.

2.4 | Statistical analysis

Numbers (N) and percentages (%) were reported for all ME, AE, and NM categories as well as for their contributory factors. We used a Cohen kappa reliability statistics to assess an interjudge reliability. All analyses were performed using Statistical Package for Social Science SPSS V.17.0.

3 | RESULTS

3.1 | Content analysis of cases study

Of all 65 respondents, 36 (55.3%) met the inclusion criteria. Thirty-six reported cases were analysed. Of all participants, 52.9% were women and 47.1% were men, aged from 23 to 58 years (mean age was 40.25). Physicians were 25, pharmaceutics were 6, and nurses and midwives were 5. Due to discrepancies and misses in the written data, valid responses were 34 of 36, with a 94.4% response rate. A qualitative content analysis was conducted on the narratives in all 34 valid case files. To demonstrate the content analysis process procedure, only 5 cases were randomly selected from a total of 34 valid cases and classified into 3 type: UEs, MEs, and NMs, (Table 1). The contributory factors preceding the events were analysed using Robert Yin's procedure.[16] The 4-step process of the content analysis and the condensation description of the cases are presented in Table 1.

In compliance with the Leape classification framework, we performed a classification of reported cases based on the type of events/incidence and the cause leading to them[18] (Table 2). Reported cases were divided into the following: UEs, MEs, and NMs. In our study, a total of 29 MEs in 34 cases were reported. In 85% of the cases, an average of 1.83 contributory factors were identified, the most common being "Incompetence," "Neglect," "Severe work overload," and "Shortage of staff." The second most common causes were "Failure to adhere to the established standards rules and protocols" and "Poor communication" (Table 2). Summarized data of the reported cases of UEs, MEs, and NMs are presented in Table 2.

The reliability of the 2 authors' judgments on the presence of UEs was lower (κ = .57) when compared with that of MEs and NMs (κ = .67). No doubt, it is more difficult to judge negligence as one of the contributory factors, resulting in a lower degree of reliability (κ = .52). However, the overall agreement of judgments on all codes was excellent (95%).

The reported UEs, MEs, or NMs were being shared during councils or reports, and measures to address their consequences, as well as preventive measures for their reoccurrence, were taken.

4 | DISCUSSION

Errors disclosure is an element that contributes to the creation of a culture of safety and as such must be accepted as a strategy in health care institutions. For the first time in Bulgaria, health care professionals reported cases of UEs, MEs, and NMs The cases were collected, processed, and analysed based on our original conceptual framework. The results of our study reveal that health care professionals are inclined to share their own experience related to patients' safety regardless of the lack of information and communication technology (ICT) reporting system in our country. It should be noted that respondents recognize better reported events related to active medical errors, occurring in the process of health care delivery compared with latent errors. Similar findings are documented in other studies.[11,19] It is true that some medical errors are less visible and insensitive, and the positive steps in the processes and systems to correct

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TABLE 1 The 4-step content analysis process[a]

Meaning Units	Subcategory	Main Category (Effect)	Contributory Factors (Cause)
Case no. 7: Damage of the foetus "A female, undergoing in vitro fertilization. After a visit to her General Practitioner, she consented to have the measles, mumps, and rubella vaccine. Later, pregnancy occurs. Fetal damage is established and therapeutic abortion is necessary."	Diagnostics error: Poor communication between the General Practitioner and the patient during history taking and physical examination.	Medical error	- Incompetence - Neglect - Poor communication between physicians and patients - Poor communication between medical professionals - Inadequate staff training prior to introduction of new equipment - Lack of financial and material resources
Case no. 15: Foreign body lost in the operation field "14 days following hospital discharge a female patient, who has had a surgical procedure returns to the hospital with high fever, general malaise, signs of peritonitis and operation wound infection. A gauze lost in the operating field is established."	Treatment error: Malpractice, incompetence, and poor communication in the medical teams.		
Case no. 16: Treatment with novel equipment "Following treatment with new laser equipment at the ocular clinics, a considerable number of patients present with eye complications."	Treatment error: Lack of adequate training prior to introduction of new equipment.		
Case no. 25: Undesirable complication during high-risk invasive surgical procedure During surgery on a young man to remove nasal polyp, perforation of dura mater occurs and cerebrospinal fluid leakage. The procedure was performed according to the established protocol, and no errors were established. The complication was recognized on time and adequately treated.	Related to therapeutic procedures	Undesirable events	- High-risk invasive procedure - Anatomic and physiologic differences
Case no. 29: Medication administration error A nurse, shortly after appointment to a very busy primary care surgery, prepares a wrong vaccine to give to a child. The General Practitioner identifies the error on time and rectifies it.	Treatment related: The wrong vaccine has been prepared by the nurse, but the error was recognized and rectified by the attending physician	Near miss	- Incompetence - Neglect - Work overload

[a]Table 1 shows examples of the 4-step content analysis. After careful reading, the text was divided into meaning units and then condensed. The codes were sorted into subcategories and main categories.

