

PATIENT SAFETY AND MEDICATION ERRORS IN THE PROVISION OF HEALTH CARE SERVICES-CHALLENGES FOR CONTEMPORARY PRACTICE

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Non-maleficence represents one of the basic ethical principles that health care providers should be guided by during service delivery. Establishment of patient safety is nowadays recognized as an issue of global concern in health care and a critical component of quality management. The aim of this paper is to provide a literature review of the patient safety and medication errors concept, with special attention given to defining the most significant terms, analyzing the causal factors and reviewing their classification. Raising awareness about the importance of patient safety has resulted in an increase in the number of medication error studies over the last decade. The traditional approach which makes health workers responsible for reduction of incidents is replaced by the modern concept which implies the involvement of all stakeholders at all levels of the system. In developed countries, the application of prospective risk management models for specific health care processes has already started. However, all these studies are mainly carried out at the secondary and tertiary levels of health care, while they are almost non-existent at the primary level. In the Republic of Serbia, a Rulebook on indicators of the quality of health care has been recently adopted, but a trend of significant lack of data regarding patient safety can be noticed due to inadequate reporting. It is necessary to continue with the homogenization of terminology and to increase the number of analyses of causal factors with the aim of prospective risk identification, particularly in developing countries such as the Republic of Serbia. *Acta Medica Medianae* 2016;55(2):57-64.

Key words: patient safety, medication errors, risk management

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Introduction

Ever since ancient times and the time of Hippocrates "Primum non nocere" or "First, do no harm" has been declared as the main principle that health care providers should be guided by during service delivery. This Latin phrase represents the basis of medical ethics and reflects the connection between patient safety on the one hand and their well-being on the other (1).

Establishment of patient safety is nowadays increasingly recognized as an issue of global concern in health care and a critical component of

quality management. The World Health Organization (WHO) defines patient safety as „The absence of preventable harm to a patient during the process of health care (2)”, and yet can be defined as „The avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care (3)”. Its improvement in health systems requires a comprehensive approach at all levels, as well as the involvement of all stakeholders with the aim of managing current and potential risks. World Alliance for Patient Safety-WHO has defined the preconditions for reducing medication errors incidence, as the most important factor influencing patient safety (4):

- 1) Development of reporting systems for occurred medication errors;
- 2) Detecting systemic weaknesses that predispose failure occurrence;
- 3) Implementation of continuous education and training of health workers, and
- 4) Reconfiguration of the health care system.

However, despite a growing interest in achieving patient safety and quality management in health care, a low level of awareness of the importance of medication errors and adverse events is still widespread among different actors. This is especially important for developing countries and

countries in economic transition, such as the Republic of Serbia, with significant lack of researches in this area and inadequate recording of incidents in health institutions.

The aim of this paper is to provide a literature review of the concept of patient safety and medication errors. Special attention is given to:

- 1) Review of definitions of the most significant terms in the field of patient safety;
- 2) Analysis of the factors that determine the occurrence of medication errors and adverse events;
- 3) Review of the classification of medication errors, with special reference to the errors that arise during the process of dispensing.

Material and methods

The authors have carried out a desk research of available electronic databases such as PubMed, MEDLINE, Google Scholar and Web of Science from the start of each database to December 2014 for English-language scientific papers. Relevant tertiary sources of information were also included. The following terms or phrases were used in the search process: patient safety AND terminology OR definitions OR taxonomy, medication errors AND incidence OR types OR causes, dispensing errors, medication errors AND classification, risk assessment tools.

