

QUALITY ASSURANCE IN PHARMACEUTICAL OPERATIONS

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ABSTRACT

The specialized literature does not confer a consensual definition of the quality in the pharmaceutical procedures. Nevertheless, most definitions imply the satisfaction of eth customers' needs. The customers of the pharmaceutical procedures are the patients and also the professional persons from the domain of health that prescribe, issue and administrate medicines. The pharmacist is a professional person who is in direct contact with the patient, being the first professional person to whom the patients address when the affection is a mild one and they need counselling regarding the medication or diagnostic. The more complex the medication of the patient is, the more probable the side effects shall be. The morbidity and mortality may be consequences at the error of medication. The appearance of some medicines increases directly proportional to the errors of prescribing the medication. The quality in using the medication implies the choice of the medicine, the optimization of the compliance of the patient with the treatment, avoiding side effects, assuring the therapeutical objectives. The possibilities of appearing the errors being numerous, it is easy to understand why the assurance and improvement of the quality of the pharmaceutical procedures are important aspects for pharmacists and patients. The present paper has as purpose the qualitative improvement of the pharmaceutical procedures by the help of the pharmacist, thus the pharmacy becoming a supplier of pharmaceutical care of the best quality.

Keywords: *quality assurance, patient care, pharmaceutical operations, pharmacist*

INTRODUCTION

At the world level, there is the concern for building a new health system adapted to the 21st century. In this regard, the system that assures quality care in pharmacotherapy and assessment of the quality of using the medication represents a guarantee efficient and safe pharmacotherapy for the patient and society. The assurance of quality in pharmaceutical care represents more and more solicited and important concerns for the profession of pharmacist [5].

Quality may seem an ambiguous term, as we can recognize quality when we see it, but the definition of quality is most of the time subjective. In Webster's Dictionary quality is defined as a level of excellence [11]. This definition helps at analyzing the definitions of the specific quality from the domain of health and supports the idea according to which quality represents continuous excellence.



From the definition given by the Office of Technology Assessment we can assert that in the process of medical care, quality may be measured and used for the care offered to the patients. Although the patients are not always the best arbitrators of the quality of the pharmaceutical care, as they may not know what they want, may not have clear ideas about what they need. Therefore, the pharmacist has the duty to offer services of qualitative care to the patient [1].

Pharmaceutical services

The pharmacies take an integral part from the system of health care. The pharmacists are authorized professional persons for assuring pharmaceutical care in health and they develop their activity in conformity with the legislation and regulations in force, as well as the strict and professional rules [12]. This is the vision of the international organizations: World Health Organization (OMS) and the European Commission [15].

The pharmaceutical services represent the assembly of all actions performed by the pharmacist, necessary for warranting the pharmaceutical care of the population. Their purpose is to ensure the best answer to the needs and health problems of the population entirely and of the patient individually. The pharmaceutical services are part of the health system and have as a purpose the improvement of the health condition and increase of life quality of the population [6], [8], [9], [13], [14].

If we focus on the **European Union**, a report of the **Pharmaceutical Group of European Union (PGEU)** classifies the pharmaceutical services according to the frequency of their supply in the member states. Thus, they consider the **release of medicines based on medical prescription as an essential service** performed by the pharmacist, met in all the member states, in some countries being remunerated as a service, in other countries the benefit being related only to the markup (as it is the case of Romania). In the category of the pharmaceutical services frequently supplied, we find the **measuring of the different clinical parameters** (glycemia, body weight, blood pressure, cholesterol), **collecting the expired or not used medicines from the population, programs for giving up smoking, programs for managing different chronic** diseases (diabetes, arterial hypertension, asthma), as well as the night service (on-call). Among the services that begin to take shape in certain states, mainly in countries with developed economy, are found **anti-flu vaccination**, phone or online counseling, as well as the counselling and **monitoring of the patient to the initiation of a new treatment** [6], [8], [9], [14].

