

REVIEW ARTICLE

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Management of pharmaceutical risk factors – warranty of patient's safety

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Abstract

Background: The dispensing process is an integral part of the quality use of medicines and together with patient counseling forms the core of professional activities of a pharmacist. The process of dispensing and counseling is composed of a succession of steps, which if interrupted or completed incorrectly, could result in poor quality outcomes for the patient and less than desirable consequences for the pharmacist. The sequelae to serious dispensing errors may be far-reaching, including patient morbidity and mortality, increased health expenditure due to hospitalization and treatment, and loss of credibility and professional standing for the pharmacist, along with the risk of litigation and financial loss. This study is concerned with the process of drug delivery, including the risk factors that increase the likelihood of medication errors and the measures that can be implemented to achieve a quality process. The goal is evaluation risk factors in community pharmacies that have a negative impact in providing pharmaceutical assistance to patients and developing quality criteria for working conditions.

Material and methods: This research is a systematic evaluation where selected studies data were combined quantitatively, to obtain a summary value.

Results: The most important risk factors affecting the pharmaceutical assistance to the patients were identified and criteria of quality working conditions were developed.

Conclusions: Effective risk management in the community pharmacy contributes to quality assurance; anticipation and optimization of the means of control; establishing increased confidence in the management system; implementation of the concept of responsibility for all staff.

Key words: community pharmacy, risk factors, working conditions.

Cite this article

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Introduction

In community pharmacies, the release process is an integral part of the rational use of medicines and, together with the patient's counseling, forms the basic professional activities of a pharmacist. These activities allow the efficient and safe administration of medicines by patients. The release and counseling process is a succession of steps that, if not interpreted correctly, could lead to negative consequences for the patient and undesirable situations for the pharmacist [1]. Some of the most serious consequences can be major medication errors, including trauma and in some cases patient's death, increased health expenses due to hospitalization and treatment, and loss of credibility in the pharmacist's professional skills, along with the risk of litigation, and financial loss [2].

With the increasing emphasis on providing high quality results based on services in pharmaceutical care, it is appropriate for the pharmacist to self-evaluate in all activities to ensure that they provide the highest quality services, both in terms of consumers, as well as from a professional point of

view. This study is concerned with the process of drug delivery, including the risk factors that increase the likelihood of medication errors and the measures that can be implemented to achieve a quality process [3].

Purpose – evaluation of risk factors in community pharmacies that have a negative impact in providing pharmaceutical assistance to patients and developing quality criteria for working conditions.

Material and methods

This research is a systematic evaluation in which the data from the selected studies were combined quantitatively, to obtain a summary value. The research was carried out in 4 stages:

1. Formulation of the question to be investigated and the criteria for including the studies;
2. Selection of studies through databases;
3. Identification of eligible studies (elimination of ineligible studies);
4. Filling in the missing and necessary information, analyzing it and drawing conclusions.

Results and discussion

Studying the specialized literature we have identified few studies that analyze the impact of risk factors in providing pharmaceutical assistance to the population and in the current knowledge of the best methods to reduce medication errors. Quality research is needed to determine the effectiveness of the following interventions, which would contribute to the prevention of risk factors and their consequences:

- Identifying situations where medication errors may occur in order to improve safety and confidence in the system through continuous remedial actions;
- Studying each error to determine the factors that made its appearance possible;
- Evaluation of errors produced for applying the necessary corrections or preventing them in the future;
- Installing a computerized alarm system, which warns of the potential risk that may have a negative impact on the provision of pharmaceutical assistance;
- Organizing thematic trainings related to the topic of the management of the factors that contribute to the appearance of medication errors;
- Involvement of pharmacists in reporting the factors that determine them when making mistakes.

The risk is the possibility of being hurt or of having caused various damages. It is a phenomenon commonly encountered in every day life, often associated with the term "insecurity". ISO (International Organization for Standards), in the document entitled "ISO/IEC Guide 73 Risk Management – Vocabulary – Guidelines for use in standards" defines risk as "A combination of the probability of an event and its consequences". Other definitions for risk are: chance to lose; the possibility of losing; uncertainty affecting the outcome; dispersion of expected results.

Risk is an uncertain event that, if it occurs, adversely affects the objectives of an activity or a group of activities. And this happens either because an unplanned thing happened in the course of an activity, or because something that was planned did not happen as planned [4].