Results

The concept of patient safety and medication errors

Safety in the health service provision process and reduction of medication errors represent a significant part of the quality, as a wider concept. The Institute of Medicine's (IOM) the six key dimensions of the health care quality: efficiency, effectiveness, equitability, timeliness, patient centeredness and safety as the most critical one (5). Nowadays, safety and quality are often viewed as "Yin and Yang" of the health care i.e. concepts that are opposite, but at the same time complementary. The main purpose of quality is to ensure the right care for the patient, while the focus of safety is to provide it in the right way i.e. quality is about doing the right thing and safety about doing it right. Furthermore, the measure of quality is based on an estimate of whether you helped the patient, and the measure of safety is whether you harmed him/her (6). However, despite some obvious differences, the strategies used to achieve them are identical and include the design of the system in a manner that will prevent the occurrence of errors and provide appropriate quality of health care.

The first report that has addressed the issue of medication errors was published by Lucian Leape (1994), a Harvard surgeon, who first pointed out that the responsibility for their development should not be sought in the individual but in the entire system, and that is necessary to work

on creating an environment that is not minded to punishment but to encouraging incidents reporting (7). Several years later, in 1999, IOM released the landmark report *To err is Human: Building a Safer Health System* (8), which described the consequences (morbidity/mortality and costs) of medication errors in the health care system for the first time. The fact that each year approximately one million people in the United States suffer from preventable medical injuries and 100,000 die as a result of these injuries, has shocked both professional community and general public. In addition to losses in human lives, it is estimated that preventable medication errors result in considerable economic costs due to additional health care, reduced work productivity, as well as potential long-term disability. Errors also "cost" countries in terms of loss of confidence in the health care system by patients and a decrease in health care professionals' and service users' satisfaction. WHO called upon all member states to prioritize the resolution of this problem and launched the World Alliance for Patient Safety in 2004, whose member has been also the Republic of Serbia since 2008.

Definitions of terms related to the context of patient safety

Raising awareness about the importance of patient safety has resulted in an increase in the number of studies over the last decade. However, significant problems for researchers have been noticed. The lack of methodological uniformity and heterogeneity of patient safety terminology and definitions significantly hamper the synthesis of the existing scientific knowledge and the comparison of results. Defining international taxonomy for patient safety is therefore necessary, because it would not only facilitate global monitoring and reporting of errors, but also contribute to the understanding of these incidents through better information on their prevalence, types, causes, severity and consequences, as well as to the synthesis and comparison of the obtained data (4). WHO has attributed significant importance to this issue and developed the conceptual framework for the International Classification for Patient Safety (ICPS) (9). Review of the most significant patient safety terms and their definitions is given in Table 1.

Traditional versus modern approach to medication errors

The work environment in which medication errors and omissions are considered as unacceptable creates pressure on health care providers and reflects on their work. Consequently, if an error occurs, health workers feel embarrassed, scared and frustrated because of failure to provide the best possible health care. This blame and train approach is based on the fact that pharmacists, physicians and nurses are trained not to make

Table 1. Review of the most significant patient safety terms and their definitions

Patient safety	<p>„The identification, analysis and management of patient-related risks and incidents, in order to make patient care safer and minimize harm to patients [10]“</p> <p>„Freedom from accidental injuries during the course of medical care; activities to avoid, prevent, or correct adverse outcomes which may result from the delivery of health care [10]“</p> <p>„Actions undertaken by individuals and organizations to protect health care recipients from being harmed by the effects of health care services [11]“.</p>
Quality of care	„Degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge [12]“
Medication error	<p>„A failure in the treatment process that leads to, or has the potential to lead to, harm to the patient [13]“</p> <p>„An error in the processes of ordering, transcribing, dispensing, administering, or monitoring medications, irrespective of the outcome [14]“</p> <p>„Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer [15]“</p>
Adverse event	<p>„An undesired patient outcome that may or may not be the result of an error [16]“</p> <p>„A negative consequence of care that results in unintended injury or illness which may or may not have been preventable [17]“</p> <p>„An undesirable event occurring in the course of medical care that produces a measurable change in patient status [18]“</p>
Adverse drug event (ADE)	<p>„A patient injury resulting from a medication, either because of a pharmacological reaction to a normal dose, or because of a preventable adverse reaction to a drug resulting from an error [12]“</p> <p>„An injury from a medicine or lack of an intended medicine [19]“</p> <p>„Adverse drug events may have resulted from medication errors or from adverse drug reactions in which no error was involved [20]“</p> <p>„There are two types of adverse drug events (ADEs): those caused by errors and those that occur despite proper usage. If an adverse drug event is caused by an error it is, by definition, preventable. Non-preventable adverse drug events (injury, but no error) are called adverse drug reactions (ADR) [21]“</p>
Adverse drug reaction (ADR)	„A response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function [10]“
High-alert medications	„Drugs that bear a heightened risk of causing significant patient harm when they are used in error [22]“.
Risk assessment	„The process that helps organizations understand the range of risks they face—both internally and externally, the level of ability to control these risks, the likelihood of recurrence and their potential impacts [23]“.
Risk management	„Identifying, assessing, analyzing, understanding, and acting on risk issues in order to reach an optimal balance of risk, benefits and costs [23]“.
Near-miss	<p>„An event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention [24]“.</p> <p>„Unexpected or unplanned events in the provision of care that could have, but did not, lead to harm, loss or damage [25]“.</p>

