STUDY OF QUALITY STANDARDS APPLICATION IN BUCHAREST COMMUNITY PHARMACIES

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Abstract

The concept of quality standard is a modern notion, frequently used in specialty literature [1, 2, 3] to identify reference points, minimum requirements that need to be respected by the pharmacist, the supplier of pharmaceutical services. The presentation of the method of implementing quality standards in the pharmaceutical activity, performed in this paper, has followed a quantitative (of the number of pharmacies) and qualitative (of the evaluation criterias) exposure. The introduction of these regulations in pharmacies was evaluated by special evaluation teams and it has been ascertained that, in general, the implementation of the quality management system was initiated and is under development.

The research undertaken has demonstrated that the quality concept application in the evaluated pharmacies in Bucharest represents an important step that endorses the assurance of organisational competitiveness, the modeling of practices dependent on the actual tendencies, in an effective and efficient manner.

Keywords: quality standards, Good Pharmacy Practice Guidelines

Introduction

The Good Pharmacy Practice Guidelines (GPP) approved through the Order of the Health Minister no. 75/2010 [8] are fundamental instruments for carrying on the pharmacist profession.
The specific standards that regulate the Good Pharmacy Practice activity are useful by being applied to the pharmaceutical profession on a national level [4, 5]. The proposed guidelines recommend a set of objectives which are in the interest of the patients and the professionals involved in providing pharmaceutical care [12].

Each professional association is responsible for time allocation and the appropriate resource training, aimed towards successfully implementing these standards, in community and hospital pharmacies.

In 1992, FIP (The International Pharmaceutical Federation) has presented standards for pharmaceutical services, under the title of „Good pharmacy practice in the community and hospital pharmacies” [11]. According to the European model, the National Pharmacists College of Romania has suggested standard procedures (towards a main activity or towards multiple subactivities) that can be adapted, filled in, developed and applied to each pharmacy, by the chief pharmacist [12].

The quality of pharmaceutical care depends on a good professional practice, which is developed, in time.

The human factor (the pharmacist) is the main element of growing therapeutic efficiency [1], thus forming and adapting it professionally involves the accumulation of practical and legislative knowledge, referring to sickness prevention/health maintenance, managing the various pathologies.

These standard procedures and the implementation and evaluation methodology thusly represent a guarantee for carrying out a high quality pharmaceutical activity.

The evaluation of Good Pharmacy Practice (GPP) Guidelines, within the pharmaceutical units (pharmacies), is undertaken in accordance to an Evaluation grid.

The GPP certificate, handed out after inspection, is valid for one calendaristic year from the moment the pharmaceutical unit has been evaluated and is a mandatory document for concluding Contracts with the Social Health Insurance Companies in regards to providing compensated/free drugs [13].

The evaluation grid was used to assess both the premise’s conditions that should be accomplished (exterior signalling, timetable, area, drug and employee circuit), standard work procedure compliance, as well as the employed specialty personnel (training for GPP compliance discussion, drug delivery method, preserving/archiving prescriptions, the existence of a complaint notebook).
In the case in which the minimum score is not accomplished (22 points) [10] by not fulfilling certain conditions stipulated in the Good Pharmacy Practice Guidelines, the pharmacies will be reinspected to check for the implementation of the corrective measures which have been recommended by the evaluating pharmacists.

At the end of the inspection, a written statement of the investigation of how the GPP guidelines are met is filled out in duplicate, in which, if needed, the chief-pharmacist’s objections are included.

In this paper we aimed to analyse, in a survey developed in Bucharest, Romania, the method of applying good pharmacy practice guidelines. We identified the level of quality standard implementation and assessed if these are fulfilled by the evaluated pharmacies.

**Materials and Methods**

The materials used were evaluation grids (762) and written statements gathered by the Bucharest College of Pharmacists from the evaluation teams, in March-April 2013. The evaluation grids were based on 33 questions grouped under 8 main evaluation criteria for the pharmaceutical care units. The evaluation subjects were in regard to the following aspects of the acting legislation: exterior signalling, mandatory display, the existence of a pharmaceutical license, space organisation, drug and personnel circuit, specialty personnel, the implementation of good pharmacy practice guidelines, the activity of prescription drug preparation as well as stipulations regarding the release of drugs and other health products to the population. The method used for data processing was descriptive analysis.

**Results and Discussion**

The quantitative analyses of the 762 written statements describe how the pharmacies are distributed throughout the 6 districts of Bucharest (Figure 1).
According to Figure 1, the following findings for the evaluated pharmacies in Bucharest can be ascertained: 199 units are located in the 2nd District, and 68 units in the 5th District.

The maximum score that can be reached, according to the Pharmaceutical College Decision [10], was established to be 30 points. In order for the current year’s GPP Certificate to be validated, 22 points were required to be obtained. The pharmacies that did not carry on prescription drug preparation activities, could receive a maximum of 27 points.

Figure 2 shows the pharmacies grouped according to the achieved score – 30 points, between 27 and 29, and 22-26 respectively.

It has been established that 22% of the pharmacies achieved maximum score (30 points), while 1% pharmacies achieved 22 points.

We further analysed pharmacies after their compounding activity.
Figure 3.
Distribution of pharmacies by medicine preparation activities

It has been noted that 66% of the pharmacies gave up the drug preparation activities. 34% of the analysed pharmacies have compounding activities.

Other deficiencies were related to: traceability, the existence of substance records, magistral preparations and elaborations, as well as the correct appliance of labelling and preserving guidelines.

Figure 4.
Percentage of deficiencies in evaluated pharmacies

It can be ascertained that the majority of the pharmacies that undertook prescription drug preparation respect the 5 criterias previously mentioned. Substance, packaging and final preparation traceability was ensured in over 85% of the cases, while 76% of the pharmacies had registries for substance, magistral preparation and elaboration evidence.

It has been found that some pharmacies had issues regarding the lack of confidentiality space (12%), a plan of personnel training and evaluation (12%), the lack of existence of a separate area for drug receipt (7%), clear boundaries for the storage area and the chief pharmacist’s office (7%), as well as for the lack of work and cleaning charts (5%).
Other deficiencies identified at pharmacies

88% of the pharmacies had an "easy to identify and patient-accessible" confidentiality space and a personnel training and evaluation plan for the current year.

The delimitation of the receival and storage areas, and the chief pharmacist’s office was adequate in 93% of the cases.

95% of the pharmacies had up-to-date work and cleaning charts and written statements for completed control operations.

Over 95% of the evaluated health care professionals knew and follow the prescription drug release method.

Conclusions

The study led to the following conclusions. 76% of the pharmacies achieved scores between 27 and 30.

Prescription drug preparation activity takes place in Bucharest in a percentage of 34% from the analysed pharmacies. Prescription drug preparation is one of the activities that define the pharmacist profession according to the 95/2006 Law regarding sanitary field reform, Title XIV and Deontological Code [6, 7]. By order of the Health Minister no. 344/2010 [9] this activity became optional. Its nonexistence may represent a deficit.

Other noted issues were: lack of a confidentiality area (12%), not delimiting the drug receival and storage area and the chief pharmacist’s office (7% of the cases). Only 5% of health care professionals responded incompletely at questions regarding prescription drug releasing methods.

The study revealed that most of the pharmacies in Bucharest implemented and comply with the Good Practice Guidelines for seen in standard operating procedures. This allows the increasing of the level of transparency in pharmaceutical activities and for the flexibility of the efficient patient-oriented services.
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