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PHARMACOLOGY AND DRUG SAFETY

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Abstract

This article analyzes the relevance of the pharmacovigilance system in modern conditions, its role in ensuring the safety of medicines, and its practical mechanisms. In recent years, the expansion of the range of medicines, the increase in the share of biological drugs and generics, as well as the increase in self-medication among the population, create the need to further improve the pharmacovigilance system. The article comparatively highlights the effectiveness of the processes of identifying, registering and analyzing adverse reactions. It also considers the issues of sustainable control of the safety profile of medicines, protecting patient health, and strengthening trust in the healthcare system through strengthening pharmacovigilance on a scientific basis.

Introduction

Materials and Methods.

The rapid development of the pharmaceutical industry has led to a sharp increase in the number and variety of drugs. Every year, hundreds of new molecules are introduced into clinical practice. At the same time, biological drugs, biosimilars and generics are expanding their market share. This process, while creating new opportunities for the healthcare system, also raises safety issues.

Results and Discussion.

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Practice shows that some side effects that were not identified during clinical trials may appear after the drug is widely used. This is because clinical trials are conducted with a limited number of participants and for a certain period of time. In real life, the drug is used in combination with other drugs of different ages, genders, comorbidities, and other conditions. Therefore, the pharmacovigilance system — a mechanism for continuous monitoring of the safety of drugs — has become an integral part of the modern healthcare system.

In recent years, it has been noted that hospitalizations due to adverse drug reactions worldwide account for a significant proportion of total hospitalizations. This increases the importance of the problem not only medically, but also socio-economically.

Pharmacovigilance is a scientific and practical activity aimed at identifying, assessing, understanding, and preventing the side effects of drugs. Its main goal is to balance the benefit-risk ratio of the drug.

The difference between clinical trials and practical use is as follows:

Criteria	Clinical trial phase	Implementation stage
Number of participants	Limited	Very wide
Selection criteria	Definitely	Free
Monitoring	Under control	Under different circumstances
Side effect detection	Limited	It will be more fully revealed

This table shows that a full assessment of the safety of a drug is possible only in real-life practice. Therefore, pharmacovigilance is a logical continuation of clinical trials.

In countries with a well-established pharmacovigilance system, adverse reactions are detected early and prompt action is taken. For example:

- Amendments to the instructions for use of the drug
- Revision of dosage restrictions
- Prohibition of use for certain groups

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A comparative analysis of effectiveness shows that:

Indicator	Weak pharmacovigilance	Strong pharmacovigilance
Late detection of side effects	High	Low
Treatment costs	Excess	Optimized
Patient safety	Relatively low	High
Trust in the system	Slow	Strong

These data indicate that improving pharmacovigilance directly increases the effectiveness of healthcare. Because the pharmacovigilance system is not limited to recording adverse reactions, but also includes a mechanism for their in-depth analysis, determining the cause-and-effect relationship, and reducing future risks. In other words, pharmacovigilance is not a passive observation, but an active management tool. It is this aspect that makes it a strategic component of the modern healthcare system.

From this point of view, in-depth study and systematic development of pharmacovigilance provides a number of practical advantages.

First of all, it becomes possible to predict risks in advance. The adverse reactions collected in the database, the age characteristics of patients, concomitant diseases, and combinations of drugs used are analyzed, and risk groups are identified. This serves to make scientifically based decisions on who to prescribe a particular drug to with caution or not to recommend it at all. As a result, complications are reduced, and the treatment process is more stable.

Secondly, it becomes possible to compare the safety profile of generic and original drugs. Generic drugs, which are theoretically recognized as bioequivalent, can sometimes react differently in practice due to differences in excipients or technological processes. Pharmacovigilance data help to identify these differences and serve as a basis for improving drug policy.

Thirdly, in conditions of polypharmacy, it is important to identify drug interactions. Especially in elderly patients, the metabolic load increases due to the simultaneous intake of several drugs, and the likelihood of side effects increases. Through pharmacovigilance, real clinical outcomes of drug interactions are studied and safe combinations are formed.

Fourthly, the issue of improving the culture of drug consumption of the population is also directly related to pharmacovigilance. Open and reliable

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information about side effects reduces the population's negligent attitude to self-medication. The responsibility of doctors and pharmacists increases, and the patient understands the need to take the drug consciously and according to the instructions.

Thus, a thorough study of pharmacovigilance is not only a statistical reporting tool, but also an important factor in managing clinical safety, increasing economic efficiency and ensuring stability in the healthcare system.

Especially in elderly patients, the simultaneous use of several drugs (polypharmacy) increases the risk of side effects. The pharmacovigilance system helps to control this situation.

Conclusion

The above analysis shows that ensuring the safety of medicines is not limited to the stage of production or registration. This process requires continuous monitoring. The more perfectly the pharmacovigilance system is organized, the more stable and reliable the healthcare system will be.

The relevance of pharmacovigilance is directly related to the expansion of the range of medicines and their rapid global distribution. To achieve high efficiency, the following systematic measures are necessary:

Recommendations for improving the effectiveness of pharmacovigilance

Problem	Why is it important?	How is it done?	Expected result
Side effects are rarely reported	Statistical information is lacking	Mandatory electronic reporting system	Accuracy and speed increase
The qualifications of specialists are not sufficient	High risk of error	Continuing education courses	Quality monitoring
Database fragmentation	Analysis becomes difficult	Centralized national platform	Unified control system
Public awareness is low	Self-medication is on the rise	Educational programs	Security increases

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Thus, strengthening the pharmacovigilance system will not only reduce adverse drug reactions, but also strengthen the economic sustainability of the healthcare system and the population's trust in medical services. Ensuring the safety of medicines is not a one-time process, but a continuous and responsible control mechanism. It is this approach that will serve the sustainable development of the pharmaceutical industry.

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