Most of the time, when planning an initiative, we try to establish the level of our expectations in relation to that initiative. Any deviation from these expectations that evolve adversely to our interests is a form of risk manifestation. Events recorded in case of risk manifestations are often consequences of the interdependence of some risk factors [5].

Risk factors are the factors that contribute to the formation of the risk situation or its aggravation, in certain contexts. The main consequence of the risk factors present in the community pharmacy are medication errors.

Medication errors generally refer to errors in the release process (e.g., wrong drug delivery or improper concentration, incorrect indications, the medicine distributed to the wrong patient, etc.) which are not detected and corrected before the patient leaves the pharmacy and which can lead to undesirable results [6]. The specialized literature indicates little information about the current statistics of medica-

tion errors. In the Republic of Moldova, according to the information of the Agency of Medicines and Medical Devices, it is difficult to obtain concrete data regarding the rate of medication errors, because pharmacists tend not to report errors unless the consequences have been particularly serious and / or it is possible to make a claim for compensation for the harm caused to health.

According to Lloyd N. Sansom, PhD in Pharmaceutical Sciences, University of Australia, statistics maintained by the Pharmaceutical Council of Victoria (Australia) in May 1985 revealed 78 errors reported in 156 weeks. This is equivalent to a bi-weekly report or a single error for every 1.7 million prescriptions issued – an incredibly low rate.

An analysis of prescriptions in the United States of America suggested that 5% of prescriptions contain at least one type of medication error.

Researchers Allan EL., Barker K.N. and Malloy M.J. from the Department of Pharmaceutical Care System at Auburn University in the United States of America used a sophisticated technique to study the nature and frequency of medication errors and the quality of patient counseling in 100 randomly selected community pharmacies. In 100 orders issued based on prescriptions, 24 medication errors were detected, 4 of which were significantly serious. It was concluded that the problems related to counseling and assistance in the community pharmacy require attention to the application of quality management [7].

The studies carried out so far have primarily involved the prevention of errors in pharmacies and the most important steps have been identified to improve the medication process, but the factors that can cause medication errors and their consequences have been neglected. The factors contributing to these errors were declared by the researchers, insignificant, with no evidence on them, however, they still affect the pharmaceutical assistance provided to patients [8].

The risk factors present in the community pharmacy are disorders of the three elements that make up the work system (pharmacist, workload and work environment). The main categories of risk factors present in the community pharmacy are:

1. Risk factors specific to the pharmacist, which can be manifested as:

- His wrong actions (choosing a wrong concentration or product);
- Omission of the verification procedure;
- Reduced communication with the patient;
- Lack of experience or knowledge;
- Misinterpretation of a prescription;
- The patient's misunderstanding of the problem and treatment.

2. Risk factors specific to the workload, which can be manifested as a result:

- An oversized task in relation to the pharmacist's capacity or lack of personnel;
- Additional work, fatigue and frequent interruptions;
- Pressure of responsibilities;
- Overload.

3. Risk factors specific to the work environment, which can be manifested as:

- *Factors of the technical environment*: endowment with information systems, the pharmacist's position, the correct arrangement and endowment of the workplace;
- *Factors of the physical environment*: luminous atmosphere, sound environment and microclimate;
- *Factors of the psychosocial environment*: stress, overwork, psycho-emotional state [9].

To analyze the pharmacist's own risk factors that have a negative impact on the occurrence of medication errors, an analysis of each type of error is required. The main reason for choosing an incorrect concentration or product is described as a result of thinking like: "looks the same" or "sounds about the same", respectively the similarity in sounds or letters of the drug name. Common sources of errors are due to too long names, including capital letters within the drug name, difficulties in differentiating drug concentrations and forms due to soils indicating prolonged effects, etc. Some packages or labels contribute to errors, because the identification of the drug is unclear as to its safety. Sometimes the information on the label is not readable and easily understood by all users.

The pharmacist, in addition to exercising his obligations to deliver the appropriate medicines, will need to apply his communication skills wisely. Good communication and counseling is a condition, without which the performance of the quality pharmaceutical act is an unattainable project. It is through the successful communication with the patients that it will be possible to provide psychoemotional assistance and counseling, with the training of rational medication administration skills. The correct communication assumes the pharmacist's ability to identify the way of predisposing the patient to listen and fulfill those recommended by the specialist.

Sometimes, the pharmacist does not have enough time or skills to listen to the patient and to take into account his emotional state. However, the experience of a good relationship means understanding and trust between the pharmacist and the patient, which can be achieved through communication and counseling [10].

