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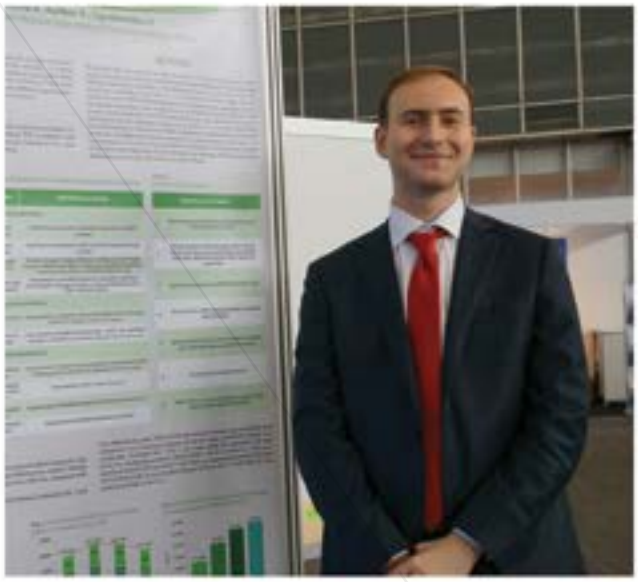
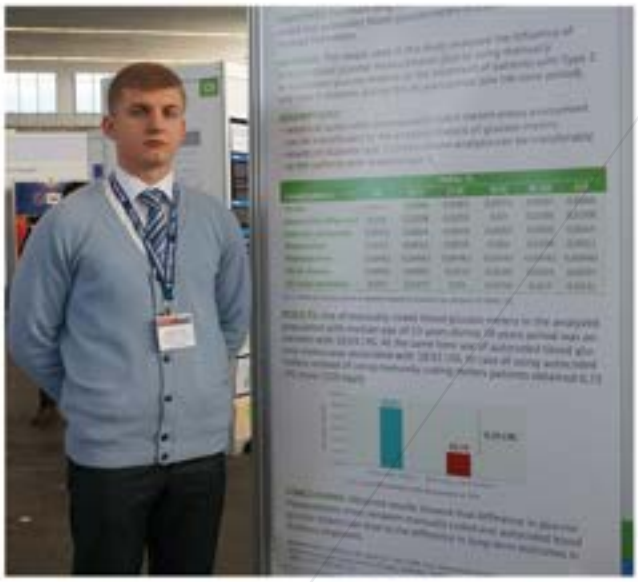
- ФАРМАКОЭКОНОМИКА ТУБЕРКУЛЕЗА: МЕТОДОЛОГИЧЕСКИЕ ОСОБЕННОСТИ ПРОВЕДЕНИЯ ИССЛЕДОВАНИЙ
- ФИНАНСИРОВАНИЕ СИСТЕМЫ ЗДРАВООХРАНЕНИЯ НА РЕГИОНАЛЬНОМ УРОВНЕ. ВЗАИМОСВЯЗЬ КАЧЕСТВЕННЫХ И КОЛИЧЕСТВЕННЫХ ПОКАЗАТЕЛЕЙ С ВЕЛИЧИНОЙ ФИНАНСИРОВАНИЯ ЗДРАВООХРАНЕНИЯ



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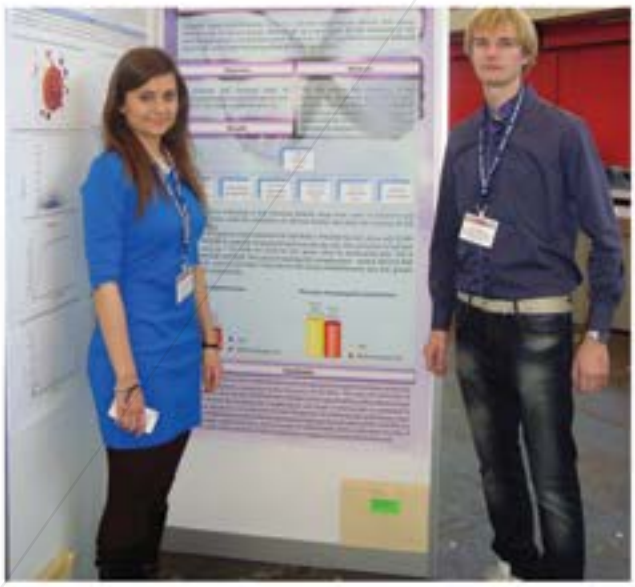

