medicines of various groups in the treatment of DM II is replete with several features and involves the possession of a certain amount of information by the appropriate specialist and the patient himself. In this sense, this requires a qualitatively new approach to the pharmaceutical care of these medicines, adequate coordination of the order of their administration with well-known recommendations for nutrition, physical activity, etc. important events, which not only have not lost their significance in the treatment of diabetes (in particular, DM II), but have acquired special significance against the background of clarified facts, significantly increasing the survival of such patients and improving their quality of life

Aim. The present work aimed to study the spectrum of used antihypertensive medicines in patients with DM II in a hospital clinical base of the university and to develop recommendations for the rational use of antihypertensive therapy in this group of patients.

Materials and methods. 38 patients with AH and DM II were examined by questionnaire survey and analysis of case histories in a hospital clinical base of the university. These were patients aged 46 to 70 years (mean age 59 ± 0.43 years). Among them were 22 women and 16 men. The diagnosis of DM II of varying severity was available for at least 3 years. The effectiveness and tolerability of the treatment was taken into account according to the dynamics of patient complaints and the need to change the treatment regimen, as well as the long-term results of treatment, evaluated according to control examinations

Results and discussion. Three groups were used as antihypertensive medicines: ACE inhibitors, calcium channel blockers and diuretics. In some cases, they were used in combination. In 23 patients (60.5% of all patients), an ACE inhibitor was used as the main antihypertensive medicine, in 28.9% – a calcium channel blocker, and another 10.6% used a diuretic (mainly a thiazide group). One antihypertensive preparation was used in 52.6% of the examined population, and the remaining 18 (47.4%) took 2 antihypertensive medicines. The most common combination is an ACE inhibitor or calcium channel blocker with a diuretic. The ACE inhibitor (for example, lisinopril) turned out to be the most acceptable at the first stage of the selection of therapy in most clinical cases. With tolerance or intolerance to ACE inhibitors, the use of a calcium channel blocker is indicated. At the second stage, taking into account the presence of organ dysfunctions and pathology of target targets, international recommendations are taken as the basis and additionally prescribed preparations with dose adjustment of already taken.

Conclusions. In the treatment of AH and concomitant DM II, the predominant use of ACE inhibitors was revealed, which were used in 60.5% of patients. To achieve the target blood pressure in patients, monotherapy was used in 52.6% of patients and a combination of two or three medicines in 47.4%. An unreasonable prescription of several preparations and their dosages was observed in about a third of the examined patients. Based on the results of the work, practical recommendations were developed on the rational selection of antihypertensive therapy in the studied patient population.

EVALUATION OF THE STATE
OF RISK-BASED QUALITY MANAGEMENT TOOLS IMPLEMENTATION
IN CLINICAL TRIALS OF DRUGS IN UKRAINE

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Background. Issues of development and implementation of quality management tools in practical activity have recently received a lot of attention from both foreign and domestic scientists. Nowadays, the work on identification of the need for harmonization of quality management systems (QMS) of different parties and organizations involved in the processes of clinical trials (CT) of drugs organizing and conducting, development of methods for the efficiency of quality management tools

which are already known and used in practice use improvement, as well as the developing newer and more effective ones is actively being done.

For this reason, it is necessary to analyze the current state of use of quality management tools in the CT field in Ukraine in order to substantiate the need to develop methods of using these tools, staff training, as well as the implementation in practice of current approaches to quality management. To date, these tasks are extremely relevant to the realities of the CT market development in Ukraine.

The aim of this work was to study the current state of quality management tools implementation in the CT of drugs field and evaluation of their use in practice.

Materials and methods. In order to identify the problems and determine the need to create ways to improve the QMS, we conducted a survey of 217 national specialists who work in the field of CT of drugs organizing and conducting. The questionnaire that was offered to the respondents consisted of two parts. The first part contained general questions on the education, experience, place of work and responsibilities that respondents fulfilled in CT, as well as experience in professional development through trainings and seminars on Good Clinical Practice. The second part covered the following issues: a) implementation of the QMS in the organizations involved in the implementation of the CT; b) assessment of the respondents' knowledge regarding the basic approaches and techniques for CT of drugs quality management; c) the use of quality management tools.

The general characteristics of the respondents were calculated using descriptive statistics methods. The frequency of use of certain quality management tools was assessed according to the respondents' answers. Frequency of use was evaluated as a percentage according to the respondents' choice of quality management tools that they use in their practical activities from the following list: risk-oriented quality management methods, routine quality control by a quality management specialist, the CAPA-planning method, method of monitoring / audits.

