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Descriptive overview

Methodological foundations of medicines management within the framework of accreditation of medical organizations

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Abstract

Medicines management is one of the main factors in ensuring the quality and safety of medical care, especially in the context of accreditation of medical organizations.

The presented work aims to assess the current state of medicines management, which promotes rational use of medicines, improving the effectiveness of treatment, reducing risks to patients and optimizing resources in accordance with accreditation standards. To achieve this goal, we analyzed regulatory acts, international and domestic experience, as well as a comparative analysis of methodologies for assessing the rational use of medicines, including WHO indicators and ASHP approaches (MUE, FOCUS-PDCA).

Based on the obtained data, it is planned to develop a methodology for assessing the rational use of medicines within the framework of accreditation, which provides for regular monitoring of their use and introduction of practical control tools. Such tools allow to objectively assess the quality of medicines use in medical organizations and form effective measures to improve pharmaceutical management.

Keywords: medication management, patient safety, accreditation, polypragmasy, medication error, rational use of medicines.

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Introduction

Medicines are a prioritized component of the care provided to patients. They are used for diagnostic, symptomatic, preventive, curative and palliative treatment and disease management [1]. Medication management is a critical component of modern healthcare and a requirement for international and national accreditation, affecting patient safety, treatment outcomes and prevention of medication-related complications. Whether it is a simple over-the-counter pain reliever or a complex prescription drug, proper medication management is paramount to achieving optimal treatment outcomes [2].

The processes involved in prescribing, dispensing, taking and monitoring medicines are highly complex and prone to error. More than half of adults were regularly taking prescribed drugs in the United States in 2021, according to data from a Statista Consumer Insights survey. Out of the 2,000 people surveyed between July and August 2021, more than a third of respondents were taking prescribed medicine daily and one in five were taking prescribed medicine several times a day. [3]. This trend of increasing consumption of medicines is also characteristic of many other countries, which places a special responsibility on health care systems to ensure patient safety.

Globally, the World Health Organization (WHO) estimates that medication errors and unsafe practices are among the leading causes of injury and preventable harm in health systems [4]. According to WHO, direct losses from such errors amount to about 42 billion US dollars annually, not including indirect losses associated with lost work capacity and productivity [5]. Studies show that harms associated with medication errors account for up to 50% of all reported preventable harms in health care, with prescribing and monitoring errors considered key risk factors [6].

Numerous data show that medication errors can occur at all stages of the medication management process. For example, in European hospitals, prescribing errors range from 0.3% to 9.1% and dispensing errors from 1.6% to 2.1% [7]. Similar figures are found in other studies, emphasizing the importance of strict quality control at every step: from the selection and prescription of the drug to its actual administration by the patient.

A recent study conducted in the United Kingdom deserves special attention. According to its results, 28% of 237 million medication errors were potentially clinically significant [8]. Furthermore, a detailed analysis showed that errors can occur at all stages of the process: prescribing (21.3%), transcription (1.4%), dispensing (15.9%), administration (54.4%) and monitoring (7.0%) [8]. These figures reflect the complexity of the drug supply system and confirm the need to implement multi-level control and continuous improvement of standards.

The general picture is complemented by the data of Spanish researchers, according to which medication errors account for 37.4% of all adverse events occurring in medical organizations [9]. This once again emphasizes that the problem of medication errors is global in nature and requires a systematic approach to its solution: implementation of accreditation standards, process optimization, staff development and development of cultural values of patient safety.

Thus, the analysis of the presented data shows the scale and seriousness of the problem of medication errors.

The purpose of this article is to assess the current state of medication management in medical organizations, review international and domestic experience, and develop a methodology for assessing the rational use of medicines within the framework of accreditation of medical organizations. The review is aimed at identifying key factors affecting patient safety and treatment effectiveness, as well as at implementing control and monitoring tools that comply with accreditation standards.

Methodology

This article uses qualitative analysis, including documentary analysis of regulations, international standards and practical recommendations on medicines management. The study is based on the study of existing literature sources, reports of the World Health Organization (WHO), data from national and international accreditation systems, as well as statistical data on medication errors and their consequences. A comparative analysis of different methodologies for assessing rational use of medicines, including WHO indicators and ASHP approaches (MUE, FOCUS-PDCA) was carried out. Thus, the methodology of the study is aimed at systematizing the available information, identifying key problems in the management of medicines and formulating recommendations to optimize pharmacotherapy in medical organizations.