The pharmacist is the professional from the domain of health, easily to be approached, who is in direct contact with the patient, being the first professional to whom the patients address when the affection is a mild one and they need counselling related to the medication or diagnostic [1].

Pharmaceutical care

Pharmaceutical care consists of the responsible provision of the therapy with medicine for obtaining some clear results that improve or maintain the quality of the patient's life. Pharmaceutical care is a term with international recognition, defined as being the practice in which the pharmacist assumes his responsibility for

the needs of the patient regarding the medicine and is considered responsible for the satisfaction of these needs [1].

Therefore more and more, the task of the pharmacist is to ensure that the treatment with a medicine of a patient is properly indicated, is the most efficient available, the most suitable possible and the most convenient for the patient. By assuming this direct responsibility for the health needs of the patient, the pharmacists may bring a significant contribution to the result of the therapy with medicines and the quality of the patients' life [2], [6], [8], [9], [14].

Methods of assuring the quality

In the domain of pharmacy, the raw materials or the structure for qualitative care are numerous and different: the number of pharmacists on a shift, the area of confidentiality, the quality of the pharmacists, the total area of the pharmacy, the bibliographical materials about medicines and access to on-line information, the stock of medicines and the counselling areas.

As the pharmacists are responsible for all the stages of using the medicines, the processes within the pharmacy may refer to any of these stages: prescribing, release, administration and monitoring. Among the indicators of the processes there are found the compliance with the clinical norms, the percentage of the prescriptions evaluated from the point of view of fairness and the percentage of the patients counseled.

The results represent the stimulant of the management of the therapy with medicines, which determine the pharmacists to assume a role in educating the patients and the management of the chronic diseases. Among these activities, they succeed to improve the pharmaceutical care of the patients through: (1) Increase of the control of the patients on their medical affections [3], [7] and (2) Decrease of using the resources from the budget of the system of health insurances [7]; (3) Improvement of the knowledge of the patients regarding the diseases and their medication [2], [11]; (4) Increase of adopting and maintaining the non-pharmaceutical regime [11]; (5) Increase of satisfaction of patients regarding the care they benefit from [4], [7]; (6) Saving the money of the patients [4], [7]; (7) Improvement of the quality of the patients' life [2], [11].

The capacity of the pharmacists to identify, settle and prevent the problems related to medication, as well as assuming the responsibility in the domain of chronic diseases make the object of many papers, their results representing the final purpose of the therapy and they may be analyzed through more methods [1], [2], [4], [10].

One of the methods, the model "Extension for Community Healthcare Outcomes ECHO®", suggests three types of results of the medical care: economical, clinical and humanistic. The project ECHO® is an approach of managing the disease that has as purpose the increase of the knowledge of the suppliers and standardization of the best practices for screening, care and treatment of a disease. ECHO® is based on a basic principle of learning related on cases, in which the clinicians and the suppliers of pharmaceutical care attend a teleconference meeting hosted by a central team for presenting individual cases, in



order to consult a multidisciplinary team of specialists and for studying the cases. The discussion related on the case are interactive, exploiting the ideas of a multidisciplinary team. The sessions of ECHO® offer the possibility of building a dynamic community of trainees.

The economic results include direct costs and consequences, both medical and nonmedical, and indirect costs and consequences as well as nonmaterial costs. Such an approach is necessary for helping at the optimization of the increasing costs associated with chronic diseases and diseases that may be prevented with the help of pharmaceutical care [5].

The clinical results are medical events that occur after the disease or the treatment. The criteria of the clinical results include morbidity and mortality, the incidence rates or the spread of the symptoms. These criteria represent a direct measure of the quality, but are difficult to assess in the pharmacy. For the evaluation of the results, in pharmacy can be used specific indicators or markers, for instance glycosylate hemoglobin (HbA1C), blood pressure (HTA)-indicator of the probability of a stroke.

