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THE RISK OF ERROR IN MEDICATION PRESCRIBING – LEGAL AND INSTITUTIONAL GAPS

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Abstract: The safety of the medical act is a patient's right, which involves minimizing the risk of unnecessary damage in medical care, thus medical workers become fully responsible for error prevention. At the same time, at an international level there is more and more evidence about the harm caused to patients as a result of inadequate medical care, where the irrational use of medicines is among the frequent causes. This problem was also identified through an extensive research carried out in hospitals and primary care medical institutions in the Republic of Moldova. The article describes the causes of the low level of monitoring of the rational use of medicines both at the central and institutional level. The authors identify the existing normative gaps, as well as the respective solutions to improve the situation.

Keywords: patient safety, rational use of medicines.

INTRODUCTION

Patient safety is one of the 14 fundamental rights declared in the European Charter of Patient Rights, which states that every individual has the right to be protected against harm caused by the poor functioning of health services, malpractice and medical practice errors and has the right of access to services and treatments that meet high safety standards [1].

The concept of patient safety involves minimizing the risk of unnecessary harm in medical care, taking into account system resources, context and currently available scientific knowledge [2]. The World Health Organization (WHO) believes that universal health coverage cannot be achieved if patients are not treated safely. Sustainable Development Goal Number 3 mentions the importance of safety in healthcare [3,4].

The guarantee of this right requires hospitals and health services to continuously monitor risk factors, and medical workers become fully responsible for the prevention of the risk of error and the safety of the medical act at all stages and through all its components.

At the same time, the WHO warns that adverse events due to healthcare are among the top 10 causes of death and disability worldwide. Poor health care results in higher morbidity, increased utilization of health services, and exaggerated economic costs. Annually, about 134 million adverse events due to unsafe care are recorded in hospital care in low- and middle-income countries, which are the cause of 2.6 million deaths [3].

The most harmful errors are related to the diagnosis, prescribing and use of medicines [5]. A detailed analysis of more than 74 thousand medical records of patients in countries with advanced economies determined that one patient in 10 is harmed during hospital care, and 7.4% of events were fatal. The most frequently encountered injuries are recorded following surgical interventions (39.5%) and as a result of incorrectly applied medication (15.1%) [6]. A study carried out in hospitals for acute diseases in Portugal identified an 11.1% incidence of adverse effects, among which the irrational use of drugs constitutes about 18.3% [7].

Irrational use of medicines (IUM) ranges from prescription, distribution, storage, preparation and administration, wrong dose, wrong medicine, to the simultaneous use of a large number of medicines, administration of potentially inappropriate medicines, antagonists, medicines that are not indicated clinical as well as medication duplication.

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The irrational use of medicines is becoming an extremely serious global problem, which damages substantially the health of the population. In developing and transition countries, less than 40% of public sector patients and only about 30% of private sector patients are treated according to treatment standards set out in guidelines and protocols [8]. Medication errors are three times more common in children than in adults [9]. About 13% of prescriptions for children contain errors [10], the cause being determined by differences in the age and weight of children [11].

Another group at increased risk for adverse effects from medication is the elderly population, resulting from the multiple morbidity characteristic of old age, which increases the complexity of therapeutic behavior and the use of several drugs simultaneously to treat each individual condition. Also, elderly patients are at an even greater risk of adverse effects due to reduced kidney and liver function, leaner body mass, and other physiological changes specific to aging [12]. The risk of adverse effects and harm increases with the number of interacting drugs. In particular, harm can result from drug-drug interactions as well as drug-disease interactions [13].

The phenomenon of irrational use of medicines has also been found in studies conducted recently in the Republic of Moldova [14]. The analysis of about 500 observation sheets of some therapeutic hospital departments identified 71% cases of polypharmacy, 40% cases of ineffective prescription of drugs, 32% cases of disregarding contraindications, 15% cases of simultaneous administration of therapeutically incompatible drugs.

The analysis of about 625 medical files from different curative institutions in the country demonstrated that in 30% of cases the prescription of drugs was wrong, among them being the incorrect and inappropriate selection of the drug, the incorrect determination of the dosage regimen, the lack of evidence of possible drug interactions , disregarding contraindications, insufficient control of the drug's action, polypharmacy, etc. In 48% of cases the patients were simultaneously administered 5-6 medications, and in the remaining 52% of cases – seven or more drugs. [15].

A large proportion of adverse events can be avoided. According to some estimates, from 43% [6] to about 53% [7] of errors committed in the hospital sector could be prevented, as well as about 80% [5] of errors committed in the field of primary health care.