Accreditation of medical organizations: history of development, international standards and medicines management

Accreditation of medical organizations is a public recognition of the level of performance and quality of services provided by a medical organization by an external body in relation to a given set of standards. According to a study conducted in Egypt, the average patient satisfaction in accredited medical organizations was significantly higher than in non-accredited ones [10]. Such an increase in the level of satisfaction is explained by the fact that the accreditation process motivates medical institutions to continuously improve the quality and safety of medical care.

In Kazakhstan, the accreditation system was formed gradually within the framework of the State Program "Salamatty Kazakhstan for 2011-2015" and the joint project of the Ministry of Health of the Republic of Kazakhstan (MH RK) with the International Bank for Reconstruction and Development "Technology Transfer and Institutional Reform in the Health Sector of the Republic of Kazakhstan" [11,12]. In the period from 2009 to 2015, an accreditation procedure for medical organizations was developed and successfully implemented, aimed primarily at improving the quality and safety of medical services in accordance with accreditation standards [13]. During the implementation of this project, the MH RK closely cooperated with relevant international organizations and attracted foreign experts to improve accreditation standards and develop a quality management system for medical services. Since 2009, Kazakhstan has been continuously cooperating with international organizations to further improve accreditation mechanisms. A significant milestone was the Accreditation Center for Quality in Healthcare (ACQH) joining the International Society for Quality in Healthcare (ISQua) in 2019 [14]. ISQua accredits organizations with the right to accredit health care institutions in the field of health care and is the only organization in the world with such authority. Among the

international accreditors recognized by ISQua are Joint Commission International (USA), Accreditation Canada (Canada), CHKS Assurance & Accreditation (UK) and others [14]. Thus, passing accreditation by ISQua confirms that the national accreditation system of medical organizations in Kazakhstan is built in accordance with globally recognized principles and standards.

Within the framework of international accreditation, especially by Joint Commission International (JCI), the most important element of ensuring patient safety and improving the quality of medical care is medication management. JCI's requirements for Medication Management and Use (MMU) and related subchapters cover all stages of medication handling in the organization. These standards allow minimizing the risks associated with incorrect prescribing or misuse of medicines, which ultimately contributes to improving the effectiveness of treatment and reducing the likelihood of adverse outcomes [1].

At the national level, in accordance with the Order of the MH RK dated November 5, 2021 № KP DSM-111 "On approval of standards for accreditation of medical organizations" [15], also provides requirements similar to international standards. In particular, the section "Safety of medicines and medical devices" enshrines the mandatory management of medicines. These standards, as well as JCI norms, emphasize the rational use of medicines, quality and safety control at the stages of procurement, storage, prescribing and monitoring the results of therapy. In addition, they require medical organizations to implement RULS (rational use of medicines) as one of the fundamental practices to improve the quality of services and protect patients from medication errors. In Kazakhstan, the regulatory and legal basis for RILS is formed by the Order of the Minister of Health of the Republic of Kazakhstan dated November 3, 2020 № KP DSM-179/2020 "On Approval of the rules for the assessment of rational use of medicines". The document was developed in pursuance of subparagraph 48 of Article 7 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On the health of the people and the health care system", and it defines the procedure for assessing the rational use of medicines in health care organizations [16]. According to domestic researchers, using the national framework allowed the evaluator agency and healthcare organizations to identify organization-specific gaps and triggered improvements in the use of medicines [17].

Kazakhstan's accreditation system, being adapted to international standards and recognized by ISQua, attaches great importance to the management and rational use of medicines. This ensures not only high clinical results of treatment and patient satisfaction, but also strengthens confidence in the domestic healthcare system at the global level.

Key aspects of irrational use of medicines

Contrary to global and domestic public health aspirations for standards of rational pharmacotherapy, irrational use of medicines remains an acute problem. As a result of overuse, underuse, or misuse of medications results in wasted scarce resources and widespread health hazards [18]. Medication errors occur due to systemic problems and/or human factors such as fatigue, poor environmental conditions or staff shortages that affect prescribing, transcription, dispensing, guidance and monitoring practices. These errors can lead to serious harm, disability and even death [19].