The risk factors inherent to the workload exist in two forms of manifestation:

1. Under / oversize the requirements imposed on the pharmacist, respectively requirements not appropriate to his possibilities.
2. The inappropriate content or structure of the workload in relation to the purpose of the work system or to the requirements imposed by the risk situations.

This form of manifestation of risk factors is based on disregarding the physical and mental possibilities of the pharmacist. As a result, the degree of difficulty and complexity of the workload can lead to either under-solicitation or over-applying of the pharmacist.

The conditions that can lead to the appearance of risk factors are:

- The physical request produced by:
 - Static effort;
 - Forced or vicious work positions;
 - Dynamic effort.
- The psychic request produced by:
 - High volume of work;
 - Difficulty of decisions to be made in a short time;
 - Repetitive operations;
 - The monotony of work [11].

For a proper adaptation of each pharmacist to the work process, to the demands of each patient, and also to ensure a major efficiency in the activity, the aspects related to the working environment, the conditions under which the pharmacist carries out his activity are also taken into consideration. According to A. Tabachiu, we appreciate the most important elements of the environment, which must be taken into account when organizing the workplace:

1. Technical environment;
2. Physical environment;
3. Psychosocial work environment [12].

The study of the technical environment of the workplace, of the physical environment and human activity in modern production is ergonomics. In the design of the technical equipment, in its location in the workspaces and in the preparation of the personal protection equipment, the anthropometric data are taken into account.

Another objective of ergonomics is the arrangement of workplaces, which are realized taking into account some essential conditions:

- o The pharmacist must be in a proper, natural position;
- o Ensuring freedom of movement;
- o The working table, the information and control devices must be in the optimal visual and normal area;
- o Standardizing the placement of information devices in a suitable grouping and placement, for similar places;
- o The pharmacist's working position in accordance with the plan and direction of the objects he works with and the technological flow;
- o Efficient placement of technical equipment, technical documentation.

The position of the pharmacists influences the way of performing the work operations and the resting state. An inadequate posture leads to decreased work productivity, overwork, illness and stress [13].

The elements that can be taken into account to evaluate the *physical environment* are: the ambient light, the sound environment and the microclimate (temperature, humidity, air movement). It is considered that these factors can exert their influence on the physiological and psychological processes, having consequences on labor productivity and security, regardless of the specific activity.

The indicators of the physical environment are evaluated starting from the consideration of the following aspects: productivity (labor efficiency); physiological processes (physiological measurements); psychosociological processes (boredom, routine).

The light environment is particularly important, being a basic condition of the normal conduct of the work process. Lighting conditions the proper reception of information visually.

It is necessary, for the efficiency of the work, to ensure an adequate light environment, not too weak, because it would overload through the effort of accommodation, but not too strong because it overloads the prolonged muscular contraction of the pupil. In the pharmacy service room there must be both natural and artificial lighting. The coefficient of natural lighting must be 1-1.5 [14].

The sound work environment is a consequence of secondary and direct sources. Z. Bogathy believes that the most harmful factor in the environment is noise, as it can cause fatigue, and implicitly, the decrease in productivity in work, both from a quantitative and qualitative point of view. Noise is a consequence of the disordered overlapping of sounds with different frequencies and intensities.

For the study of the sound environment, a study was conducted in the community pharmacies in the USA, regarding the association between ambient noise and correctness of drug delivery from pharmacies. Pharmacists were monitored video for 23 days. Video data analysis was used to detect unpredictable, predictable, uncontrollable and controllable sounds.

The study aimed to determine the significance of the sounds of the environment in detecting errors in drug delivery. Noise was found to have a significant effect on pharmacists, increasing the incidence of medication errors by 3.23% [15].

For efficient work performance it is important to consider the microclimate in which the human body feels in thermal equilibrium. The parameters in which the temperature must be kept in a room to ensure comfort are: 18°- 24° C in summer and 17°- 22° C in winter; the optimum humidity is 30-70% and the air speed is 4-8 m / sec.

The psychosocial phenomena that develop in the work process and which designate the psychosocial environment influence, in their turn efficiency and job satisfaction, through the existence of cooperative or, on the contrary, conflictual relations and stress situations.

Studies on stress and professional burnout reported that pharmacists in community pharmacies are exposed to higher levels of stress.

Stress and professional burnout should be exploited regularly in each pharmacy and it is recommended to develop individual and organizational stress management in them. Since pharmacist studies are mainly based on the pharmaceutical sciences, further training in stress and emotion management needs to be promoted [16].

