ON THE RELEVANCE OF MONITORING OF THE MEDICINES SAFETY

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ABSTRACT — Along with the development of the social system the reorganization and improvement of public health take place. But no country with a high level of economic development allocate sufficient funds for public health costs. This problem has become relevant also in Kazakhstan since the 90s of the last century.

In the dynamic conditions of society at the same time the reorganization and improvement of public health take place accordingly to the material level of the country development. This also applies to the medicines' policy. One of the important aspects of the national medicines' policy is the development of an effective mechanism of medicines' supply to population and public health institutions [5]. Special attention in conditions of healthcare reorganization requires the pharmaceutical supplies, due to its high economic component in the cost. Great attention around the world is devoted to the issues of selection and proper prescribing of medicines.

In Kazakhstan, this issue was sharply raised since the early 90s of the last century, when unfavorable trends in public health indicators occurred simultaneously [4], and numerous foreign medicines, sometimes not always of proper quality appeared in the market. Constant growth of the prices for all services, including those for medical ones and the medicines have led to a situation when "in no other country there are sufficient funds for health care costs" (WHO, 1995).

The most important part of practical health care, providing the high-quality medical care to the population of the Republic of Kazakhstan, are health centers of stationary type. Despite the introduction of restrictive measures to improve the quality of care into the practice of health centers recently, important issues of the safety of pharmacotherapy remain unresolved. Introduction of clinical protocols for treatment and diagnosis only to a certain extent streamlined the medical staff and hospitals in general, however, this measure has not led to the achievement of progressive results in clinical and, moreover, in the economic scale [6]. The



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application of such recommendations by itself is not sufficient to change the behavior of doctors. Medicinal budgets of health care institutions today are not able to provide the full need of hospitalized patients in the medicinal therapy. At the same time there is an acute issue of searching for effective ways to optimize pharmacotherapy. Apart from this problem the issues of rational antibiotic therapy should be highlighted [9]. The currently ongoing reform in Kazakhstan medicines' supply and updating of national medicinal policy requires introduction of modern scientific approaches to solving the problem of rational use of medicines.

According to WHO, "the rational use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their individual needs, for an adequate period of time and at the lowest cost to them and to society."

Thus, when security monitoring of the conducted pharmacotherapy attention should be paid to the

system of rational use of medicines which provides the most cost-effective medicine for the treatment of the individual patient sickness in order to obtain the maximum therapeutic effect [11].

Implementation of the system of rational medicines use provides the opportunity to simultaneously solve the problems of the clinical and economic nature in practical medicine. Pharmacoeconomic analysis is a tool for determining the costs and benefits associated with different methods of treatment, which makes effective use of medicines budgets and health care budgets in general [1].

Rational medicines use is primarily directed to the selection and proper use of medications with proven clinical efficacy and safety. Economic evaluation of the use of medication assumes the analysis of all clinical effects of treatment with the given medication and quantitative assessment of the direct and indirect costs associated with its use.

Many government policies in various countries limit the use of expensive drugs. Often, however, only the cost of the medication is taken into account, but the potential effectiveness of therapy with these drugs is not assessed [14]. At the same time, from the point of pharmacoeconomics application of more expensive, but more effective and safer medication can ultimately lead to better therapeutic result and thus reduce the potential costs associated with the duration of treatment and hospitalization, treatment of complications of pharmacotherapy, prevention of side effects of medicines, including antibiotics [2].

Irrational use of antibiotics leads to the development of a vicious circle: the means that could be used for prevention and treatment of diseases, are spent on managing and treating the wrong selection and treatment, thus the harm and damage is done to the health of the population is harmed and the country's healthcare budget. As a result of irrational use of medicines, such as those in the U.S. each year 8.76 million hospitalizations associated with errors in drug therapy (to treat the effects of spent 47.4 billion dollars) are recorded, as well as 115 million visits to physicians because of problems with drugs (\$7.5 billion), 76.3 million additional prescriptions for correcting errors pharmacotherapy (1.93 billion dollars) are issued, 200,000 deaths related to the misuse of drugs are recorded. Serious adverse events are recorded at 2.1 million people in the country annually and are the fourth leading cause of death. The number of victims of medicinal therapy exceeds three times the number killed every year in car accidents [19].

Of all visits to the doctor 3–15% are due to the deterioration of health linked to the use of drugs; the cause of 3–5% of hospital admissions are the side

effects. It was found that on average, the side effects occur in 10–20% of hospitalized patients, and in developing countries, their number reaches 30–40% [19]. With proper selection and use of medicines about half of all side effects could be prevented. The consequence of uncontrolled, broad, long-term and irrational use of antibiotics has become an increasing problem of microbial resistance to almost all classes of antibiotics, and the patient's death from severe infections. In the U.S. as a result of resistance to antibiotics about 60 000 people die each year and more than \$4 billion is spent additionally [3].

Problem of rational choice of medicines is complicated by an enormous number of registered medicines. Currently, over 9000 products circulate on the pharmaceutical market in Kazakhstan; in Russia — more than 13,000 kinds of medicines, in Japan — 15,000, in the USA - 19,000. Every year thousands of pharmaceutical products worth more than U.S. \$200 billion are sold in the world. This problem is acute in Kazakhstan due to the widespread use of antibiotics [18]. In hospitals of Kazakhstan medicines' side effects are monitored retrospectively upon applying the "yellow cards". When checking a number of medical institutions of the regional center, we found a misunderstanding of the significance of such medicines' monitoring among doctors, as well as their concern that they may be punished for presenting the information on the side effects of medicines.

Not even is conducted an adequate analysis of the obtained retrospective reports of the side effects of medicines, including antibiotics [17].

While conducting a retrospective analysis of pharmacotherapy with antibacterial medicines in the therapeutic department of the emergency hospital it was revealed that antibacterial medicines of the cephalosporin antibiotics group and fluoroquinolones were prescribed. Prescribing of the abovementioned drugs are conducted empirically, without prior analysis of antibiogram pathogen. This, in its turn, leads to undesirable pharmacoeconomic costs without the desired effect, and without control of side effects of medicines [20].

Thus, while conducting a literature review and analysis of medical records of in-patients, once again we see the need for research to determine the importance of monitoring for side effects and pharmacoeconomic analysis of antibacterial medicines of beta-lactam group and fluoroquinolones in therapeutic practice.

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