WHO highlights some of the most common examples of irrational use of medicines [18]:

- Use of an excessive amount of drugs per patient (polypragmasia). In a study conducted in Russia, it was found that more than half of elderly outpatients are subjected to polypragmasia. Based on the 2012 Bierce criteria, irrational drug therapy was found in 20% of elderly patients, and based on the STOP and START criteria - in 43.3% and 66.6%, respectively [20];

- Inappropriate use of antimicrobials. According to a study conducted in 2023 in 14 countries in the WHO European Region, one third (33%) of respondents purchased and used antibiotics without a prescription. In some countries, more than 40% of antibiotics were obtained without a doctor's prescription. In comparison, in a similar survey conducted in EU countries in 2022, only 8% of respondents were taking antibiotics without a prescription [21];

- Overuse of injectable drugs (when oral dosage forms are appropriate). As many as 16 billion injections are prescribed in LMICs each year. In some cases, more than 70% of injections are unnecessary or can be given in other dosage forms such as oral medications [22];

- Prescribing outside of evidence-based clinical guidelines. Studies show that off-label prescribing is a common practice in various medical specialties such as pediatrics, oncology, obstetrics and gynecology. In some cases, the share of such prescriptions reaches 40-60% of the total number of drug applications in these areas [23];

- Inappropriate self-prescribing of medications, often prescription drugs (self-medication). Statistics show that each year about 6% of Americans over the age of 12 use prescription drugs not prescribed by a doctor. Among this group, it is particularly alarming that approximately 12% of prescription abusers subsequently become dependent on these drugs. [24];

- Non-compliance with dosing regimens. According to a study, 30% to 60% of patients suffering from severe chronic diseases do not adhere to the prescribed treatment [25].

Methodological basis for control and improvement of rational use of medicines

To assess and optimize processes within a medical organization, indicators are widely used to track the timeliness and quality of service delivery in accordance with the requirements of standard operating procedures or clinical protocols. Deviation from the set standards inevitably leads to a decrease in the quality and efficiency of treatment.

The management of the medical organization annually determines priority indicators of quality and safety - both for the entire organization and for its individual structural subdivisions. The results of monitoring of these indicators are included in quarterly and annual reports, which ensures transparency of processes and the possibility of prompt management decisions to improve pharmacotherapy.

To improve the management of medicines, the WHO identifies indicators that characterize the rational use of medicines in a medical organization:

- average number of drugs prescribed in the MO;

- the percentage of use of a particular category of drugs in the MO;

- percentage of parenteral use of medicines in the MO;

- percentage of prescribed drugs included in the list of essential medicines;

- percentage of adequately labeled drugs in the MO;

- Percentage of patients aware of how to take the medicine;

- availability of clinical guidelines in the MO [26].

The practical application of such indicators greatly simplifies the monitoring and analysis of current prescribing and use practices, which ultimately contributes to the optimization of pharmacotherapy.

ASHP (American Society of Health-System Pharmacists) has developed a recommended MUE (Medication Use Evaluation) approach for medication use management in health care settings, the main objectives of which are to identify deviations from standards of care, compare current practices with recommended practices, prevent or reduce adverse drug reactions, create educational programs, etc. The American Society of Health-System Pharmacists effectively utilizes the FOCUS-PDCA method in medication management to improve the rational use of medications. The method combines two concepts: process analysis and improvement (FOCUS) and the Deming cycle (PDCA).

Steps include: F - find the process to be improved; O - organize a team that knows the process; C - refine current knowledge of the process; U - understand the causes of variation in the process; S - select a process improvement. P - plan: develop a solution; D - do: implement the improvement; C - test: evaluate the results; A - act: determine what changes are needed to move forward and implement those changes [27].

Thus, WHO recommendations and ASHP practical tools based on indicators and assessment methodologies provide a comprehensive approach to rational use of medicines. Regular monitoring, data analysis and implementation of continuous improvement mechanisms help to improve patient safety, clinical outcomes and rational use of health care resources.