mistakes. If mistakes occur, they are then publicly blamed and punished, which leads to the strong pressure on individuals to conceal made mistakes, instead of admitting and discussing them (26). This is one of the most important negative consequences of the traditional approach. By this approach, in case of failure, the question of who is responsible is raised, instead of conducting a system analysis with the aim of explaining what led to error occurrence (27).

Unlike the traditional approach, the modern concept does not tend to blame the individual, but to find and understand the systemic causes of incidents by creating a cultural environment that encourages reporting of errors and discussion about them.

Causes of medication errors

The so-called approach Five Rights of Medication

Administration, which implies the application of the right drug for the right patient in the right dose, the right route and at the right time has become a widespread practice of health professionals. However, despite that fact, errors still occur, including the fatal ones. The Institute for Safe Medication Practices (ISMP) has identified critical system elements that may have an impact on medication errors occurrence (26):

1) Patient information - incomplete and inadequate collection and use of demographic and clinical patient data (e.g. gender, age, height, weight, smoking habits, allergic reactions, pregnancy status, medication review, adverse drug reactions, etc.).

2) Drug information - insufficient health care professionals' knowledge of drugs (the maximum recommended single and daily dose, contraindi-

cations, route of application, precautions, cross-reactions, extemporaneous preparation, storage conditions, etc.);

3) Communication among health care workers - misunderstandings resulting from poor and ineffective communication among health workers and the absence of collaborative practice i.e. team collaboration.

4) Drug labelling, packaging and nomenclature - similar names of drugs, visually similar packaging and/or their improper labelling.

5) Drug storage and distribution - storage in a manner that predisposes errors (e.g. possession of more than necessary quantity of supplies, storing look-alike or sound-alike drugs next to each other);

6) Environmental conditions- inadequate working environment such as poor lighting, high noise levels, cluttered work space, work overload, as well as adverse psychological factors (e.g. poor interpersonal relationships).

7) Health care workers' competency and education- inadequate and/or insufficient training and education of health professionals about interventions to reduce medication errors, the significance of their reporting and overall risk management implementation in health care service provision.

8) Education and active patients' involvement- the lack of adequate education of patients about their own health status and treatment, as well as their insufficient encouragement to participate actively in the process of health care.

9) Quality of health care and risk management implementation - the lack of supportive strategies for reporting, analysis and reduction of medication errors in healthcare institutions, and also creating a cultural environment oriented towards punishment rather than retrospective or prospective systemic causes' identification.

Classification of medication errors

Prescribing errors

Identified types of prescribing errors include the so-called prescribing faults and prescription errors (28). Prescribing faults can be characterized by a failure in the prescribing process which results in irrational, inappropriate or ineffective prescribing, and can be further divided into omission (failing to do the right thing/underprescribing) and commission (doing something wrong/overprescribing). On the other hand, prescription errors can be defined as a failure in the prescription writing process that results in a wrong instruction.