Among the main causes that increase the risk and probability of the occurrence of adverse events are considered gaps in the organization of preventive measures, insufficient tools for a correct management of the quality of the medical act, inadequate organizational culture, shortage of personnel, etc. [16]. At the same time, the WHO recommends 12 interventions that need to be carried out at the level of health systems to reduce the impact of the irrational use of medicines and, respectively, increase the safety of patients in the process of providing medical car. [17].

A recent study conducted at the national level in the Republic of Moldova determined a high risk for the occurrence of adverse events in public medical institutions, both hospitals and primary care, due to numerous problems in the organization of measures and tools to prevent the irrational use of medicines [18].

METHODS

The study included the application of questionnaires to 34 hospital institutions and 24 primary medical care institutions, both from the urban and the rural sectors. The question sheets were completed by the managers of medical institutions, where the process of monitoring the use of medicines in the institution was described. The questionnaires contained 18 questions, half of which were open-ended. In particular, the questionnaire allowed us to identify the role and volume of involvement of the institutional structures and the managerial body of different stages in the process of monitoring the rational use of medicines in the medical institutions included in the research.

At the same time, 15 in-depth individual interviews were conducted with representatives of the central authorities in the health system and 5 focus group discussions (medical practitioners) in order to collect opinions on the effectiveness of the existing mechanisms that monitor the prescription of drugs in medical institutions in the country, both from the primary care sector as well as specialized assistance. The accumulated qualitative results were analyzed using the method of interpretive phenomenological analysis, which allowed us to identify the key issues through the final conclusions, as well as the formulation of recommendations.

RESULTS

The research identified a number of gaps in the organization of process of the rational use of medicines, namely:

- Lack of a centralized approach and accountability

At a national level, there is no univocal and uniform approach to monitoring and promoting the rational use of medicines in the country's medical institutions, both in hospital care and in primary care. There is no centralized record of this process, and a structure responsible for coordinating, verifying and promoting the rational use of medicines coulnd't be identified.

On one hand, the central authorities involved in the quality management activities in health do not have sufficient resources (legal instruments and human resources) in order to achieve the functional attributions that refer to the monitoring and control of irational use of medicines (IUM) at the national level. On the other hand, the normative framework relevant to the monitoring and control process of the IUM is insufficient, sometimes ambiguous, in some cases outdated and does not ensure the continuity of the process.

Due to inconsistencies at the legislative level, since 2012 [19], it has become impossible to check IUM within hospital institutions for the central structures that previously dealt with this field.

Although polypragmatism has a negative impact on the quality of medical services, this phenomenon is not monitored and has no impact on the institutional contracts concluded annually with the National Medical Insurance Company.

At the same time, practically all managers of primary care institutions and the majority (83%) of managers of hospital institutions believe that the currently existing regulatory framework for the control, monitoring and prevention of polypragmatism in medical institutions is insufficient. An essential revision of all normative acts that refer to this field is necessary.

Insufficient monitoring at a national level

The structures that currently exist at the institutional level, responsible for activities relevant to the IUM monitoring and control process (Quality Councils, Pharmacotherapeutic Formulary Committee, departments for monitoring, evaluation & integration of healthcare services) do not fully fulfill their duties due to some gaps in the normative framework that regulates their activity, the lack of specialized personnel, as well as the lack of knowledge regarding the monitoring and control of IUM among the members of these structures.

Clear responsibilities and duties are not determined for monitoring and controlling the rational use of medicines in medical institutions, they are carried out without regularity and adequate involvement. Even if one of the basic measures in the monitoring of IUM is the internal medical audit, in many medical institutions the subject of polypharmacy is not adequately evaluated through the procedures of this audit. In most medical institutions there are no dedicated people who possess sufficient knowledge and skills for the proper organization of the internal medical audit process.

Following the discussions with people involved in the evaluation and audit process, we were frequently given the opinion that the current regulatory framework regarding the medical audit needs an obvious improvement. The Order of the Ministry of Health [20] with reference to this subject contains a heavy text, it is very loaded with theoretical parts and the instruments and methods of applying its provisions in practice are not clearly explained. The respondents noted that they want a much more accessible and clear document, with a concrete algorithm for carrying out the audit procedures.

At the same time, doubts were expressed with reference to the inconsistency between the provisions of two orders of the Ministry of Health [20, 21] regarding the performance of the activities of the members of the internal medical audit group, where in one document the coordinator is a full time employee, carrying out the medical audit in the institution, and in another it is stipulated that the members of this group carry out their activity unpaid, in addition to the basic professional duties. Only in a few tertiary level hospital institutions are employed such coordinators who, in the opinion of many respondents, would be very necessary and important in the process of organizing the correct and efficient internal medical audit.

