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10TH ADRIATIC AND 7TH CROATIAN CONGRESS OF PHARMACOECONOMICS AND OUTCOMES RESEARCH

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10TH ADRIATIC AND 7TH CROATIAN CONGRESS OF PHARMACOECONOMICS AND OUTCOMES RESEARCH

2-4 June 2022 Pula, Croatia

Guest Editor: Dinko Vitezić

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Section for Pharmacoeconomics and Outcomes Research, Croatian Society for Clinical Pharmacology and Therapeutics, Croatian Medical Association

UNDER THE AUSPICES

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EDITORIAL

I admit I have now gotten used to writing an introduction devoted to a congress in pharmacoeconomics on a yearly basis. Each year, with a particular joy, I announce good discussion topics, excellent lectures and presentations and above anything else, a great opportunity for networking with other colleagues.

Thus, this year as well, clinical pharmacologists, economists, physicians, pharmacists and all other health professionals who deal with the issues of health expenditure, drug pricing and health policy will gather in Pula Croatia from June 02. - 04. to rationally assess the real values of medicines in comparison to their efficacy and cost.

The tenth Adriatic and the seventh Croatian congress of pharmacoeconomics and outcomes research has traditionally been organized by the Section for pharmacoeconomics and outcomes research of the Croatian Society for Clinical Pharmacology and Toxicology.

As is mentioned in the congress call, after numerous assessments of health related issues in Croatia and neighbouring countries, this congress has now become devoted to exploring solutions for the ever present problems of tendering, supply and reimbursement of particularly expensive medicines as well as solutions for improvement of relations and communication with national health authorities.

It is my great pleasure to see names of numerous lecturers and participants who will undoubtedly contribute with their lectures and presentations to ongoing health related discussions.

Finally, I wish you all a very successful and pleasant meeting!

Ksenija Makar-Aušperger
Chief editor of the jurnal Pharmaca

FOREWORD

Dear Colleagues,

It is our great pleasure that we have succeeded, in spite of all obstacles and challenges, in the organisation of the 10th Adriatic and 7th Croatian Congress of Pharmacoeconomics and Outcomes Research, which is held at the Conference Center of **Park Plaza Histria Hotel** in **Pula, Croatia**, from **June 2-4, 2022** (http://pharmacoeconomics-congress.eu).

The main objective of this year congress is to intensify and enhance professional and scientific discussions and collaboration between various stakeholders on the following topic:

'ACCESS TO HEALTH IN CENTRAL AND EASTERN EUROPE (CEE) – HOW TO MINIMIZE THE EQUITY GAP BETWEEN WEST AND EAST?'

After several years in which we have been focusing to problem identification, assessment and measurement, mostly around patient access and equity rights to innovation, and identifying the gaps to more developed EU countries, the main goal of this year Congress is to focus on finding solutions. During our 10 years journey, the capacity of CEE countries to focus on solutions has improved, both at Academia and Government from one side, to Health Technology Industry on the other side. Additionally, and most importantly, Patients capacity to be involved and consulted in this process have also significantly improved, so we believe all pre-requisites have now been met to start focusing on the most optimal solutions for which we need all stakeholders to be at the same table, discussing, agreeing and implementing these solutions, especially in the following area, being also the sub-topics of this year's congress:

- New Pharmaceutical Strategy in Europe
- The future of Joint Clinical Assessment in Europe
- Health economic aspects of Cancer Care in CEE considering Europe's Beating Cancer Plan
- Sustainability of patient access and medical innovation funding
- Importance of patient outcomes as KPIs for national health care strategies and policy
- Importance of collecting and sharing Big Data to improve patients' outcomes

However, the full congress agenda also comprise other important topics as well, such as development of health care policies, pharmaceutical pricing and reimbursement, comparative efficacy studies, outcomes research, value of health and health interventions, and many others.

Our Congress has established itself as the forum (i) to share research and help advance the science of health economics within the Adriatic region, (ii) to give opportunity for networking and interacting, and (iii) to get involved in debating controversial and complex issues of the health care involving a range of stakeholders. We are proud that during the past 10 years our annual Congress has become a reference point in the field of pharmacoeconomics and outcomes research in our region since we are not shying away from explicitly discussing pressing challenges, such as conditions of severe economic constraints within our jurisdictions.

We are glad that we have attracted participation from different countries in the region and wider and numerous distinguished professionals and speakers. As every year, we have organized several plenary sessions, round table discussion, issue panels, and research presentations.

It is important to note that we, as the organizers, will ensure participation of a wide range of stakeholders within the health care: the health care professionals (local, regional and international), members of academia, different associations, regulatory and payer authorities, politicians, and last but not least the pharmaceutical industry.

This Congress is organized by the Section for Pharmacoeconomics and Outcomes Research of the Croatian Society for Clinical Pharmacology and Therapeutics, Croatian Medical Association and under the auspices of the Croatian Ministry of Health. The overarching goal of the Congress organizer is to advance public health care policies to maximize societal welfare and optimize diffusion of and access to innovative health care technologies, so that patients can reach their full life and health potential.

With kind regards,

Prof. Dinko Vitezić, MD, PhD

Congress President

Prof. Igor Francetić, MD, PhD

Congress President

President, Section for Pharmacoeconomics and Outcomes Research, Croatian Society for Clinical Pharmacology and Therapeutics

PROGRAMME

THURSDAY, 2 JUNE 2022

Pre-Congress Workshop in Collaboration with HTx H2020: FACILITATION OF PATIENT ENGAGEMENT TO HTA AND RELATED POLICY DECISIONS IN CENTRAL AND EASTERN EUROPE

Plennary session:

Wim Goettsch: How the HTx project about next generation HTA can support patient centered, societally oriented, real-time decision-making on access to and reimbursement for health technologies throughout Europe?

Matteo Scarabelli: Patients and HTA- in search of the break-even point

Saskia Knies: The Dutch experience of patient engagement in HTA

Dalia Dawoud: The NICE experience of patient engagement in HTA

Zoltan Kalo: Transferability of best HTA practices to Central and Eastern European Countries

Maria Dimitrova: Can we and how to engage patients in HTA in CEE countries? Results from a literature review on possible barriers

Ivvet Jakab: Most critical barriers of patient involvement in HTA in CEE countries: what different stakeholder groups think?

Roundtable 1:

Feedback from senior patient representatives on draft recommendations to facilitate patient engagement to HTA in CEE countries

Moderators: **Ivvet Jakob, Matteo Scarabelli**

Roundtable 2:

Feedback from senior policy experts on draft recommendations to facilitate patient engagement to HTA in CEE countries

Moderators: **Maria Dimitrova, Zoltan Kalo**

13:00 Lunch (for Pre-Congress Workshop participants)

CONGRESS OPENING CEREMONY

14:00 Welcome address by Congress Vice-President **Igor Francetić**

14:10 Welcome addres by ISPOR CEE TF President **Bertalan Nemeth**

14:20 Welcome address and formal Congress opening by Congress President **Dinko Vitezić**

KEY NOTE SPEECHES

14:45 **Pedro Marques (EFPIA):** What happens in Brussels doesn't stay in Brussels: the opportunities and reach of the EU Pharmaceutical Strategy

15:10 **Romana Jerkovic (MEP):** A pharmaceutical strategy: challenges and opportunities

15:35 **Discussion**

15:55 Coffee break

THE FUTURE OF JOINT CLINICAL ASSESSMENT IN EUROPE- DIFFERENT SCENARIOS AND POSSIBLE IMPLICATIONS TO CEE COUNTRIES

Chairmen: Zoltan Kalo, Natalija Petković

16:15 **Wim G. Goettsch:** From EUnetHTA21 to the EU HTA regulation; what is needed for a smooth implementation?

16:35 **Iñaki Gutiérrez-Ibarluzea:** The importance of context when assessing health technologies in an EU HTA framework

16:55 **Ansgar Hebborn:** EU HTA regulation - innovative industry perspective

Round table discussion: The Future of Joint Clinical Assessment in Europe- Different Scenario

Moderator: **Zoltan Kalo**

18:00 Roundtable Conclusion and Closure of Day 1

18:45 Welcome Reception

20:00 Dinner by Invitation (Congress Committee Members, Invited Speakers, Sponsors)

FRIDAY, 3 JUNE 2022

SUSTAINABILITY OF PATIENT ACCESS AND PUBLIC FUNDING OF ATMPs, PERSONALIZED MEDICINE AND RARE DISEASES THERAPIES

Chairmen: **Guenka Petrova, Luka Vončina**

9:00 **Saskia Knies:** ZIN HTA/pharmacoeconomics general evaluation process with the focus of ATMPs evaluation

9:20 **Antal Zemplényi:** Update on the cost-effectiveness threshold in Hungary: applying multiple thresholds to reflect equity considerations

9:40 **Judit Bidló:** Outcome based PVA - expectations vs reality

10:00 **Bertalan Németh:** Delayed payment models and their application for ATMPs

10:20 **Maria Kamusheva:** Do we need a new pricing and funding model for orphan medicinal products in CEE countries - a case with Bulgaria

10:40 **Ana Bobinac:** Cost per QALY and LYG - what is the acceptable ICER threshold in Croatia?