Conclusion

Rational use of medicines is important to ensure patient safety, improve treatment efficacy and reduce costs. Medication errors remain a global problem requiring a comprehensive approach. Modern approaches such as WHO indicators and ASHP methodologies (MUE, FOCUS-PDCA) help to optimize pharmacotherapy. These tools allow to objectively assess the quality of medication use and improve treatment processes. The synergy of these approaches facilitates the introduction of global practices into national and international healthcare systems, which is confirmed by the accreditation of medical organizations. Implementation of RILS with innovative tools and standards is necessary to improve the quality of medical care.

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Authors' contributions.

Conceptualization by A.M.; methodology by A.M.; verification by G.Zh.; formal analysis by A.M., G.Zh.; writing (original drafting) by A.M.; writing (review and editing) by G.Zh.

All authors read and agreed to the final version of the manuscript and signed the copyright transfer form.

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Медициналық ұйымдарды аккредиттеу шеңберінде дәрілік заттар менеджментінің әдіснамалық негіздері

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Түйіндеме

Дәрілік заттарды басқару медициналық ұйымдарды аккредиттеу контекстінде медициналық көмектің сапасы мен қауіпсіздігін қамтамасыз етудің негізгі факторларының бірі болып табылады.

Ұсынылған жұмыста дәрі-дәрмектерді ұтымды пайдалануға, емдеу тиімділігін арттыруға, пациенттер үшін тәуекелдерді азайтуға және аккредиттеу стандарттарына сәйкес ресурстарды оңтайландыруға ықпал ететін дәрілік заттарды басқарудың ағымдағы жағдайын бағалау мақсаты қойылған. Осы мақсатқа қол жеткізу үшін нормативтік актілерге, халықаралық және отандық тәжірибеге талдау, сондай-ақ ДДҰ индикаторлары мен ASHP (MUE, FOCUS-PDCA) тәсілдерін қоса алғанда, дәрілік заттарды ұтымды пайдалануды бағалау әдістемелеріне салыстырмалы талдау жүргізілді.

Алынған мәліметтер негізінде аккредиттеу шеңберінде дәрілік заттарды ұтымды пайдалануды бағалау әдістемесін әзірлеу жоспарлануда. Әдістеме оларды қолданудың тұрақты мониторингін және бақылаудың практикалық құралдарын енгізуді көздейді. Мұндай құралдар медициналық ұйымдарда дәрі-дәрмектерді пайдалану сапасын объективті бағалауға және фармацевтикалық менеджментті жақсарту үшін тиімді шараларды қалыптастыруға мүмкіндік береді.

Түйін сөздер: дәрілік заттарды басқару, пациенттердің қауіпсіздігі, аккредиттеу, полипрагмазия, дәрі-дәрмек қатесі, дәрілік заттарды ұтымды пайдалану.

Методологические основы менеджмента лекарственных средств в рамках аккредитации медицинских организаций

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Резюме

Менеджмент лекарственных средств является одним из основных факторов обеспечения качества и безопасности медицинской помощи, особенно в контексте аккредитации медицинских организаций.

В представленной работе ставится цель оценить текущее состояние по управлению лекарственными средствами, которая способствует рациональному использованию препаратов, повышению эффективности лечения, снижению рисков для пациентов и оптимизации ресурсов в соответствии с аккредитационными стандартами. Для достижения этой цели нами проведен анализ нормативных актов, международного и отечественного опыта, а также сравнительный анализ методологий оценки рационального использования лекарственных средств, включая индикаторы ВОЗ и подходы ASHP (MUE, FOCUS-PDCA).

На основе полученных данных планируется разработать методику оценки рационального использования лекарственных средств в рамках аккредитации, который предусматривает регулярный мониторинг их применения и внедрение практических инструментов контроля. Такие инструменты позволяют объективно оценивать качество использования медикаментов в медицинских организациях и формировать действенные меры для улучшения фармацевтического менеджмента.

Ключевые слова: менеджмент лекарственных средств, безопасность пациентов, аккредитация, полипрагмазия, медикаментозная ошибка, рациональное использование лекарственных средств.