Internal medical audit missions related to the clinical risk of polypharmacy are not adequately performed and understood. Some participants in the study noted that, in the institutions where they work, the results found following the medical audit carried out are used by the administration as a benchmark for sanctions and punishments, while the audit, by its essence, should lead to constructive corrective actions, improvement and training. Most respondents admitted that the internal medical audit performed in the institution was never directly related to the clinical risk of polypharmacy.

"Unfortunately, in our institutions the attitude towards risk management is very formal. Many managers simply do not understand what this field is." (representative of the Health Authorization and Accreditation Directorate, National Agency of Public

Health).

Only about half of the managers of public hospital institutions (53%), and only every third (33%) manager of PMC institutions appreciated the process of monitoring the rational prescription of drugs and avoiding polypharmacy as satisfactory. About 30% of the managers of hospital institutions and 21% of managers from primary care evaluated it as insufficient.

Insufficiency of Clinical Protocols

The National Clinical Protocols (NCPs) are developed by multidisciplinary groups of specialists, established in each field, in accordance with the recommendations of international diagnostic and treatment guidelines, based on scientific evidence. Based on the NCP, each medical and sanitary institution is obliged to develop and apply Institutional Clinical Protocols (ICP), which are also the priority tools for respecting the rational use of medicines in medical institutions.

However, both doctors from hospital institutions (68%) and those from primary care (45%) admit that clinical protocols are not always followed in establishing treatment practices. During focus group discussions, some doctors admitted that there are cases when they allow themselves to be influenced by patients in prescribing treatment in order to increase satisfaction, increase their image in front of the patient by prescribing complicated and complex treatments; some doctors want to have the fastest and most pronounced therapeutic effect. Some doctors confirmed that the phenomenon of abusive use of injections still continues to exist. The main reason is mentioned, in the vast majority, the conviction of a large number of the population that injections are much more effective than other forms of drug administration.

At the same time, doctors' dissatisfaction with the fact that not all diseases currently have NCPs or they have not been updated for a long time has been expressed to us. Retired doctors prefer old methods and ignore clinical protocols; they have insufficient knowledge of evidence-based medicine, stereotyped thinking, without going into details.

Insufficient involvement of specialist pharmacologists and clinical pharmacists

According to international practices, pharmacists-clinicians have an important role in controlling the rational use of drugs in hospital institutions [22]. In some countries, the standards describe the number of patients that should be monitored by a clinical pharmacist per day, these being from 5 to 30 patients, depending on the profile of the diseases – intensive therapy or long-term treatments [23].

Even if at USMF "Nicolae Testemițanu" the training of such specialists through residency was initiated, in the country's hospitals the respective functions are not provided in the personnel lists, and the managers of public health institutions do not seem to be interested in hiring such a specialist.

Clinical pharmacologists are also important in this field, this function being included as mandatory in the staffing of hospital institutions. However, there is an insufficient coverage of such specialists at the national level, as there are very few requests from medical institutions to open places for residency, not understanding the role and importance of these specialists in the institution's professional team. Some managers honestly admitted that "they didn't even think they needed such a specialist". Out of 34 hospital institutions included in the study, the presence of the clinical pharmacologist was confirmed in only 5, all of them being at the republican or municipal level. None of the district-level hospital institutions have employed such a specialist.

In conclusion, the multitude of identified problems suggest the importance of a comprehensive approach to the process of promoting the rational use of medicines in the Republic of Moldova, as complex measures are needed at different levels and with the involvement of several actors. It is important to develop, at the central level, a clear vision regarding the organization of assurance, monitoring, control and promotion of the quality of services in the health system. It is also important to strengthen the coordination capacities at the national level, which would fully ensure the collaboration with the subdivisions at the institutional level for monitoring the process of the rational use of medicines in health institutions. No less important is the promotion of a unified concept of ensuring IUM control at the institutional level through specialists and concrete structures dedicated to this field, based on a legal framework and clear regulations.

A solution to promote the strict control of IUM within medical institutions would be to encourage competitiveness through the differentiated accreditation of medical service providers and the correlation of the degree of accreditation obtained with the differentiated financing of the institution, with different contracting rates. Respectively, medical institutions would be motivated to aim for high rates, with a high quality of services.

Of course, the quality of the medical act is the responsibility of each medical worker. However, strict quality control must be ensured continuously by the health system and the management of each medical institution, in part, through clear regulations and effective tools, in order to avoid the occurrence of damages and serious harm to the safety of the medical act.

Conflict of interest

The authors declare that they have no conflict of interest.

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