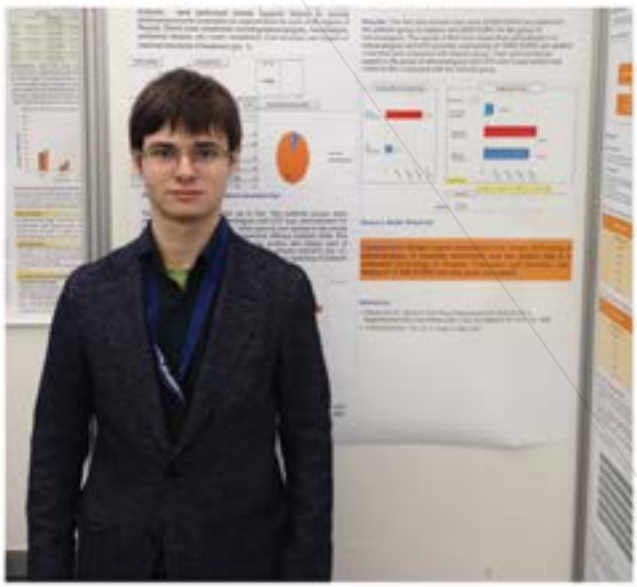

XVII ANNUAL EUROPEAN CONGRESS OF INTERNATIONAL SOCIETY FOR PHARMACOECONOMICS AND OUTCOMES RESEARCH, 8-12 NOVEMBER 2014, AMSTERDAM

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Abstract: *Main presentations and educational seminars which took place during Annual European congress of International Society For Pharmacoeconomics and Outcomes Research (ISPOR) are covered.*

Key words: *ISPOR, pharmacoeconomics, health technology assessment, health economics, cost-effectiveness analysis, cost-utility analysis, EQ-5D, modeling, multiple-criteria decision analysis, patient registries.*

Specialists in the pharmacoeconomics, health technologies assessment, health economics, representatives of the pharmaceutical society and other experts were able to find more than 1760 presentations during XVII Annual European congress of International Society For Pharmacoeconomics and Outcomes Research (ISPOR) which took place in Amsterdam, the Netherlands in November 8–12.

First plenary session was dedicated to the creating sustainable healthcare systems in Europe using health technology assessment (HTA). Carin A. Uyl-de Groot paid attention to the reform of European healthcare system and to the increase of the role of HTA tools in making decisions. Differential pricing in the Central and Eastern European countries was discussed by Zoltan Kalo paying attention to the peculiarities of the structure of prices for pharmaceutical products in this region. Lieven Annemans, author of «Health Economics for Non-Economists» spoke on the theme « High quality of care for all within a sustainable health care system».

Second plenary session was dedicated to the topic « Earlier Access To Innovation – Is It Worth It?» during which 2014-2015 ISPOR President and Director Adrian Towse, pointed on the necessity of the usage of pharmacoeconomics methods on the early stages of the health technologies development. Senior Medical Officer of European Medicines Agency (EMA) Hans-Georg Eichler presented the regulatory agencies perspective, highlighting the measures conducted on the organization of early implementation of HTA in regulatory processes. Heads of German and English HTA agencies (IQWIG and NICE) approved the policy of HTA implementation in the early stages of technology development.

Third plenary session was dedicated to the theme «Health Care Evidence: Can We Get To The 'Real World'?». Professor Finn Borlum Kristensen in the eponymous speech highlighted the importance of the obtaining data from the real clinical practice for the increase of studies validity. Professor Lars Pedersen shared the longstanding positive experience of the patient registries usage in the Norwegian healthcare system, professor Hilary Pinnock told about the results of the effectiveness study in patients with bronchial asthma in real clinical practice.