TABLE 2 Percentage of reported UEs, MEs, and NMs, and their contributory factors (N = 34)

Reported Events	N (%)	Factors and Causes of Occurrence[a]	N (%)
I. UEs	3 (8.83)	Differences related to the patients' health status and other external factors	3 (100.0)
II. MEs including the following:	29 (85.29)	Professional incompetence (lack of experience and qualification)	11 (37.93)
(1) Diagnostics errors	9 (26.47)	Negligence, over self-reliance	11 (37.93)
(2) Medication errors	8 (23.53)	Severe work overload, distress, and shortage of time and staff	11 (37.93)
(3) Blood transfusions	3 (8.82)		
(4) Treatment errors (including hospital-acquired infections, surgical procedures, etc)	9 (26.47)	Failure to adhere to standards, rules, and protocols	8 (27.59)
		Poor communication	8 (27.59)
		Lack of material and other supplies	4 (13.79)
III. NMs	2 (5.88)	Related to diagnostics and treatment	2 (100.0)

Abbreviations: MEs, medical errors; NMs, near misses; UEs, undesirable events.

[a]Most of reported cases are related to more than one contributory factor; for this reason, the total of percentages is >100%.

them take a long time.[19-21] Unfortunately, the world experience has shown that not all human errors including MEs are preventable and could be completely eliminated.[6,22-25] In our study, the respondents found it more difficult to recognize UEs and MEs related to management failures, ie, system errors compared with personal errors. On the other hand, recent investigations have revealed that, due to the

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working environment and peculiarities of the work place, some health care professionals from different specialties are exposed to a burn-out syndrome, which may lead to an increase in errors in medical practice.[26] In the international literature, definitions of terms related to patient safety culture such as negligence, medical error, mistake, malpractice, adverse event, undesirable event, unwanted event, and others are often mixed or overlapping. Some events have various definitions but in fact carry the same meaning.[13,19] It is well known that ambiguous definitions of the terms meaning often leads to errors and omissions in information collection and analysis. Finally, it is impossible to compare results on a national and international level.[4] The most important reason for that is the lack of uniform and standardized taxonomy related to patient safety on an international level. Usage of nonstandardized methods and instruments in information collection and patient selection as well as various ICT reporting systems are other important factors.[4] International experience has shown that PSRS vary widely, which often results in confusion among experts, policymakers, and health care professionals.[4,21-24] Therefore, it is very important to establish clear definitions, objective criteria, and valid instruments in order to measure precisely the percentage of UEs and MEs. This fact gave us the ground to put forward our own original definitions. Regarding MEs in our study, the most common causes are negligence, incompetence, and work overload. In other studies, medication errors are the most frequently reported (38%), followed by errors in treatment (36%) and errors in communication and recording (25%).[27] Eminent authors of leading Harvard and Australian studies reveal that about half of the reported adverse events occurring among inpatients resulted from surgery.[28,29] Complications from drug treatment, therapeutic mishaps, and diagnostic errors were the most common nonoperative events.[29,30] Communication issues are a leading cause for MEs based on other studies.[30,31] Other researchers have established that in patients' opinion, the most common cause of adverse events are interpersonal problems, followed by medical complications and process-related problems.[30,31] More than half of the errors reported by nurses are medication related according to another study.[32] Based on Fernald et al, communication problems (70%), diagnostic tests (47%), and medication errors (35%) were the most frequently reported errors.[33] The first step to prevent the UEs and MEs is to identify them, followed by introduction of measures and ICT reporting system to prevent them.[2,4]

Our study has some limitations. Representativeness is not claimed as the convenience sampling method was used for the health care professionals selection. Comprehensiveness of the proposed classification framework could not be claimed as well as due to the limited number of analysed cases. It should be noted that the willingness of the respondents to share their personal experience related to patient safety could be biased by their current position as students and attributed to their desire to please and the need to be liked by the researchers who are at the same time their teachers. Another limitation is the lack of uniform and standardized taxonomy of the used terms related to patient safety in our country, making comparisons of the results with other studies difficult. Further clarification and unification of the terminology of the measuring tools and the PSRS for UEs and MEs is necessary.

5 | CONCLUSION

Health care professionals appear able to report UEs, MEs, and NMs that occur in medical care practice. They appear more willing to report and distinguish incidents related to MEs than to UEs and NMs. Sharing knowledge and providing support through an open communication and trust among health care providers on the one hand and the patients, mass media, and society as a whole on the other hand is one of the major objects in creating patient safety culture. This is the major reason to attempt to implement an ICT for reporting UEs and MEs in Bulgaria.

CONFLICTS OF INTEREST

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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