11:00 Coffee break

Charman: **Igor Francetić, Boba Bolanča**

11:15 **Dinko Vitezić:** Patient access to Orphan Medicinal Products - increasing interest of EU authorities

11:35 **Svetoslav Tsenov:** Availability of ATMPs in CEE

11:55 **Tea Strbad:** Availability of orphan medicines through the Croatian health insurance system

12:15 **Slobodan Jankovic**: Advanced therapy medicinal products and drugs for rare diseases in Serbia

13:00 Lunch break

EUROPE'S BEATING CANCER PLAN/ IMPORTANCE OF PATIENT OUTCOMES AS KEY PERFORMANCE INDICATORS FOR NATIONAL HEALTHCARE STRATEGIES AND POLICY

Chairmen: **Jurij Furst, Tea Strbad**

14:00 **Luka Voncina:** Is it too expensive to fight cancer? Analysis of incremental costs and benefits of the Croatian National Plan Against Cancer

14:20 **Maria Dimitrova:** Assessment of patient access to breast cancer therapy in Bulgaria

14:40 **Boba Bolanca:** Pre-reimbursement access to oncology drugs in EU

15:00 **Viktorija Erdeljić Turk**: Dosing of immune checkpoint inhibitors: cost-saving initiatives

15:20 **Pero Draganić:** Availability of Oncological Drugs in Croatia and Consumption in the Last Decade

16:00 Coffee break

HEALTH CARE OUTCOMES AND EXPENDITURES IN CEE

Chairmen: **Dinko Vitezić, Bertalan Nemeth**

16:15 **Marcin Czech:** The recent developments in patient access to innovative technologies in Poland

16:35 **Antal Zemplényi:** The application of coverage with evidence development schemes for medical devices in Central and Eastern Europe

16:55 **Svetoslav Tsenov:** Assessing public healthcare spending in Central and Eastern Europe and its implications

Roundtable discussion:

Healthcare Outcomes and Expenditures in CEE

Moderator: **Dinko Vitezić**

18:15 Roundtable conclusion and closure of Day 2

SHORT PODIUM COMMUNICATION SESSION

Chairmen: **Jelena Matuzović, Robert Likić**

18:30 **Slobodan Jankovic:** The cost of illness of childhood pneumonia – pharmacoeconomic study based on data from Balkan country with recent history of socioeconomic transition

18:35 **Vanesa Benković:** Croatian health insurance fund budget in Croatia 2005-2021 - did exiting the closet bring any difference?

18:40 **Karolina Kalanj:** Hospital payment method in Croatia – the opportunity for understanding costly care

18:45 **Slobodan Janković**: Enzyme replacement and substrate reduction therapy for Gaucher disease - evaluation of market authorization, reimbursement status and expenditure in Serbia

18:50 **Martina Vukoja**: Consumption of psychotropic drugs in primary health care in Herzegovina - Neretva county, comparison of data from 2020-2021

18:55 **Damir Detic**: Cost comparison of atrial fibrillation treatment options - conventional vs. ablation, 15 years payor's & societal perspective, Croatian example

19:00 **Tanja Novaković**: Costs of hypercholesterolemia treatments in Croatia

19:05 **Maria Dimitrova:** Is Bulgaria ready for digital transformation of the health care system: a pilot study among stakeholders?

19:10 **Slobodan Janković:** Cost effectiveness of miglustat vs smptomatic therapy of Niemann-Pick disease type C

19:15 **Sven Plese:** Strategies for allocation of intensive care resources during the COVID-19 pandemic

19:20 **Ines Svajcar**: Challenges in nursing during the COVID-19 pandemic in Croatia

19:25 **Bruno Buric**: Benzodiazepine utilization in Croatia: a case of overprescribing and misuse

19:30 **Dominik Ljubas**: Differences in pandemic mitigation measures adherence among youth in Croatia

20:30 Congress dinner/Ribarska koliba

SATURDAY, 4 JUNE 2022

PHARMACEUTICAL PRICING AND VALUE BASED HEALTH CARE

Chairmen: **Viktorija Erdeljić Turk, Dinko Vitezić**

9:00 **Iñaki Gutiérrez-Ibarluzea:** The concept of life cycle of health technologies and the management of uncertainty in health

9:20 **Livio Garattini:** Pharmaceutical pricing in Europe: time to take the right direction / Pricing vaccines and drugs in Europe: worth differentiating?

9:40 **Andrej Janzic:** The simulation of the different External Reference Pricing Model on the listed prices

10:00 **Saskia Knies:** Collaboration within the Beneluxa initiative

10:20 **Valentina Prevolnik Rupel:** Implementation of VBHC in Slovenia

10:40 **Damir Detic:** How clinical efficacy of hip implants relates to long term costs for payor - a Croatian example

10:55 Coffee break

HEALTH ECONOMIC AND OUTCOMES RESEARCH STUDIES OF PRIORITIZED DISEASE AREAS

Chairmen: **Sanja Sarić Kužina, Livio Garrattini**

11:15 **Jurij Furst:** Challenges in diabetes mellitus treatment

11:35 **Spela Zerovnik:** Outcomes of treatment of diabetes using the RWE

11:55 **Bertalan Németh:** The importance of cost–effectiveness principles in times of a global pandemic

12:15 **Zsuzsanna Petykó:** Reconsidering the role of drug repurposing in the post-covid era

12:35 **Robert Marčec, Robert Likić:** Intravenous immunoglobulin (IVIg) therapy in hospitalised adult COVID-19 patients

12:55 **Tereza Saric:** Impact of COVID-19 pandemic on utilisation of healthcare services in Croatia

CONGRESS CLOSURE AND FAREWELL

COLLABORATIVE ASSOCIATIONS' MEETING

14:00 Feedback from the 10th Adriatic and 7th Croatian Congress on Pharmacoeconomics and Outcomes Research

14:30 Proposal for venue, topics and committees for the 11th Adriatic Congress on Pharmacoeconomics and Outcomes Research

15:15 Collaborative regional research opportunities

CONGRESS OPENING CEREMONY – ABSTRACTS OF KEY NOTE SPEECHES

WHAT HAPPENS IN BRUSSELS DOESN'T STAY IN BRUSSELS: THE OPPORTUNITIES AND REACH OF THE EU PHARMACEUTICAL STRATEGY

Pedro Marques
European Federation of Pharmaceutical Industries and Associations
E-mail: pedro.marques-efpia.eu

The Pharmaceutical Strategy and its implications to European patients and institutions. The launch of the package on the revision of the pharmaceutical legislation, as well as the regulations on orphan medicinal products and paediatric medicines, by the European Commission, at the end of 2022 represents a a once-in-a-generation opportunity to ensure Europe is able to benefit from the advances in medical science, respond quickly to patients' needs and remain a global leader in pharmaceutical discovery. Get it wrong and we risk accelerating the loss of cutting-edge technology to other regions, increasing our reliance on countries outside of the EU for life saving treatments and vaccines and delaying access for European patients to the latest advances in care.

A PHARMACEUTICAL STRATEGY FOR EUROPE: CHALLENGES AND OPPORTUNITIES

Romana Jerković
Member of the European Parliament
University of Rijeka Medical School, Rijeka Croatia

EU's pharmaceutical strategy provides a new stable and flexible regulatory framework, which addresses the vulnerabilities that emerged with the COVID19 pandemic, while supporting competitiveness, boosting innovation and calling for a greener industry. The pharmaceutical sector is one of the EU's strongest industries with the €109.4 billion trade surplus. It is experiencing rapid change and innovation, with major advances in biotech products, personalized medicine and gene therapy. However, despite this progress, many Europeans still do not have access to these highly developed therapeutics and treatments. This, along with the bottlenecks in the supply chain, lack of transparency in price information and insufficient investment in R&D (due to the absence of commercial interest in the areas such as antimicrobial resistance, cancer and rare diseases) remains the key problem that the Pharmaceutical strategy for Europe aims to solve. The strategy is an integral part of the European Health Union, concept born out of EU's endeavours to mitigate the consequences of COVID 19 pandemic, to improve resilience of health systems and to strengthen the bloc's preparedness and response mechanisms. Which role does the Pharmaceutical strategy play in building the European Health Union, what are its flagship initiatives and can they optimize the value of spending while simultaneously fostering competition are the questions that will be analysed during the presentation *Pharmaceutical strategy for Europe: challenges and opportunities*.

THE FUTURE OF JOINT CLINICAL ASSESSMENT IN EUROPE- DIFFERENT SCENARIOS AND POSSIBLE IMPLICATIONS TO CEE COUNTRIES

THE IMPORTANCE OF CONTEXT WHEN ASSESSING HEALTH TECHNOLOGIES IN AN EU HTA FRAMEWORK

Iñaki Gutierrez-Ibarluzea[1,2,3]

[1]Head of Knowledge Management and Evaluation. Basque Foundation for Health Innovation and Research. Ronda de Azkue, 1. 48902 Barakaldo. Bizkaia

[2]Coordinator of Osteba, Basque Office for HTA. Donostia-San Sebastian, 1, 01010 Vitoria-Gasteiz. Araba

[3]President i-HTS. Köln. Germany

Health Technology Assessment (HTA) in accordance with the last definition proposed by HTAi and INAHTA is "a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system". The same definition states that "…the overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context". Bearing in mind that definition, does it make sense to promote joint assessment in the European Union to maximize resources and improve decision making processes? Someone that studies the proposed intervention, and its possible consequences would have the rapid temptation to say immediately no. However, this would be a very superficial approach to answering the question. The main aspect to consider is which the intended consequences and the unintended consequences of implementing the intervention are. It makes sense that considering the limited resources of public bodies and the need to promote efficient approaches to budget allocation, including the assessment of the attributes and value of a technology, any intervention that maximizes the use of those resources should be promoted. Nevertheless, this intervention should be concerned about the unintended consequences of not considering the problem in its full extension. Does it suffice to analyze the value once and at a central level in a context in which different ways of funding, different structures of services, different professionals, diverse standards of care, different cultural, religious and socioeconomic conditions coexist? The answer in this case is once again no. It is obvious that we can do extra efforts to share our analysis in a more efficient way and that knowledge management should a matter of high priority in Europe, in which we share a similar approach of what an efficient health care system should be. Notwithstanding, we do need to work locally, to provide to decision makers better approaches to the measurement of value in those domains in which local analysis makes sense, that is, analyzing the local outcomes of interest for the stakeholders, comparisons against the standard of care, organizational, ethical, legal, economic, social and environmental consequences and their impact in the targeted health care system and society.