Satisfactory working conditions contribute to both the physical and mental well-being and professional performance of pharmacists. That is why it is important to promote the creation and implementation of an adequate and comfortable working environment – a working environment that favors the quality of the pharmaceutical assistance provided to patients. Other factors that generate risks in the community pharmacy are shown in figure 1.

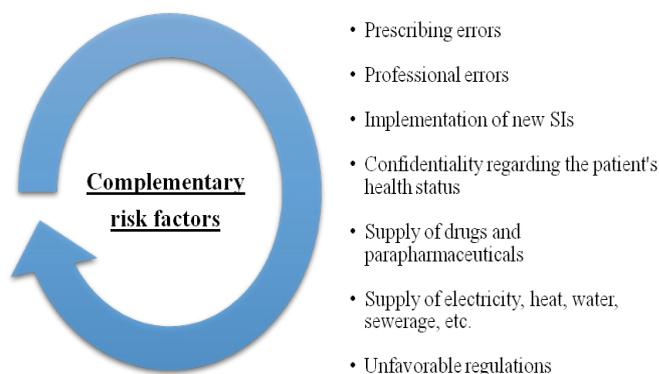


Fig. 1. Complementary risk factors [17].

Any risk factor, once identified and estimated from the perspective of the magnitude of its effects, creates a new "picture", different from the current one. The new perspective viewed from the perspective of risk gives the opportunity to identify new situations, which can be positive or neutral but easily transformed into opportunities.

Most of the risk factors present, at least theoretically, equal chances to materialize or remain at the potential level, so to generate or not the risk situation.

Management of pharmaceutical risk factors. Managing pharmaceutical risk factors (Figure 2) means identifying and evaluating risks, as well as establishing how to respond to risks, that is, to put in place means of internal control that would mitigate the possibility of their occurrence or the consequences they would have if they materialized

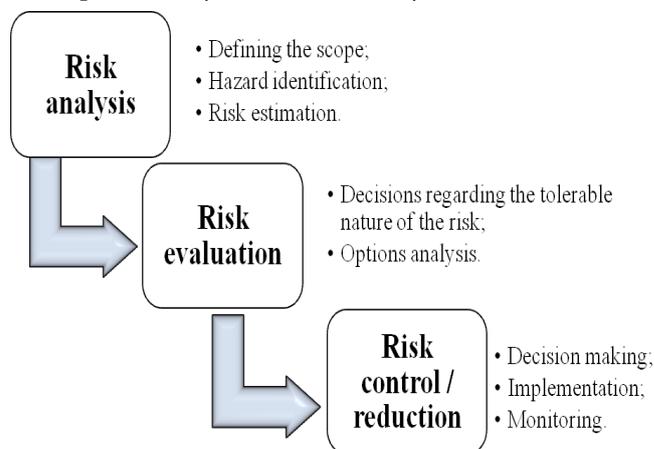


Fig. 2. Stages in the risk management process.

Risk factors can be identified using different methods:

- a) Elaboration of checklists that include potential sources of risk, the members of the activity implementation team, the deadline, etc. ;
- b) Synthesizing the documentation of the activities identical to the one in progress;
- c) Promoting the experience of the personnel involved in activities to identify risk factors;
- d) Establishing the risks arising from the outside [18,19].

But this is not enough. In most cases it is impossible to notice all the specific features of an activity. For example, the human factor has long been declared as the most uncontrol-

lable element of any system. It is possible to speak of risks arising from arrogance, ignorance or even fear, voluntary or involuntary actions, psychological particularities, etc.

Conclusions

Risk management is a cyclical process that involves monitoring and solving the risk factors of the pharmaceutical activity.

Effective risk management in community pharmacies contributes to:

- a) Quality assurance:
 - Offers reasonable assurances that the objectives will be achieved;
- b) Anticipation and optimization of the means of control:
 - It allows the identification of the main risks faced by pharmacists;
 - Mobilizes available resources to address risk factors in an appropriate manner;
- c) Establishing the increased confidence in the management system:
 - Risk factor management is an essential part of the managerial and control environment;
- d) Implementation of the concept of responsibility for all staff employed:
 - Each manager is responsible for the identification and effective management of risk factors in the field;
 - Pharmacists realize the purpose and roles regarding risk factor management.

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Author's contribution

NCB conceptualized the idea, conducted literature review, wrote the manuscript, revised and approved the final text.

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Ethics approval and consent to participate

No approval was required for this review study.

Conflict of Interests

No competing interests were disclosed.