The studies emphasize the effect of the advanced pharmaceutical care on the adherence of the diabetic patients to treatment and the efficiency of the therapeutical results related to medicines that improve eventually the quality of the patient's life. More and more important part of the activity of the pharmacist becomes the provision of information related to the modality of using the medicines by each patient, as every person is different, with different particularities, unique affections and needs of medical care [1].

The methods of human evaluation are the methods for the evaluation of the impact of the disease and its treatment on the quality of life based on the health condition of the patient, preferences and satisfaction of the patient and application of the pharmacotherapeutic decisions.

The quality of life was defined as the evaluation of the functional effects of the disease and of the therapy prescribed, as they are perceived by the patient. These effects are physical, emotional and social effects on the patient [5].

The human results are the consequences of the disease or treatment on the functionality of the patient in society or on the actual and future quality of life. These consequences may be classified as positive and negative. An example of a positive result is that the expected effect from a medicine to be manifested accordingly, this being a modality of measuring the efficiency of using the respective medicine. A negative result is the occurrence of a side effect or negative after having used a medicine. The pharmacoeconomic evaluation must include the possibilities of measuring both types of results. The evaluation of the positive results only may mislead with regard to the costs, by excluding the costs caused by the negative results [5].

The human results include criteria of the human aspects, such as the satisfaction of the patients and the quality of life. A survey related to the satisfaction of the patients regarding the services of pharmaceutical care may be useful for the evaluation of the results in case of the patients that benefit from these services. Most

of the surveys include either specific measures for a disease, or general measures for maintaining the health condition. In exchange, an evaluation of the quality of life may be useful for establishing the impact of the therapy with medicine on the patient in general.

Building an economic model may help the pharmacist anticipate the impact that the decisions of using the medicine have on the patient and on the health system and rush the process of reevaluation regarding the management of formulating decisions regarding the policy of using the medicines, while new medicines enter the market and replace the old ones. The most recent application of the pharmacoeconomic principles and methods is for justifying the value of different services of pharmaceutical care [5].

Standardization is considered one of the most powerful instruments for improving quality. When a person does the same thing every time, the chances to make errors decrease significantly. In the pharmacy, standardization is the easiest method, the most widespread and the most efficient for improving quality. In fact, the transition to standardization stimulated the critical ways that are focused not only to prevent errors, but also to optimize the results, the reduction of the costs and obtaining the satisfaction according to the American Pharmacists Association. These supportive systems may be used for alerting the pharmacist regarding the possible problems.

Another mechanism that may help the pharmacists is the use of protocols and verification lists, which diminish the confusion according to the Agency for Healthcare Research and Quality. The protocols usually prevent issuing a prescription until it is approved by a final verification by the pharmacist. The policies and protocols diminish the confusion.

The improvement of the access to information leads to the improvement of quality. The studies reveal the fact that the pharmacists take decisions for using the medicines more correctly, if they have access to complex and complete information about the patients, as well as the treatment profile, allergies, comorbidities [13].

CONCLUSION

If we apply the ideas mentioned above in the pharmaceutical practice, we may state that the qualitative improvements shall produce the clinical results wanted, such as an increased quality of life, as well as a greater satisfaction of the patients. In the end this will make the pharmacy create the image of a supplier of pharmaceutical care of the best quality.

The processes for improving the quality were used for monitoring the errors of medication and for avoiding the errors of prescribing.

In general, the techniques for improving the quality were used in an institutional frame, but they become more and more frequent in eth pharmacies that offer services of assisted care.

Quality represents the essential component of the competent and professional pharmaceutical practice. Many of the changes for improving the quality are simple,

may be fast implemented but they have a massive impact on the quality of the patients' care.

Quality in the domain of the pharmaceutical care reached a position of maximum visibility and the pharmacist is recognized as the key – actor in this process. Therefore, the pharmacists shall be required more and more to be involved in assuring the quality of all the segments within the system of using the medicines.

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