SUSTAINABILITY OF PATIENT ACCESS AND PUBLIC FUNDING OF ATMPs, PERSONALIZED MEDICINE AND RARE THERAPIES

REIMBURSEMENT DECISION MAKING IN THE NETHERLANDS USING HTA, THE EXAMPLE OF ATMPS

Saskia Knies
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The Dutch healthcare system is financed through a number of insurance schemes. The Health Insurance Act covers curative interventions and is provided by competing private health insurance companies. These companies are obliged to cover the same basic benefit package (BBP), and all Dutch citizens are obliged to have an insurance from one of the insurers. The BBP covers a broad range of healthcare services; including general practitioners' care, hospital care, mental healthcare, pharmaceutical care and medical devices. The content of the BBP is decided on by the Minister of Health (MoH). However, most of the content is described in legal descriptions of reimbursed healthcare, defining the healthcare domains concerned allowing for an "open system". Similar to other countries, healthcare costs constitute a significant part of total public spending in the Netherlands, and it continues to grow. This growth is a concern for the Dutch government which aims to keep healthcare affordable, while keeping good quality and accessible care. Policy instruments to limit these cost increases are therefore required. Health technology assessment (HTA) can be seen as one such instrument. In practice, the emphasis in HTA research is often on providing evidence regarding cost-effectiveness of new interventions relative to a relevant comparator. Through allowing the explicit consideration of all relevant aspects in reimbursement decision-making, HTA enables transparent decision-making and allocations of scarce resources while keeping an eye on the overall health system goals. Based on the information provided through HTA research, decision makers may decide which interventions should be reimbursed or not from the BBP. In the Netherlands the reimbursement decision-making process has been gradually developed in which the evidence obtained in HTA research plays an important role. This decision-making framework and process embeds the assessment of four criteria: necessity, effectiveness, cost-effectiveness and feasibility. This process has been operationalised and is currently most systematically applied for the evaluation of pharmaceuticals. In the last couple of years a new type of pharmaceuticals, namely Advanced Therapy Medicinal Products (ATMPs), came on the market bringing new challenges for decision-making. Challenges are both related to the evidence available on their effectiveness and the prices of the ATMPs. The long-term effectiveness are seldom clinically confirmed and therefore highly uncertain. In addition, the prices of ATMPS are estimated between €300,000 and €3,000,000 per treatment, which increase the stress on the already constrained healthcare budgets.

UPDATE ON THE COST-EFFECTIVENESS THRESHOLD IN HUNGARY: APPLYING MULTIPLE THRESHOLDS TO REFLECT EQUITY CONSIDERATIONS

Antal Zemplényi
Center for Health Technology Assessment and Pharmacoeconomics Research, University of Pecs, Hungary

Objectives: Cost-effectiveness thresholds (CETs) play a particularly important role in the reimbursement decisions of health technologies in countries with limited healthcare resources. Our goal is to develop a scientifically solid proposal for a revised cost-effectiveness threshold, as part of the planned review of the Hungarian health economic guidance.
Methods: The Threshold Working Group of the Hungarian Health Economics Association performed a targeted review on CETs in European countries. International trends on CETs served as a basis for our recommendation, which was discussed at the Association's workshop and deliberated at an expert committee meeting with representatives from the national health technology assessment (HTA) and healthcare payer bodies, and academic HTA centres.
Results: The current Hungarian CET is one of the highest among European countries relative to GDP per capita, and even higher in nominal value than the CET applied by NICE. As opposed to the current, single Hungarian threshold, other European countries apply multiple thresholds. The Working Group recommends that Hungary should also apply multiple CETs in the range of 1.5–3 times GDP per capita with stratification according to the relative quality-adjusted life-year (QALY) gain of the new technology. In addition, multiple CETs in the range of 3–10 times GDP per capita is recommended for technologies in rare diseases.
Conclusions: CETs should be aligned with the country's economic performance and should reflect societal preferences. Our recommendation may increase the efficiency of healthcare resource allocation in Hungary by strengthening the role of HTA in the reimbursement decisions and favouring new technologies with higher QALY gain.

DELAYED PAYMENT MODELS AND THEIR APPLICATION FOR ATMPS

Bertalan Németh
Syreon Research Institute, Budapest, Hungary

Objectives: Health technologies with high upfront costs put enormous pressure on payers, especially in lower-income countries, like in Central and Eastern Europe (CEE). One of the key examples of such technologies is Advanced Therapy Medicinal Products (ATMPs), including cell, gene, tissue-engineered and somatic-cell therapy medicines. The growing affordability concerns led to the conceptual development of several innovative payment models, many of which have already been tested in early technology adopter nations. We aimed to list potential barriers to implementing delayed payment models and draft recommendations on how to address them.
Methods: We conducted a survey, an exploratory literature review and an iterative brainstorming about potential barriers and solutions to implement delayed payment method models in the CEE region and the lower-income countries of the Middle East. A draft list of recommendations was validated in a virtual workshop with payer experts from the two regions, then finalized at a workshop. This presentation outlines the key learnings regarding ATMPs.
Results: Eight different barriers were identified in 4 areas, including transaction costs and administrative burden; payment schedule; information technology; and data infrastructure and governance. 15 practical recommendations were prepared to address these barriers, including recommendations that are specific to lower-income countries, and recommendations that can be applied more universally, but are more crucial in countries with severe budget constraints.
Conclusions: The main results of this policy research can be considered as an initial step in a multistakeholder dialogue about implementing delayed payment schemes in CEE countries.

DO WE NEED A NEW PRICING AND FUNDING MODEL FOR ORPHAN MEDICINAL PRODUCTS IN CENTRAL AND EASTERN EUROPEAN COUNTRIES – A CASE WITH BULGARIA

Maria Kamusheva[1 2], Plamena Grigorova, Maria Dimitrova, Zornitsa Mitkova, Alexandra Savova, Manoela Manova, Konstantin Tachkov, Guenka Petrova

[1]ISPOR Bulgaria

[2]Faculty of Pharmacy, Medical University Sofia, Bulgaria

Despite the adopted schemes on the EU level for early access to orphan medicinal products (OMPs) for satisfying the unmet rare diseases (RDs) patients' needs, still there is a gap between the date of their marketing authorization and actual entering the market in the Central and Eastern European (CEE) countries. The objective is to identify the main challenges for financing and to recognize the need for development and implementation of new pricing and funding models for OMPs with focus on Bulgaria as one of the CEE countries. METHODS: It is a two-part study: (1) a document-based, macro-costing analysis for identifying the costs paid by the National Health Insurance Fund (NHIF) in Bulgaria for OMPs for a 10-year period (2011 – 2021) after the legislative changes in the financing mechanisms of RDs treatment; (2) discussion among experts from the academia and national pricing and reimbursement body followed by a detailed analysis on the need for new pricing and funding models for OMPs. RESULTS: The legislative changes in Bulgaria about the reimbursement of OMPs was adopted in 2011. The payment responsibilities was transferred from the Ministry of Health to the NHIF aimed at providing better RDs patients' access to OMPs. For the analyzed period, the OMPs costs have increased (from 14 637 823 € in 2011 to around 74 mln € in 2021) representing almost 6% and 15% from the total NHIF costs for medicinal products, medical devices, special and dietetic foods in the respective year. Considering the increasing trend for OMPs costs, their huge economic impact, the tendency for developing more innovative health technologies for RDs patients and other factors related to the adopting of more comprehensive treatment services and diagnostic methods in the field, the experts defined several basic challenges: (1) need for further discussions among all stakeholders on differentiation of separate fund for OMPs; (2) necessity for more sophisticated methods for assessment of OMPs cost-effectiveness based on their performance in real-life conditions; (3) setting a higher willingness to pay cost-effectiveness threshold for OMPs; (4) adopting better working legal mechanisms for application of performance-based risk sharing agreements for OMPs. CONCLUSION: OMPs have a huge impact on the budgets but their availability on the CEE countries' markets is crucial. A number of studies demonstrated their specifics which require more sophisticated mechanisms for pricing and funding especially under the conditions of limited resources and the latest breakthroughs in genetics for RDs.

COST PER QALY AND LYG - WHAT IS THE ACCEPTABLE ICER THRESHOLD IN CROATIA?