Educational workshops were held during the Congress, where participants were able to gain knowledge of the theoretical foundations for conducting pharmacoeconomic studies, to see the methods in practice and to ask questions from leading experts in this field.

One of the workshops was devoted to the application of cost-effectiveness analysis in clinical studies. According to experts, the design of clinical trials should be planned in such a way that upon its completion, it was possible to conduct the economic evaluation of its results and cost-effectiveness analysis as part of clinical studies. Attendees also discussed the possibility of inclusion in the study the determination of the efficacy endpoints of economic significance, even at the planning stage of clinical trials, which should increase the internal validity and timeliness of data obtained during the clinical study. This fact should increase the value of the results for decision-makers; consider evidence of economic value along with clinical efficacy when making decisions about resource allocation. Thus, it should be noted that the planning of clinical research requires close interaction between clinical departments with specialists in the field of pharmacoeconomics.

At the seminar «Development, validation, and use of observer-reported outcomes in clinical trials: challenges and solutions» were discussed the methodological and practical issues of inclusion in clinical studies evaluation of the conditions of the patients that would be implemented not only by the doctor or by the patient, but to some observer, such as: parents, caregivers or spouses. Introduction of estimation parameters by outside observer of the condition of the patient is especially important in clinical trials in children of younger age, and in patients with cognitive impairments who are not able to give an independent assessment of their condition. As a practical application of this assessment was given a study in patients with a rare disease-cystic fibrosis at the age of 0 - 6 years, where the description of the health status of the child was held by parents. According to experts, the obtained data can be useful to determine the patient's state of health outside the health care setting and are a source of additional information about the disease. They can serve as additional criteria for the effectiveness of treatment, which can further be used to estimate the benefits of therapy

Section «Making models more acceptable for decision-makers» was dedicated to finding answers to the questions: is there a need for creation of complex models? Can the decision-makers assess the reliability of such models?

In the United States in October 2014 the respondents: consultants, government representatives, representatives of hospitals, public health officials, managers, presenters in pharmaceutical industry, representatives of the scientific community took part in the online survey.

The results showed that the respondents use the models in which are obtained: 45% cost-effectiveness/ cost-utility analysis, 28% - budget impact analysis. Only a small proportion of respondents (less than 12%) do not experience difficulties with understanding methods, based on which the model is constructed. The majority of respondents (about 40%) use the model during the evaluation of the drug as a base for building their own model, while 22% of respondents use the model unchanged. The majority of respondents (57%) believes that they are able to build a model for decision-making. In the end, the speakers formulated the following conclusion: the model must possess not only reliability, but should also have practical importance, i.e. it should allow to make a specific conclusion about the possible/ not possible inclusion of drug in the system of reimbursement.

During the section «Medication adherence studies» speakers presented information obtained through their own research on the following diseases: diabetes, asthma and HIV infection. The main problem, which sounded in all the speeches was the imperfection of modern methods of monitoring adherence to therapy, leading to a significant difference in outcome research and built based on their findings. In general, the issues raised in this section the questions showed its relevance and availability. Medical and scientific community is interested in researches related to the study of the impact of adherence to therapy on patient outcomes.

During the section «Hypothetical versus experience-based EQ-5D Valuations: what are the implications for health economics evaluations?» in the field modifications simulation using Monte-Carlo method was demonstrated experience.

Martin Troyer and his colleagues proposed a simulation method, which allows to reduce the volume of the analyzed cohort in 1000 times (i.e., if previously it was required to conduct a simulation of a cohort of 1 000 000 people, now it is only needed 1 000). The time spent in the performance of the simulation, is reduced

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by 96%, and the reliability of the results remains at a comparable level. Another group of scientists under the leadership of C. Gupta developed a modification for the Monte-Carlo method, using which it is possible to overcome barriers in the form of the small size of the cohort and the large number of States that can reach patients. Needless to say, the methods have some limitations, but it is obvious that you may benefit from the use of these methods.