The presence of statistical significance of the impact of the work experience in CT on the frequency of use of quality management tools for respondents was estimated using the analysis of the conjugate tables method.

The methods of generalization and synthesis were also used in the work. The calculations were made with the help of MS Exel 2010 and StatSoft Statistica 10.

Results and discussion. Most of the respondents (91.7%) had medical education, experience in the field of CT more than 10 years (36.4%), participated in more than 10 CT (29.5%), worked at the clinical site (CS) (89.4%) and fulfilled the duties of researcher or co-researcher (62.2%).

According to the respondents opinion, the method of monitoring / audits (48.4%) and routine internal quality control (47.5%) were determined as the most used CT quality management tools for ensuring the proper level of quality in the processes of CT organizing and conducting. Only 42.4% of respondents use a systematic approach to quality assurance of CT processes.

The CAPA-planning method is used in practice by only 6% of respondents. Although regulatory documents and auditors require the elimination and prevention of identified nonconformances in the processes of CT organization and conduct using this tool, which should be included in the QMS of the organization. This result may be due to a misunderstanding of how this method is used and the need for additional training for CT staff on the practical use of different quality management tools.

Risk-based approaches to quality management are used by only 9.7%, although the effectiveness and validity of their use has been proven in numerous scientific articles. Such results may be due to lack of experience in their use, available guidance on how to use these tools, insufficient information on the benefits and results of use, experience in the field of CT organizing and conducting, or the need for additional staff training.

The study of the impact of the factor "experience in the field of CT" on the frequency of application of different quality assurance tools in practice has shown that the most supportive group for using the "routine quality control" and "monitoring / auditing" tools was the group with experience over 10 years in the field of CT organizing and conducting (54.4% and 54.4% respectively). Among all groups, a broader use of risk-oriented approaches to CT quality management and CAPA-planning was

identified in the group of respondents with work experience less than one year (11.9% and 9.5%, respectively). Although the use of the method of analysis of the conjunction tables for the comparison of groups showed no statistically significant differences between the frequency of use of instruments by groups of respondents with different experience in the field of CT organizing and conducting (p-level = 0,58 > 0,05; evaluation by the χ^2 criterion).

Such a general tendency for low frequency of risk-based methods use for the quality level of CT organization and conducting improvement requires further study of the causes of the present situation. Possible factors that may have led to this may be insufficient specialized training of staff on aspects of quality management, the complexity of practical perception of new methods, and lack of ease in use. In addition, the tendency indicates that utilitarian methods of CT of drugs quality control are widely used today.

It also should be emphasized that only half of the respondents (50.7%) consider that such a component of successful implementation of QMS in the practice of any organization as a systematic approach is comfortable in use. This can be one of the influential factors that cause the slow implementation of the QMS in the CT of drugs system in Ukraine as a whole, and in the work of CS, in particular, where the key CT processes are directly conducted.

Conclusions. A conducted survey of CT specialists has shown that routine quality control tools are often used by organizations, and risk-oriented tools are not widely used. Impact of factors "experience in CT" and "functional responsibilities performed during CT" have no statistically significant effect on the frequency of use of quality management tools.

Therefore, it is appropriate to work on development of methods for the active implementation of risk-based tools in practice, as this can also increase the assessment of ease in use of different quality management tools, including the risk-based ones.

APPROACHES TO STATE REGISTRATION AND CLASSIFICATION OF GENERIC MEDICINES IN UKRAINE, THE UNITED STATES OF AMERICA AND COUNTRIES OF EUROPEAN UNION

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Introduction. An important element in the treatment of any disease is the use of medicines with proven efficacy and safety. Such drugs are original or innovative drugs. They go through a full cycle of clinical trials and register on a complete dossier. Therefore, by the time of entry into the pharmaceutical market of the country, these drugs have confirmed efficacy and safety in use. But there are not only original drugs, but also generic ones, which are manufactured after the end of patent protection of innovative and have the same active substance, its quantity and dosage form. So, generics would have the same efficiency and the same safety profile with the original drugs. Generic drugs take up most of the pharmaceutical market not only in Ukraine, but also in other developed countries such as the United States of America (USA) and countries of European Union (EU). For the appropriate use of generics as a replacement for the original medicines, it is necessary to have a sufficient level of evidence for the interchangeability of these drugs. The proven bioequivalence of the generic drug to the original confirms their therapeutic equivalence (identical efficacy). The use of generic drugs can reduce the cost of treatment. According to the Food and Drug Administration (FDA) the use of generics has reduced USA spending on treatment 1,67 trillion dollars from 2007 to 2016. Thus, bioequivalence studies for generic drugs not only improve treatment efficiency and safety, but also minimize treatment costs.