Ana Bobinac[1 2]**,** Elizabeta Ribarić
[1]University of Rijeka Croatia
[2]Center for Health Economics and Pharmacoeconomic
E-mail: anabobinac@gmail.com

Objective: We estimate the first monetary (or consumption) value of a health gain in Croatia and inform the debate about the appropriate "demand-side" cost-effectiveness (CE) threshold. We test the empirical support for two equity considerations: age and severity operationalized as proportional shortfall (PS), and propose a pragmatic framework for combining equity considerations with the monetary value of health into a pragmatic decision-making framework.
Methods: We use contingent valuation to calculate the societal monetary value of a QALY and life-year gained (LYG) from a representative sample (n=1400), using questionnaire design previously applied in the Netherlands.
Results: The societal monetary value of a QALY in Croatia is equivalent to 1.37 of GDP per capita (equalling €17,000). The WTP per LYG varies (end of life treatments) varies between €50,000 to €100.000 per LYG. The ratio of WTP per QALY to Croatian GDP per capita is consistent with the preferences of the Dutch population. The WTP estimates are theoretically valid and scale sensitive, thus meeting the basic criteria for practical usefulness in policy making. Age seems to be an important equity-relevant characteristic (as reflected by assigning 16% higher value to health gains for younger patients). There is a positive association between the size of the PS and WTP (which increases by 0.07% for every 1% increase in PS). We show how these preferences can be used in a single decision-making framework combining the average WTP per QALY/LYG with PS and age into a single nonlinear costeffectiveness threshold based on the WTP per QALY and LYG.
Discussion: Setting the ICER threshold requires empirical foundation. Setting a GDP-based threshold may have undesirable consequences. First, it might lead to an undesirable increase in ICER threshold following the growth of the economy. An often-cited 3xGDP-based threshold set in Croatia would lead to a paradoxical situation: the threshold would be higher than the usually cited thresholds in the UK, while at the same time, the GDP per capita in Croatia is 34% of GDP per capita in the UK.

PATIENT ACCESS TO ORPHAN MEDICINAL PRODUCTS: INCREASING INTEREST OF THE EU AUTHORITIES

Dinko Vitezić
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In the EU, it is estimated that 5000 to 8000 distinct rare diseases exist, and affect 27 to 36 million people (6-8 % of the population of the EU). According to definition in the EU a rare disease is one that affects less than 5 in 10000 of the general population. European Medicines Agency (EMA) is responsible for reviewing applications from sponsors for orphan designation and the responsible body for the assessment is the EMA's Committee for Orphan Medicinal Products (COMP). To qualify for orphan designation, a product must meet a number of criteria which are defined and assessed during this process. Regulation orphan medicinal products (OMPs) benefit from the incentives and the result of this approach is that from 2000 to 2021 the COMP discussed 3929 applications with 2572 positive opinions, 1132 applications withdrawn, 36 negative opinions, 2552 designations, 207 designated OMPs with the EU marketing authorisations and 38 extensions of indication. Two sets of data will be presented which EMA is collecting and publishing and that could be useful in the HTA assessment and for later check-up the position of OD when marketed in the EU countries. Availability and access of orphan drugs to patients is depending, after the medicine is approved, to decisions on reimbursement from HTA organisations, and/or national payers (financial possibilities of health insurance). During the process of developing the recommendation HTA will evaluate, besides others, for specific orphan drug, their relative effectiveness (RE) which usually include a clinical assessment i.e. the benefit of the new medicine to comparators already available in the same indication. In this process, the data of evaluation significant benefit from EMA COMP could improve and accelerate this evaluation and be used complimentary to RE assessment. The other set of data from EMA which could be of interest for OMPs is the obligation of reporting of marketing status data electronically (via IRIS platform) by industry for centrally authorised products (CAPs). The tool allows the creation of a database that will increase transparency on the actual marketing of authorised CAPs in the EU/EEA MS, i.e. date of placing into the market and date of cessation to market (type of cessation, permanent/ temporary; in case of temporary cessation expected date of reintroduction in the market; reasons for cessation). In conclusion, although the function of EMA is primarily regulatory, some of collected data sets could be used and of importance for decisions on reimbursement for HTA organisations and national payers and to accelerate as well as harmonise availability of orphan drugs to patients in the EU/EEA.

AVAILABILITY OF ATMPs IN CEE

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Objectives: The current presentation aims at exploring cell and gene therapies availability and development in CEE countries.
Methods: Analyzing and comparing approach to market access of cell and gene therapies in several CEE countries.
Results: Cell and gene therapies are generally approved in CEE countries. However, availability often proves to be a challenge with high pricing and lack of reimbursement being the two major factors holding back their development in the region. There are a lot of uncertainties related to market entry, reimbursement pathway, MEAs, infrastructure within countries, supply chain, patient journeys, etc.
The key factors when considering cell and gene therapies are: payment models; (re)definition of perspectives, addressing uncertainty and novel value elements. There are also others like discount rates and data exploration. When addressing uncertainty and affordability it is important to keep in mind the alternative reimbursement and financial models in terms of cost-sharing and risk-sharing agreements, value-based payments, supplier credits, bonds, consumer healthcare loans.
It is crucial to develop understanding of current market situation of existing cell and gene therapies in selected CEE countries in the following areas: regulatory approval; timespan from approval to market availability; availability for patients; pricing; reimbursement status; financing options available to patients; support provided to patients.
Conclusion: While cell and gene therapies market present sizeable opportunity globally, its potential in the CEE region is yet to be fully explored and understood.

AVAILABILITY OF ORPHAN MEDICINES THROUGH THE CROATIAN HEALTH INSURANCE SYSTEM

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The mission of the Croatian Health Insurance Fund (CHIF) is rationally invest financial resources through high quality and efficient health services and programs that will contribute to increasing life expectancy and contribute to the general health of people.
The insured person, under the right to health care from the mandatory health insurance, has the right to use medicines that have been established in current reimbursed list of medicines which is publicly available on the web site www.hzzo.hr or https://hzzo.hr/zdravstvena-zastita/lijekovi/objavljene-liste-lijekova.
On reimbursement list are numerous medicines for the treatment of rare diseases. All these drugs are 100% available to insured persons. To ensure the availability of new, innovative, smart but expensive medicines, in 2005. CHIF has established the "List of particularly expensive medicines" (PEM). It means that the CHIF is within its capabilities and available financial resources singled out special position for PEM, meaning that the stated cost of treatment with PEM is excluded from the hospital budgets.
Based on the recommendation of the hospital specialist, the use of PEM must be approved by the Hospital Medicines Committee. For the use of PEM within compulsary health insurance, the patient must meet certain criteria, which are listed with each PEM on the CHIF reimbursement list of medicines. Also, CHIF recognizes the cost of PEM if it shows the expected effectiveness (cure, stop the progression of the disease, improvement of functional status, steady state of malignant diseases, etc.).
For the past three years, many new medicinse have been put on CHIF reimbursement list and list of VEM to treat several rare diseases, some of which are intended for a completely new indication and certain new medicines are with a new mechanism of action. The VEM list includes, among others medicines, VEM for the treatment of mucopolysaccharoidosis, spinal muscular atrophy, hemophilia, Duchenne muscular dystrophy, Batten disease, cystic fibrosis, neuroblastoma, and also includes VEM for various malignancies diseases, for the treatment of rare haematological diseases, VEM used as gene therapy, etc.
In the deciding process of putting medicines on the reimbursement list of medicines and PEM list, CHIF applies different types of Managed Entry Agreements (MEAs) to make new drugs available to patients. The contract is concluded between CHIF and Market Authorisation Holder (MAH). The contract determines the relationship and the amount of MAH's participation in financing the cost of an individual PEM.

ADVANCED THERAPY MEDICINAL PRODUCTS AND DRUGS FOR RARE DISEASES IN SERBIA

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Background: Making affordable advanced therapy medicinal products (gene therapy medicines, somatic-cell therapy medicines, tissue-engineered medicines, and combinations thereof) and drugs for rare diseases poses a challenge to the health insurance funds of the most developed countries, while for less developed countries it is an almost unsolvable problem.

Objectives: The aim of this study was to analyze the current use of advanced therapy medicinal products (ATMPs) and drugs for rare diseases in Serbia, with special emphasis on economic issues. Methods: The study was designed as secondary research, based on analysis of primary data published in medical journals and in official publications of the Serbian Ministry of Health, Institute of Public Health of Serbia, Serbian Drug Agency, and Republic Fund for Health Insurance (RFHI).

Results: ATMPs in Serbia are, for the time being, limited to somatic-cell therapy medicines, mostly stem-cell preparations prepared and administered in tertiary care health facilities for the treatment of hemathological malignancies, myocardial infarction, and knee osteoarthritis. The ATMPs are reimbursed by the RFHI to the healthcare facilities through payment of services delivered to the patients (peaparation and administration of an ATMP). Drugs for rare diseases are reimbursed by the RFHI based on decisions of the special Committee for Rare Diseases. There are two ways of reimbursement: the RFHI may buy the drugs directly from suppliers through a central tender procedure on a national level, or reimburse tertiary care facilities that buy the drugs for rare diseases through a named patient purchasing procedure. In total, about 26 million euros are spent annually on drugs for rare diseases by the RFHI.

Conclusions: Current utilization of ATMPs and drugs for rare diseases in Serbia is covering only a segment of the true needs of patients with rare and other diseases that require advanced treatment. Incentives on a national level are necessary to find innovative solutions to meet true needs with available budgets.

BEATING CANCER PLAN / Importance of patient outcomes as key performance indicators for national healthcare strategies and policy

ASSESSMENT OF PATIENT ACCESS TO BREAST CANCER THERAPY IN BULGARIA

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Objectives: Recent studies show that there is a significant in between countries variation in the time to market access of innovative medicines, especially in the oncology sector. The published data also reveal that the countries in which the decision for reimbursement is based on costeffectiveness assessment and negotiations with national regulatory authorities, have much longer time to market access. The objective of our study is to examine the current state and time of patient access to medicines for advanced breast cancer (ABC) in Bulgaria as well as to identify the main barriers.

Methods: We conducted retrospective study for the period 2008-2021 on the number of medicinal products with marketing authorization for ABC in the last 12 years by searching EMA database. Time to market access was evaluated as the degree of availability, measured by the number of medicines available to patients (Availability Index) and the average time between obtaining a marketing authorization and time to inclusion in the Positive Drug List in Bulgaria. Secondly, we reviewed the regulatory framework for pricing and reimbursement in Bulgaria to identify existing barriers and propose possible approaches to accelerate and optimize the market access process for ABC medicines in Bulgaria.