As a consequence of the prescribing fault drug-related problem (DRP) may occur, which is identified as „an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes (29)“. According to the Pharmaceutical Care Network Europe (PCNE), there are 8 primary domains for causes of DRP,

out of which 4 are direct results of prescribing faults: drug selection, drug form, dose selection and treatment duration (29).

The second group of prescribing errors, prescription errors, represent the omission in filling prescriptions that results in erroneous specifying one or more data. The normal features include the patient's identity, the identity of the drug, formulation, dosage regimen, route of administration, timing, frequency and duration of administration. Illegible physicians' handwriting is stated as one of the most common causes of failure in the act of prescription writing. The results of studies showed that computerized prescribing and electronic transfer to hospital/ public pharmacies significantly reduces the risk of accidental situations and errors (30).

Dispensing errors

Medication dispensing represents a basic service of pharmacists in the process of health care delivery. This activity is very risky, declared as susceptible to failure, and as such is one of the main concerns for pharmaceutical profession (31). Dispensing error can be defined as a „Deviation from the prescriber's order, made by staff in the pharmacy when distributing medications to nursing units or to patients in an ambulatory pharmacy setting (32)“. Institute of Medicine (IOM) has published a report, stating that this type of errors occur at a rate of 51.5 million out of 3 billion prescriptions filled annually in the United States, respectively 4 per day in a pharmacy filling 250 prescriptions daily (33). It is further alleged that as many as 6.5% of these errors are clinically significant, which is a very worrying fact. Analysis of incidents encountered in the process of dispensing medicines (their incidence, types and causes) can be done by using different scientific methods. The most commonly used are: observation, questionnaires, using standardized forms for incident reporting, interviews, and focus groups. Review of advantages and limitations of these scientific approaches is given in Table 2.

A certain number of studies based on these methods were conducted with the aim to examine the types of errors that occur during the process of dispensing. The most frequent types are dispensing the wrong drug, strength, form or quantity, inadequate extemporaneous preparation of the drug, improper medication labelling with the incorrect written directions i.e. giving incorrect verbal instructions to the patient during the counselling process, failure to identify drug-related problem and dispensing the expired drug or the drug with close expiration date (34, 35). According to the literature, the highest recorded frequency of these types of errors are dispensing the wrong drug and wrong strength of the drug, and then issuing the wrong quantity and inadequate drug labelling (31, 36, 37). Furthermore, several surveys on the perception of pharmacists regarding the causes of errors that occur in the pharmacy

Table 2. Summary of the advantages and limitations of methods used for analyzing errors in the dispensing process (adjusted from [26])

Research method	Advantages	Limitations
Observation	-Possible examination of incidence, types and causes of errors; -High sensitive and objective method; -Does not rely on the willingness to report, nor awareness of occurred errors	-Possible influence on the respondents' behaviour and practice (<i>Hawthorne effect</i>); -Potential failure of observers to detect errors; -Expensive technique that requires training of researchers who conduct observation
Questionnaires	-Anonymous survey (the respondents' fear of punitive measures is reduced); -Economic accessibility; -Possibility of collecting data on a large sample within a relatively short time frame	-Possible identification of the factors that contribute to the occurrence of errors, but not their incidence and types; -Low response rate; -High level of respondents' subjectivity
Incident reports	-Possible examination of incidence, types and causes of errors; -Economic accessibility; -Possibility of continuous monitoring and long-term assessment	-Inadequate reporting of failures due to lack of anonymity (and fear of punitive measures); -Subjective underestimation of the incidence of errors
Interview	-Useful for examining the causes of errors, immediately after their occurrence	-High level of responses' subjectivity
Focus group	-Useful for examining the causes and circumstances of the error occurrence	-Cases of individual mistakes are not considered, nor their trends

have been carried out, and the following were cited as the most significant: large volume of prescriptions, work overload, fatigue, illegible prescribers' handwriting, similar drug names or external packages, as well as insufficient time for patient counseling (38). Pharmacists' education is, therefore, a significant strategy to prevent failure and is particularly important in relation to new drugs that have appeared on the market, high-alert drugs, as well as the established formal procedures for reporting adverse events in the pharmacy. Furthermore, the implementation of the work process analysis and creating an atmosphere that is not directed towards punishing pharmacists but their stimulation to report errors and publicly discuss them may significantly contribute to risk management.