In the section «The benefits of innovative medicines in central and eastern European (CEE) countries» the issue of the availability of innovative medicines for patients was raised. The speakers made a proposal for inclusion of patients communities in the decision making process. Patients may act as additional experts, i.e., to supplement and/or correct certain aspects of medical care that are hidden from public health officials. To increase the competence of the patients at issue training courses are encouraged to be conducted. The platform for this project can be EUPATI (European Patients Academy on Therapeutic Innovation). In general, health technology assessment should include along with the analysis of cost-effectiveness analysis of therapeutic effects, and analysis of patients ' satisfaction with the process of medical care.

In the session «Value Based Assessment for NICE: How to Do the Calculations» new methodological aspects of health technology assessment were discussed. In July 2013, the UK Department of Health asked NICE to take into account additional methods in health technology assessment. In response to this, NICE has developed a number of proposals for the inclusion of these new practices into their evaluation methods. For example, proportional and absolute value of QALY losses will be calculated as part of the assessment and be used as a basis for assessing the burden of disease and the broader social impact, respectively.

Mixed methods of researches were paid particular attention to in the lecture «Mixed Methods Research within Clinical Trials: Operational Considerations». Mixed methods have been defined as: «Research in which the investigator collects and analyzes data, integrates the findings, and makes inferences using both qualitative and quantitative approaches or methods in a single study». Mixed methods of researches combines qualitative and quantitative methods of research: quantitative (for example, the effectiveness of the drug in clinical trials) to test the hypothesis and to retrieve the actual data; qualitative (e.g. interviews of the patient and thematic analysis) to explore this data.

Several studies were devoted to the multiple-criteria decision analysis. The advantages of multiple-criteria decision analysis (MCDA) in healthcare were covered:

- Simple for usage by decision-makers (not more complicated that general HTA report);
- The relationship between the data and the solution: the process of organizing information is structured around the criteria;
- The transparency of the data, assumptions, deliverables;
- Systematic and complex;
- Helps to clarify multiple data and opinions;
- Does not need QALY, ICER, but can use it in the same way;
- Helps to create dialogue with stakeholders.

Rare diseases and drugs to treat were discussed at the lecture «It's not so lonely anymore: how are health system players adapting value demonstration and access pathways to address an increasingly crowded orphan and niche product area in order to optimize public health. Time limits and the procedure for approval of orphan drugs in the UK were specified. A new methodology for the assessment of rational use of orphan drugs developed by NICE (National Institute for Health and Care Excellence) was also presented. Specialists of NICE proposed to use multi-criteria decision analysis to select the efficient therapy of patients suffering from rare diseases.

Lectures on the application of statistical methods for conducting pharmacoeconomic studies «Statistical Methods For Pharmacoeconomics & Outcomes Research» noted the importance of knowledge of statistical analysis in pharmacoeconomic practice. This type of analysis is more relevant for the adaptation of foreign models to domestic practice, because they are more widely used in the modeling process. The time horizon of such models often reaches period life-time period that exceeds the duration available to the current moment randomized clinical trials and reviews. Therefore, the application of statistical methods allows to overcome the lack of information and get the results for needed time horizon.

Speakers in the session «Making Models More Accessible to Decision Makers» noted the basic elements of pharmacoeconomic models, which should be reflected from the point of view of decision-makers in health care. It was found that our studies correspond to the European research level in pharmacoeconomics. At the same time, there are differences in preferences on the part of decision-makers in health care: budget impact analysis is of great interest in our country in comparison with the estimated costs of achieving efficiency.

A poster session also took place during the congress and it was attended by lecturers and graduate students of the Department of drug provision and pharmacoeconomics. It should be mentioned that Russian studies were interesting for the representatives of various international companies and organizations.

Best General Poster Research Presentations were assessed. Three works were awarded:

- «Burden of cardiovascular complications in patients with atrial fibrillation in France» F Cotté et al.
- «Treatment Patterns and Outcomes of Patients Diagnosed with. Ovarian Cancer in the Netherlands: A Registry Study» H.G van Haalen et al.
- «An Analysis of US Medicare Beneficiaries: Burden of Direct. Medical Costs in Patients with Idiopathic Pulmonary Fibrosis» S Chen et al.

The organizers and members of the committee congratulated the winners and wished them further success.