Results: The average time to access was 613 days for targeted therapy in Bulgaria. The availability and compliance index for chemotherapy and hormonal therapy in breast cancer was 1, while the average AI for targeted therapy is 0.85. Identified barriers were divided in 3 main groups – factors related to the healthcare system, related to the pharmaceutical industry and related to the regulatory authorities. The possible approaches we suggested are related to more flexible risk sharing agreements with focus on the performance of the medicines, implementation of best practices from Western European Countries and increased use of horizon scanning, adaptive pathways and compassionate use concepts.

Conclusions: Patient access to targeted oncology therapy of breast cancer in Bulgaria is above the average for Europe and takes 1-2 years. Faster access is more evident for only biosimilars. National regulatory requirements for pricing and reimbursement have major impact on market access which reveals the need of changes in the overall approach.

IMMUNE CHECKPOINT INHIBITORS: COST SAVING INITIATIVES

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Although extremely positive from a patient perspective, entering the market of new and expensive therapies leads to increased pressure on most European health systems. Immune checkpoint inhibitors (ICIs) are monoclonal antibodies directed at cytotoxic T-lymphocyte-associaed protein 4 (CTLA-4), programmed cell death 1 receptor (PD-1) or programmed cell death-ligand 1(PD-L1). They have shown clinical efficacy in many tumors and today are established front-line treatment of multiple types of cancer.
According to reports of financial spending on medications, the highest spending in Croatia in 2020 was the for PD-1 inhibitor pembrolizumab in the amount of HRK 240,928,569 which accounted for about 8,6% of spending on the ATK L group.
Nivolumab and pembrolizumab were initially developed and approved by regulatory authorities as body weight-based dosing regimens; nivolumab 3 mg/kg every 2 weeks and pembrolizumab 2 mg/kg every 3 weeks. Subsequently, a fixed dose regimens for both ICIs based on an average patients body weight of 80 mg (nivolumab) and 100 mg (pembrolizumab) was proposed to improve the ease of use and administration, as well as to reduce presription errors. However, fixed-dose regimens were commercialised with reference weights higher than the accurate weight of patients with cancer in routine practice, which may have important economic consequences for healthcare systems.
Cost analyses have underscored the economic rationale for preferring weight based dosing in resource-constrained health care systems. Several approaches have been proposed: having smaller vial sizes, practicing vial sharing and using weigh-based dosing (capped weight based dosing, dose banding), all leading to potential budgetary savings. Assessment of clinical and economic outcomes in the real-world setting may help validate decisions and refine potential implementation.

AVAILABILITY OF ONCOLOGICAL DRUGS IN CROATIA AND CONSUMPTION IN THE LAST DECADE

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Objectives: According to the main theme of this Congress „Access to health in Central and Eastern Europe" and subtheme „Health economic aspects of Cancer Care in CEE countries" we have examined the consumption of the oncology related drugs in Croatia. Considering Europe's Beating Cancer Plan, this gives an extensive insight into cancer drug utilization, as an economic and a public health issue, thus detecting the possible obstacles. Our target is to investigate the utilization trends of cancer drugs in Croatia during the period 2011 - 2020, thus focusing on the Antineoplastic Agents (L01) pharmacological/therapeutic ATC group.
Methods: The data of drug utilization in Croatia are collected and analysed in the Croatian Agency for Medicinal Products and Medical Devices - HALMED. By applying the Anatomical-Therapeutic-Chemical methodology (ATC), the given data are used to calculate the number of defined daily doses (DDD) and the financial expenditure in the period 2011-2020.
Results: The utilization of antineoplastic drugs (L01) indicate a huge increase of more than four times (4.12), from 60.76 million Euros in 2011 to 250.08 million Euros in 2020. The utilization of the Other Antineoplastic Agents subgroup (L01X) increased even more, by 4.86 times.
Conclusions: During the period 2011-2020, the utilization of cancer drug therapy increased continuously and significantly. The biggest expenditure is noticed in the Other Antineoplastic Agents (L01X) group, which includes the most of new, efficient, specific and, after all, expensive drugs.

HEALTH CARE OUTCOMES AND EXPENDITURES IN CEE

THE RECENT DEVELOPMENTS IN PATIENT ACCESS TO INNOVATIVE TECHNOLOGIES IN POLAND

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Recent developments in the Polish health care sector reflect dynamic changes in political and economic environment. Apart from the Ukrainian refugees inflow caused by Russian invasion and more than 3 million people obtaining full health services coverage, main challenges remain stable and unchanged covering: limited access to the health care, deficit of doctors and nurses, health literacy level and responsibility for own health, underfinancing as well as access to novel treatments. They are indirectly confirmed by weak positions of Poland in widely recognized documents like the Euro Health Consumer Index or the Future Proofing Healthcare Sustainability Index. There are two main initiatives, one Polish and one European addressing these complex issues. The main assumptions of the „Polish Order" - a socio-economic program of the ruling party for the post-covid period: 6% of GDP in 2023 (40 billion EUR), and 7% - in 2027 (50 billion EUR) allocated for healthcare, Hospital Modernisation Fund, Medical Fund, coordination of oncology and cardiology care (Polish priority therapeutic areas). The main European project is the National Recovery Plan (NRP), which is a comprehensive program of reforms and strategic projects. Poland is the fourth largest beneficiary of this program – with 35,97 billion EUR for 2021-2027, out of which 4.5 billion EUR will be allocated to health care. Medicines Policy 2018-22 is a governmental strategic document based on WHO guidelines defining main directions of drug sector developments in Poland. This multi-dimensional document has been recently supported by legislative changes moving the sector towards value-based healthcare. The main objective of a Medical Fund regulation is to provide additional funding for innovations creating two new categories of medicines: health technology of a high level of innovativeness and health technology of a high clinical value. There is a clear emphasis of public decision makers to take an initiative in this process as well as a broader use of Real World Evidence focused on monitoring of the clinical and cost effectiveness of pharmacotherapy. In addition, amendments to act on reimbursement – the main regulation in pricing and reimbursement – have been announced. It is also worth stressing that after years of preparation the Plan for Rare Diseases has been accepted by the Polish government with a long list of systemic changes concerning medicines use. To finalize the list of recent developments, there is a hospital- based HTA project realised with an objective to be tested in the healthcare sector.

THE APPLICATION OF COVERAGE WITH EVIDENCE DEVELOPMENT SCHEMES FOR MEDICAL DEVICES IN CENTRAL AND EASTERN EUROPE

Antal Zemplényi

Objectives: Experiences with coverage with evidence development (CED) schemes are fairly limited in Central and Eastern European (CEE) countries, which are usually late adopters of new health technologies. Our aim was to put forward recommendations on how CEE health technology assessment bodies and payer organizations can apply CED to reduce decision uncertainty on reimbursement of medical devices, with a particular focus on transferring the structure and data from CED schemes in early technology adopter countries in Western Europe.
Methods: Structured interviews on the practices and feasibility of transferring CED schemes were conducted and subsequently, a draft tool for the systematic classification of decision alternatives and recommendations was developed. The decision tool was reviewed in a focus group discussion and validated within a wider group of CEE experts in a virtual workshop.
Results: Transferability assessment is needed in case of (1) joint implementation of a CED scheme; (2) transferring the structure of an existing CED scheme to a CEE country; (3) reimbursement decisions that are linked to outcomes of an ongoing CED scheme in another country and (4) real-world evidence transferred from completed CED schemes.
Conclusions: Efficient use of available resources may be improved by adequately transferring evidence and policy tools from early technology adopter countries.

ASSESSING PUBLIC HEALTHCARE SPENDING IN CENTRAL AND EASTERN EUROPE AND ITS IMPLICATION

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Objectives: The current presentation aims at assessing the public healthcare spending in CEE and its implications on the health outcome.
Methods: Analyzing and comparing public healthcare incomes and spending in several CEE countries.
Results: Evidence shows that better health is associated with positive economic outcomes. Over the past 60 years, all CEE countries demonstrate significant improvement in healthcare outcomes. Positive results are driven largely by growing incomes and increasing investment in healthcare. Public spending on healthcare in most CEE countries has increased at a faster rate than the EU5 since the last 12 years.
However, CEE countries still lag the EU5 on most major health indicators like deaths from cancer, cardiovascular disease, and amenable mortality rates. In addition to that public healthcare spending in the CEE countries is still less than in the EU5. In general, CEE countries spend less on health as a % of their total expenditure than the EU5. However, they dedicate more of their budgets to 'economic affairs', recreation and 'public order and safety'. At the same time most of them spend less on pharmaceuticals while access to new and innovative medicines is slower and more limited.
Demand for health services is set to rise across the CEE countries over the next 30 years driven by an aging population, a higher prevalence of chronic diseases and the development of new treatments.
Conclusion: It will take many years for health outcomes in the region to converge to those of the EU5 at the historic rate of improvement. Public spending on healthcare and innovative medicines needs to grow if the CEE countries are to catch up with the EU5, meet future demand and boost the sustainability of the public finances.