Administration errors and the role of patients in their prevention

Under these errors are considered failures made by nurses during medication administration to hospitalized patients, as well as errors made by patients themselves during the use of drugs. It is believed that the patient who is familiar with brand and generic names of prescribed drugs, their strength and pharmaceutical form, the purpose of their use, possible side effects, storage conditions and medicines and food that should be avoided because of possible interactions, is able to participate in error detection and prevention. However, unsafe use of drugs by patients is often a case in practice, and as the main causes are cited low level of adherence, health illiteracy, inade-

quate way of drug storage and accidental medication mix-ups caused by visually/audio similar names and/or packages (26).

Low level of adherence can be intentional and unintentional. Unintentional non-adherence may occur when patients do not administer drugs properly due to forgetfulness, lack of understanding of provided information (low level of health literacy), economic inability to afford medications or their physical inability (e.g. visual impairment, invalidity). Intentional non-adherence occurs when patients make a decision not to apply the therapy or to apply it differently than recommended, due to their own beliefs regarding drugs and their use. This category of non-adherence causes is called attitudinal barrier, and is the most difficult one for overcoming. As especially vulnerable population are considered older patients, in whom polypharmacy, physical disability, cognitive limitations and insufficient availability of health care due to limited income predispose a low level of adherence and the occurrence of errors in the use of drugs.

Patients characterized by a low level of health literacy often incorrectly apply medications because of misunderstanding the instructions obtained from health workers. Pharmacists, as the most accessible health care professionals, must strive for adaptation of verbal communication and written instructions to the needs of these patients (using a plain language, without technical terms, while encouraging patients to be actively involved in the medication therapy management).

Furthermore, look-alike and sound-alike drug names and packages are common causes of replacement of the drugs by patients. This usually

leads to the use of the wrong drug or strength, with even fatal consequences.

Results of studies further indicate frequent patients' practice to keep their medications in areas such as kitchen or even bathroom (26). This storage habits lead to drugs' exposure to inappropriate humidity, temperature and other external conditions that may adversely affect the stability of the medicinal product, its quality, and thereby jeopardize the patients safety.

Discussion

The increase of awareness about patient safety issues, which has emerged over the last decade, led to an increase in the number of researches in relation to medication errors. Analyzing their incidence, types and causes is nowadays considered as a part of contemporary scientific research in this field, with increasing frequency of assessment of the attitudes and practices of health professionals regarding patient safety and medication errors reporting routine. Variety of research methods are represented, such as observation, questionnaires, use of standardized forms for incidents reporting, interviews, focus groups and Delphi method, with the aim to obtain the basic knowledge in this field based on the experts' experience. In developed countries, the application of prospective risk management models for specific health care processes has already started. However, all these studies are mainly carried out at the secondary and tertiary levels of health care, while they are almost non-existent at the primary level, particularly in the pharmaceutical sector.

In developing countries, this problem of lack of research at all levels is even more expressed. In the Republic of Serbia, the Rulebook on indicators of quality of health care was adopted in 2007 (39), including those related to patient safety. The Institute of Public Health of Serbia "Dr Milan Jovanović-Batut" prepares and publishes reports on improving the quality of service delivery processes in health care facilities annually, in accordance with the aforementioned ordinance. In these reports, a significant trend of missing data

regarding the safety of patients can be noticed due to inadequate reporting by health care institutions. Due to this fact, the Institute of Public Health of Serbia "Dr Milan Jovanović-Batut" has drawn the same conclusion in reports for several years already - that our health care facilities still do not realize the importance of recording incidents and omissions, while emphasizing the necessity of raising employee awareness of the need for recording and analyzing these events in the future in order to prevent their occurrence and repetition (40-42). That makes creating corrective measures' proposal necessary, in the way of educational interventions and creation of a quality culture that encourages employees to document failures, rather than disguise them in fear of punishment. In addition, it is necessary to conduct researches of the incidence, types and causes of errors, which in Serbia are almost non-existent, especially at the primary health care level. This may allow the detection of systemic weaknesses and implementation of strategies for prospective prevention of incidents and improving patient safety in the Republic of Serbia in the future.

Conclusion

Establishing and improving patient safety is a fundamental principle of health care provision and a critical component of quality management. The traditional approach which makes health workers directly responsible for reduction of medication errors is replaced by the modern concept which implies the involvement of all stakeholders at all levels of the system for risk management purposes during the provision of services. The awareness of the importance of this problem at the global level has significantly raised during the last decade, and therefore has also increased the number of researches. However, it is necessary to continue with the homogenization of terminology in the future, as well as to increase the number of analyses of causal factors that contribute to the occurrence of medication errors, with the aim of prospective risk identification and prevention in the health care system, particularly in developing countries such as the Republic of Serbia.

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BEZBEDNOST BOLESNIKA I MEDICINSKE GREŠKE U PROCESU PRUŽANJA ZDRAVSTVENE ZAŠTITE- IZAZOVI ZA SAVREMENU PRAKSU

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Neškodljivost predstavlja jedan od osnovnih etičkih principa kojim bi trebalo da se rukovode zdravstveni radnici prilikom pružanja usluga zdravstvene zaštite. Uspostavljanje i unapređenje bezbednosti bolesnika danas je prepoznato kao problem od globalnog značaja u zdravstvu i kritična komponenta upravljanja kvalitetom. Cilj ovog rada bio je literaturni prikaz koncepta bezbednosti bolesnika i medicinskih grešaka, sa posebnim osvrtom na pregled definicija najznačajnijih termina u ovoj oblasti, analizu faktora koji determinišu nastanak medicinskih grešaka i razmatranje njihove klasifikacije. Tokom poslednje decenije je sa povećanjem svesti o problemu bezbednosti bolesnika povećan i broj istraživanja medicinskih grešaka. Tradicionalni pristup po kome su za redukciju incidenata i poboljšanje bezbednosti odgovorni zdravstveni radnici zamenjuje se savremenim konceptom, koji podrazumeva uključivanje svih aktera na svim sistemskim nivoima radi upravljanja rizicima prilikom pružanja zdravstvenih usluga. U razvijenim zemljama je započeta i primena prospektivnih modela upravljanja rizicima za određene procese u zdravstvenoj zaštiti. Međutim, sve ove studije se uglavnom sprovode na sekundarnom i tercijarnom nivou zdravstvene zaštite, dok ih na primarnom nivou gotovo uopšte nema. U Republici Srbiji je nedavno usvojen Pravilnik o pokazateljima kvaliteta zdravstvene zaštite, ali se uprkos implementaciji regulative, može uočiti trend značajnog nedostatka podataka u vezi sa bezbednošću bolesnika zbog neadekvatnog prijavljivanja od strane zdravstvenih ustanova. U budućnosti je neophodno nastaviti sa homogenizacijom terminologije, kao i povećati broj ispitivanja faktora koji doprinose nastanku medicinskih grešaka, a sa ciljem prospektivnog identifikovanja i prevencije rizika u sistemu zdravstvene zaštite, a posebno u zemljama u razvoju kao što je Republika Srbija. *Acta Medica Medianae 2016;55(2):57-64.*

Ključne reči: *bezbednost bolesnika, medicinske greške, upravljanje rizicima*

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