SHORT PODIUM COMMUNICATION SESSION

THE COST OF ILLNESS OF CHILDHOOD PNEUMONIA – PHARMACOECONOMIC STUDY BASED ON DATA FROM BALKAN COUNTRY WITH RECENT HISTORY OF SOCIOECONOMIC TRANSITION

Marina J. Kostić, Živan M. Vučković, Jana V. Desnica, Sanja M. Knežević, Jasmina R. Milovanović, Dejana T. Ružić Zečević, Ana M. Radovanović, Olivera Z. Milovanović, **Slobodan M. Janković**

Objectives: Despite the fact that incidence of childhood pneumonia has decreasing tendency; this medical condition remains significant contributor to morbidity and mortality within this age. Regarding these facts, health professionals should pay attention not only to medical but also to pharmacoeconomic consequences of treating childhood pneumonia. This study was aimed to estimate the total costs associated with treating childhood pneumonia and its main determinants from the Republic Fund of Health Insurance perspective in the pharmacoeconomic milieu of the Republic Serbia.

Methods: In order to provide data about the pharmacoeconomic aspect of treating pneumonia in the pediatric population we performed cost of illness study in retrospective manner using the "from the bottom to the top" approach. This study was performed in compliance with Consolidated Health Economic Evaluation Reporting Standards (CHEERS) for performing pharmacoeconomic studies established by ISPOR and was approved by the Ethics Committee of Clinical Center Kragujevac (N°of approval - 01/18-843). We included demographic (age and sex of patients) and medical data (number of episodes of pneumonia, number of hospitalizations, the length of hospitalizations on general word, the length of hospitalizations on intensive care unit, laboratory and imaging tests performed during hospitalizations, specialists' exams, pharmacotherapy, and hospital care,) from medical records of 82 patients who were treated due to pneumonia at Clinical for pediatrics at Clinical Centre Kragujevac during period for one year (January 2018 to December 2018). In order to convert medical into pharmacoeconomic data we used Tariff Book and the price of drugs available in electronic files at the Republic Fund of Health Insurance web page.

Results: Total costs of treating childhood pneumonia for the study population per one year were estimated at 34,829.55 EUR. The median of total costs of treating childhood pneumonia in the hospital was 42.31 EUR (40.76 EUR – 1208.95 EUR). The most significant contributor to total hospital costs were the length of patient hospitalization (22%) and noninvasive ventilation ≤24 hours (19%).

Conclusion: Our study pointed two main conclusions that total costs of treating childhood pneumonia in hospital facilities in Balkan country with recent history of socio economic transition is lower than in countries within European Union and that two main determinants of treating childhood pneumonia in the pharmacoeconomic milieu of the Republic Serbia are the length of stay and noninvasive ventilation rate.

CROATIAN HEALTH INSURANCE FUND BUDGET IN CROATIA 2005-2021 DID EXITING THE CLOSET BRING ANY DIFFERENCE?

Uršula Fabijanić, Marija Strgačić, **Vanesa Benković**

Objectives: The aim was to analyze balance sheet of national health insurance fund in the period of 2005-2021, to calculate trends and to try to explain them in their space time continuum.

Results: Structure of insured persons showed that there is a trend of continuous decline in number of insured persons. Employed part of this population is pretty much stable, making one third of total insured. Surprisingly, total number of insured is higher than total population by 260.000 which makes 6,67%, due to immigration and minor part from insured persons from Bosnia and Herzegovina. As expected, there is a continuous increasing trend in income of 110,64% and in expenditure of 92,10% from 2005 to 2021. The highest growth was in COVID years (2020-2021), when income increased 20,99% and expenditure 17,01% compared to 2019. Average structure of expenditure shows following shares: hospital 36,05%, drugs 19,10%, primary health care 16,18%, sick and maternal leave 9,15%, complementary insurance fees 4,23%, outpatients secondary HC 3,90%, CHIF employee costs and assets 2,05%, HC for war veterans and costs related to residency 0,30%, occupational safety and health 0,24%, and other 2,01%. When observing drugs cost share, it increased from 19,39% to 21,97% and financial payback from pharma industry was 8,34% in 2021. The difference in drug expenditure vs Croatian Drug Agency report might be explained by difference in listed price and actual wholesaler purchase price, by public procurement prices for some drugs, by differences in public and contracted prices in volume cap agreements and parallel export of drugs to other countries.

Conclusions: Although there is unprecedented decrease in insured persons and overall natality, a trend that will continue, Croatian politicians see health care as a priority demonstrating it in efforts to increase funds flow to HC budget. Growth of elderly share in population for sure will bring increase in overall expenditure, however question remains whether there is an optimal distribution of cost. For example, is there enough investment in prevention and eternal question - what happens inside hospital budgets. Measures such as decreasing face DRG tariffs, while their actual costs remained the same or increased, brought counter offensive behavior such as DRG miscoding and increase of hospital debts to suppliers. Apart from steady increase of expenditure for drugs, pharma companies have contributed to sustainability of HC system, through the mechanism of managed entry agreements as well by pay-back given by volume cap agreements.

HOSPITAL PAYMENT METHOD IN CROATIA – THE OPPORTUNITY FOR UNDERSTANDING COSTLY CARE

Karolina Kalanj, Jurica Toth, Marija Kadović, Stjepan Orešković

Objectives: In 2009, Croatia introduced the Diagnostic Related Group inpatient hospital payment system to improve hospital efficiency, provide funding transparency and enhance the quality of care. Implementing the DRG system calls for both technical capacity and intersectoral cooperation. Hospital outpatient services are paid using fee for service method, and it may be concluded that the payment system for the Croatian hospital network was set to measure and pay hospitals for activities produced, The objective of our study is to demonstrate that hospital efficiency, data transparency, and quality of services can be improved only if all the essential building blocks of the activity-based payment system are implemented systematically and that continuing development of the payment formula must address evolving needs of the Croatian health system.

Methods: The study is an analysis of retrospective data related to the financing and performance of Croatian hospitals funded by the Croatian Health Insurance Fund from January 1, 2009, to December 31, 2021.

Results: The gap between income and expenditure across the hospital network increased during the study period, while the number of admissions significantly decreased. The results show a 21% decrease in the total number of admissions across the hospital network in 2020 and a 16% decrease in 2021 compared to the number of inpatient episodes of care in 2019. Selected outpatient services which are the subject of additional funding, did not reach the target values and differences between allocated budgets and hospital claims were 21,16% (2019), 43,6% (2020), and 33.22% (2021). Regarding health outcomes, Croatian hospitals reported 761, 25 per million deliveries with operative procedures, and those figures are significantly higher than in Ireland (199 per million) and Australia (254 per million).

Conclusions: The research provides evidence that the implementation of activity-based funding in Croatia has failed to contribute to the improvement in hospital efficiency or the overall sustainability of the current method of funding hospitals. Setting the right price for hospital care, providing the correct information, and managing the system in a way that does not weaken the price signals should be pillars of the forthcoming Croatian hospital payment reform.

ENZYME REPLACEMENT AND SUBSTRATE REDUCTION THERAPY FOR GAUCHER DISEASE – EVALUATION OF MARKET AUTHORIZATION, REIMBURSEMENT STATUS AND EXPENDITURE IN SERBIA

Slobodan Janković, Ana Pejčić, Miloš Milosavljević

Objectives: Our objective was to evaluate market authorization, reimbursement status and expenditure on enzyme replacement therapy (ERT) and substrate reduction therapy (SRT) for Gaucher disease (GD) in Serbia. GD is a rare, autosomal recessive genetic disorder caused by a deficiency of the lysosomal enzyme, glucocerebrosidase. It has been estimated that there are about 30–50 GD patients in Serbia.

Methods: Information about market authorization and reimbursement status of ERT (imiglucerase, velaglucerase alfa, and taliglucerase alfa) and SRT (miglustat, and eliglustat) was obtained from the website of the Medicines and Medical Devices Agency of Serbia (ALIMS) and National Health Insurance Fund of Serbia (RFZO) on April 6, 2022. Annual reports on turnover and consumption of drugs publicly available on the ALIMS website for a period from 2006 to 2019 were used to extract expenditure data. The average middle exchange rate for Euro (EUR) given by the National Bank of Serbia for each observed year was used to convert expenditures originally reported in the national currency Serbian Dinar (RSD). Simple descriptive analysis and observation of chronological trends were applied. Also, total drug expenditures for available drugs were calculated annually from 2006 to 2019 and further reported as a percentage of total annual drug expenditure.

Results: Two (imiglucerase, and taliglucerase alfa) of three ERT drugs and one (eliglustat) of two SRT drugs have market authorization in Serbia. None of these drugs is included on the reimbursement list, but they could be made available to patients based on the opinion of the special commission of RFZO tasked with deciding on starting or continuing treatment of insured persons suffering from rare diseases based on the available funds in the budget. Expenditure on imiglucerase decreased from 491,010,890.00 RSD (5,947,321.83 EUR) in 2008 (when it was first reported) to 330,191,935.60 RSD (2,807,926.47 EUR). On the other hand, expenditure on taliglucerase alfa increased from 37,765,362.90 RSD (318,775.75 EUR) in 2017 (when it was first reported) to 158,776,690.10 RSD (1,350,224.59 EUR) in 2019. There was no reported expenditure on other ERT/SRT drugs in the observed period. The share of expenditure on both imiglucerase and taliglucerase alfa in total annual drug expenditure decreased from 0.74% in 2008 to 0.35% in 2019.

Conclusion: There is a need for improvement of availability and access to ERT and SRT for GD in Serbia.

CONSUMPTION OF PSYCHOTROPIC DRUGS IN PRIMARY HEALTH CARE IN HERZEGOVINA-NERETVA COUNTY; COMPARISON OF DATA FROM 2020 AND 2021

Martina Vukoja

Introduction: Drug consumption is a growing public health problem, and proper and regular monitoring of drug consumption is one of the fundamental indicators of the health status of the country. Major psychiatric disorders require long-term use of psychotropic drugs and represent a significant economic burden. Guided by the need to ensure the quality of health care, but also its economic efficiency, it is necessary to strive for the rational use of medicines.
Objective: The main objective of this research is to show the consumption of psychotropic drugs at the level of primary health care in Herzegovina-Neretva County during 2020 and 2021 and to assess the rationality of prescribing based on data on financial indicators and number of packages of prescribed drugs.
Materials and methods: Data on prescribing drugs that affect the nervous system were obtained and analyzed by the Health Insurance Institute of Herzegovina-Neretva County. The retrospective study included only electronic prescriptions with data on drugs according to ATK classification N, diagnosis according to ICD-10 classification, form, strength, drug packaging, financial report and the amount of prescribed generics in 2020 and 2021. The number of defined daily doses and the number of DDD per 1000 inhabitants per day for each individual drug were calculated.
Results: According to the data of The Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina in 2020, drugs according to ATK classification N were in the fourth place out of the total consumption of medicines with the amount of 87.145.176, 94 KM (11,74%). The total number of prescribed prescriptions in 2020 was 199.217 and 202.933 in 2021; this represents an increase of 3.716 prescriptions (1,9%). The number of patients using psychotropic drugs increased from 10.600 (15,6%) in 2020 to 12.696 (18,7%) in 2021. The most prescribed drug in 2020 and 2021 was N05BA01 diazepam 8,76 DDD/1000/day and 8,82 DDD/1000/day, respectively, most indicated for primary (essential) hypertension I10, followed by N06AB05 paroxetine and N06AB10 escitalopram. The financial share of drugs from group N in 2020 amounted to 14,7% of total drug consumption, while in 2021 it was 15,17%. N03AX09 antiepileptic lamotrigine as a drug ≈ 9% and psycholeptics as a group of drugs ≈38% recorded the highest financial consumption of drugs according to ATK classification N in both years.
Conclusion: The increase in consumption and increase in drug costs according to ATK classification N in health care requires a detailed analysis, using pharmacoeconomic methods that should help make decisions about the allocation of available funds and the development of health care. Measures are needed to streamline prescribing, control unnecessary spending in the country and improve patient welfare.

COST COMPARISON OF ATRIAL FIBRILLATION TREATMENT OPTIONS - CONVENTIONAL VS. ABLATION, 15 YEARS PAYOR'S & SOCIETAL PERSPECTIVE, CROATIAN EXAMPLE

Damir Detić

Objectives: to compare costs (for payor and for society) of atrial fibrillation treatment with drugs and with ablation in period of 15 years.
Methods: utilizing publicly available 2021./2022. data (DRG volume, DRG values, extra funding value for specific materials, drug prices, DTP prices) related to costs of conventional/drug and ablation treatment of atrial fibrillation cost comparison calculation has been performed. Total costs were assesed/projected over the period of 15 years as an combination of direct medical costs (cost incurred by payor) and cost related to (TWD) temporary work disability/lost GDP (cost incurred by society).
Results: In 15 years estimate of cost treatment of 1211 atrial fibrillation patients: 1) direct medical costs (for payor) in ablation group are estimated to be 452 K € lower than in conventional group, 2) costs related to TWD (costs for society) in conventional group are estimated to be 2,7 M € bigger than in ablation group, 3) total savings in ablation group are estimated at 3,1 M €.
Conclusion: Compared with costs of conventional treatment, for the period of 15 years, costs of ablation treatment of 1211 atrial fibrillation patients are associated with total savings of 3,1 M €. Of total amount saved, portion of savings related to direct medical costs represents 14,5 % while portion related to costs of TWD/lost GDP represents 85,50%.

COST OF HYPERCHOLESTEROLEMIA IN THE REPUBLIC OF CROATIA

Tanja Novakovic, Milica Krga, Mark Parker

Purpose: The aim of this study was to estimate the annual costs and clinical consequences of the population with hypercholesterolaemia, acquired and familial hypercholesterolaemia (FH), in Croatia, in 2021. The study estimated a reduction in cost attributable to hypercholesterolemia.

Methods: A prevalence-based cost of illness study adopted the bottom-up methodological approach. Costs were scaled from an individual patient to the total disease population, from the Croatian health care payer perspective. Both direct and indirect health care costs were included. The clinical course of the disease and resourced used were identified and quantified using local and international clinical guidelines, targeted literature and relevant on-line sources.

Results: The total estimated costs of hypercholesterolemia in 371,003 patients in Croatia were € 436,482,942 and € 24,852,364 in 16,213 FH patients. The average cost per patients was € 1,176. Direct costs accounted € 292,767,760 (67%) for hypercholesterolemia and 143,716,182 (33%) of indirect costs (sick leave costs). Among consequences of hypercholesterolaemia and FH, the highest cost components were atherosclerosis, ischemic stroke and unstable angina pectoris. Estimated reduction in cost attributable to hypercholesterolemia was € 73,191,329 and € 9,749,803 for PH.

Conclusion: The total cost of hypercholesterolaemia in Croatia is high and represents 11.8% of all health care costs. Public health policy focused on hypercholesterolemia management, timely diagnosis and defining new strategies in prevention and treatment, with additional evidence to inform clinical practice, are needed in Croatia.

IS BULGARIA READY FOR DIGITAL TRANSFORMATION OF THE HEALTH CARE SYSTEM: A PILOT STUDY AMONG STAKEHOLDERS?

Katerina Ahchyiiska, Martina Nikolaeva, Mario Fazli, **Maria Dimitrova,** Zornitsa Mitkova, Maria Kamusheva, Konstantin Tachkov, Guenka Petrova, Rossen Dimitrov

Objectives: Bulgaria is one of EU countries that faces many challenges which should be managed in order to have successful integration of a digital health system. This rose our attention to analyze the current environment, obstacles and possibilities to implement digital health in the Bulgaria.

Methods: We conducted a survey on the attitudes of different stakeholders regarding the opportunities for digital transformation of the health system in Bulgaria. The survey was done by direct questionnaire containing 21 questions, from which 3 open and 18 closed. The questions were divided in three main categories – demographic characteristics, state of the healthcare system and knowledge of digital healthcare principles and benefits of introducing digital healthcare transformation. Results were proceeded through descriptive statistics.

Results: The total number of answers is 379. About 60 % of interviewers belong to the age group 31-59 age. 70 % of them said that they are interested actively by digitalization; 30 % have heard but are not absolutely familiar with the topic; 79 % consider that information campaign before the introduction will be required; 62 % believe that digitalization should be included during the healthcare professional education;79 % of patients think e-/digital healthcare would make easier patients access to treatment; 37 % think that it could improve control over the spending in healthcare system.

Conclusions: The implementation of digital healthcare aims to help patients, improve adherence to therapy, medical services, and also set Bulgaria on the map of medical researches using future technologies.

COST/EFFECTIVENESS OF MIGLUSTAT VS. SYMPTOMATIC THERAPY OF NIEMANN-PICK DISEASE TYPE C

Medo Gutić, Miloš N. Milosavljević, **Slobodan M. Janković**

Objectives: Niemann-Pick disease type C (NP-C) is progressive neurodegenerative disorder with early infantile (<2 years), late infantile (2-6 years), juvenile (7-15 years) and adolescent (>15 years) onset. The mainstay of therapy of NP-C patients with neurological symptoms is miglustat, a drug that may modify course of the disease. The aim was to compare cost-effectiveness of miglustat and symptomatic therapy in patients with NP-C in socio-economic settings of Republic of Serbia, an upper-middle-income European economy.

Methods: Perspective of Serbian Republic Health Insurance Fund was chosen for this study, and time horizon was eighty years. Main outcomes of the study are quality adjusted life years gained with miglustat and comparator, and direct costs of treatment. The study was conducted through generation and simulation of the Discrete-Event Simulation model. The model results were obtained after Monte Carlo microsimulation of a sample with 1000 virtual patients.

Results: Treatment with miglustat was significantly expensive and associated with negative values of net monetary benefit regardless of the onset of neurological manifestations (-110,447,626.68±701,614.36 RSD, -343,871,695.13±2,577,440.68 RSD, -1,397,908,502.47± 23,084,235.03 RSD and -2,953,680,879.09 ± 33,297,412.25 RSD for early infantile, late infantile, juvenile and adolescent cohort, respectively).

Conclusions: Miglustat is not cost-effective option in comparison to symptomatic therapy for the treatment of NP-C when traditional pharmacoeconomic evaluation is employed. However, given the proven efficacy of miglustat there is a need for find ways to make this drug available to all patients with NP-C. A model of differential pricing with lower drug prices in developing countries seems to be necessary.

STRATEGIES FOR ALLOCATION OF INTENSIVE CARE RESOURCES DURING THE COVID-19 PANDEMIC

Sven Plese, Borna Miholic, Nikola Zvonimir Martinovic, Marija Jantolek, Dominik Strikic, Robert Likic

The COVID-19 pandemic will be remembered as one of the most challenging periods in recent history of medicine. The novel SARS-CoV-2 causes severe respiratory infections with a relatively high percentage of patients requiring intensive care unit admission and prolonged hospital stay. While the media outlets were busy reporting about the number of available mechanical ventilators in the country, medical professionals were strugling to provide intensive care treatment in overcrowded ICUs. Intensivists found themselves forced to make choices about which patients to continue to treat with mechanical ventilation. This led to professional and ethical dilemmas and resource allocation in intensive care became a new worry. While medical triage based on severity of illness can be one approach, the other strategy is a priori patient selection. Medical triage is used regularly in ICUs, but with the number of cases of COVID-19 infection growing, medical professionals tried the a priori patient selection approach. However, without reliable outcome predictors in COVID-19, selecting patients for ICU treatment based solely on their medical history and age, still remains a debatable approach. One of the potential strategies to avoid resource allocation dilemmas in the future is increasing the capacity of the already existing intensive care units, either through introduction of military camps or closing of the all non-essential practices, something that Croatia quite successfully did at the start of the pandemic. For now, we can conclude that the pandemic at least brought discussion about resource allocation strategies into the focus of the health authorities and decision makers.

CHALLENGES IN NURSING DURING THE COVID-19 PANDEMIC IN CROATIA

Ines Svajcar, Matea Majta, Maja Bukovcan, Dragana Petrovic, Marina Delibos, Marija Jantolek, Robert Likic

The first outbreak of COVID-19 was reported in December 2019 in Wuhan (China) and from there it quickly spread to other parts of the world. The first confirmed case of coronavirus in Croatia was on February 25th 2020. At the forefront of the fight against SARS-CoV-2 were Croatian nurses who faced numerous challenges during the pandemic that are still present today.

At the beginning of the pandemic, health workers were confronted with the problem of lack of personal protective equipment (PPE) and tests, and thus the increased risks for their own health as well as the health of their family members and patients. Soon, new challenges appeared in the form of lack of education about proper dressing up and PPE removal, as well as organization of space for the admission of patients and care for those with COVID-19. As the numbers of patients during the pandemic increased, so did the long-standing problem of a shortage of nurses in hospitals. In response, health workers were reallocated, which also imposed additional overtime hours that nurses had to work. Furthermore, nurses are mediators in communication between families and patients, so isolation of COVID-19 patients from their family and friends soon became very emotionally demanding. In a pandemic, it is difficult to allow a person to die with dignity and this is another challenge that medical professionals face. Although the patients, according to the principle of respect for autonomy, have the right to decide who will be informed about their health, and ultimately who will be present in their last moments of life, this was not possible during the pandemic. This certainly disrupted the patient-nurse relationship as well as the psychological health of the nurses themselves. Mental and physical demands of having to work during the pandemic ultimately led to burnout syndrome and inefficient performance among health care workers.

In conclusion, nurses are key members of health teams which oversee prevention and spread of infectious diseases. The covid-19 pandemic posed a number of challenges that will continue in the future. The aftermath of the pandemic raised awareness of the importance of nurses in the health care system. Healthcare facilities need to take care of their workers, highlight challenges, find solutions for them and provide safe working environment not only during a pandemic but also in everyday work.

BENZODIAZEPINE UTILIZATION IN CROATIA: A CASE OF OVERPRESCRIBING AND MISUSE

Bruno Buric, Stjepan Brnic, Robert Likic

Benzodiazepines are indicated in a number of conditions including sleeping disorders, anxiety, general mood disorders and chronic back pain. However, their use should not be chronic as these medicines are associated with serious side effects such as memory loss, increased risk of Alzheimer's disease and addiction. Benzodiazepines have been over-prescribed in many countries and one of the reasons is the lack of international consensus regarding the optimal prescription strategy for that drug group. Nevertheless, the long-term use of benzodiazepines is generally discouraged due to the drop in their effectiveness after 4 weeks of therapy as well as the increased risk of dependence.

The Croatian Health Insurance Fund (CHIF) provides a compulsory basic health insurance plan for all Croatian citizens. Interestingly, unlike in some other countries, CHIF does not impose any limitations on duration or dosage of benzodiazepine drug utilization. Since benzodiazepines are on the CHIF's main drug list, all prescriptions are financially covered which makes benzodiazepines readily available and one of the most commonly prescribed drugs in the country. Additionally, Croatian primary care physicians prefer benzodiazepines over SSRIs because of their rapid effect, few initial side effects and a small chance of fatal overdose. Increased utilization could also be explained by the outdated and noncritical benzodiazepine prescribing practices, misuse, "medicalization" of non-pathological or social problems, as well as self-medication.

A remarkably high number of Croatian patients who use benzodiazepines highlight the need for recognition and implementation of international and national guidelines on rational prescribing of psychoactive medicines. Benzodiazepine prescribing should be rationalized and regulations should be put in place in Croatia to limit the autonomy of clinicians regarding prescribing of these drugs. Good control of drug prescribing would considerably improve the quality of pharmacotherapy in this country.

DIFFERENCES IN PANDEMIC MITIGATION MEASURES ADHERENCE AMONG YOUTH IN CROATIA

Ljubas Dominik, Likic Robert

Aim: During the pandemic, young people are regarded as vulnerable and irresponsible society members. Adressing their needs and negligence towards mitigation policies is therefore important. The purpose of the study was to determine and evaluate factors that influenced mitigation measures adherence among students in Croatia.

Methods: We conducted a cross-sectional study using a questionnaire with Likert scale based questions by which certain personal and social factors affecting compliance were assessed. Effects of social factors were determined concerning possible consequences of COVID-19 on education, income, and ability to socialise with colleagues. Level of motivation, perceived health risk, peer influence, impact on physical and mental wellbeing and personality traits were used as personal factors. Differences between these variables were examined in relation to gender.

Results: 453 (74.88%) females and 152 (25.12%) males were included. Male and female respondents did not report significantly different effects of social distancing measures (2.95±1.11 vs. 3.24±1.08, p=0.074). Although frequently described in other studies, negative impacts on education and income were not observed. Interestingly, gender had neither influence on motivation towards adherence (2.82 ±1.20 vs. 2.55 ± 1.20, p=0.105) nor on being informed about COVID-19 on a regular basis (2.97±1.13 vs. 2.92±1.12, p=0.658). Male respondents reported less compliance (3.85±0.83 vs. 4.06±0.71, p=0.041) than females. In contrast, females showed more anxiety about their family members getting infected with SARS-CoV-2 (3.50±1.04 vs. 3.83±1.09, p<0.001).

Conclusion: Our study showed that interest in ongoing events regarding COVID-19 and motivation towards adherence were not gender dependent; however, the same was not reported in the literature. Despite the fact that educational, financial and social disruptions were not significantly different, individuals who are concerned and aware of risks (especially females) could be exposed to greater level of distress. Long-term effects of the pandemic should be studied in future research in order to develop better strategies for mitigation of negative effects of public health crisis.

PHARMACEUTICAL PRICING AND VALUE BASED HEALTH CARE

THE CONCEPT OF LIFE CYCLE OF HEALTH TECHNOLOGIES AND MANAGEMENT OF UNCERTAINTY IN HEALTH

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Many health systems are considering value-based health care approaches with the argue of enhancing sustainability under limited budget and resources. This argue, although valid, hides the main reason why value-based health care is gaining insights and adepts in the last decade. In fact, the hidden reason is related to uncertainty and its management or the imperfect, partial or inaccurate approach to value assessment and its determination when decisions are made. Furthermore, systems have been accustomed to make decisions when introducing technologies (reimbursement and benefit package decisions) or trying to anticipate the impact of new and emerging technologies (horizon scanning). Meanwhile, the analysis of the value of interventions when they are used in real practice, including variability of use when coexisting technologies for the same indication, or decisions around delisting technologies are still less frequent. According to Health Technology Assessment new definition, life cycle approach to determining the value of a health technology should be a must. First of all, the value of a technology under real life conditions differs from that under ideal circumstances, in fact, the patients, professionals, caregivers, systems' structure may influence the final value. Secondly, along the life cycle of health technologies the value of technologies may diminish or increase by the knowledge on who could benefit more, the improvement of the intervention, the launch of new solutions that comparatively could provide a higher value or the knowledge around unintended consequences and the learning curves of professionals and empowerment of patients, among others. Value is not immutable and should be continuously monitored to offer the best option to the individual patient. Finally, systems should make an effort to proactively interact with innovators and stakeholders in order to improve their solutions by communicating them the needs, the conditions of use, the outcomes of interest and the desired level of improvement, the clinical pathways and patients' roadmaps and the values inherent to the determination of value in a given context. This so-called early dialogue or early advice is claimed by innovators and investors as crucial for further technological advancement. The harmonization of regulatory and reimbursement practices from the very beginning helps improving the research plans of innovators by creating an efficient approach to evidence

generation that consistently convince markets and reduce their uncertainties when making decisions.

THE EFFECTS OF ERP MODELS ON PRICES AND EXPENDITURES OF MEDICINES

Andrej Janzic

The External Reference Pricing (ERP) model is well recognized and widely used in Europe. While it was primarily introduced as a cost containment measure and to limit the prices of medicines, its implementation varies substantially across countries. It's principle is to use the prices of medicines in other countries in order to set a reference price in a given country. While the general principle is the same across countries, varieties in the basket of reference countries, type of prices, methodology in transferring prices and others still exists.

The study was designed to simulate the effect of different approaches on regulated prices and consequentially on the calculated expenditure in Slovenia. The simulations were conducted on a basket of 316 on-patent medicines that were responsible for approximately 80% of the expenditure of on-patent medicines in Slovenia. The models differ in the setting of reference country basket (1 to 6 countries: AT, BE, CZ, DK, FR, PL), calculation methods (the lowest price versus average price), and 4 levels of similarity in reference product (I. same product; II. same pharmaceutical characteristic; III. same active substance, strength, pharmaceutical form; and IV. same active substance and strength).

Most of the simulated expenditure were in the range +/- 5 % from the baseline calculated expenditure. In general, the models that took into account the minimum prices provided for about 5 to 8 % lower calculated expenditure than the models with average prices. More important than number of reference countries in the formula, is which country is selected. Only small deviations in the calculated expenditures were observed between different levels of similarity to reference products, ranged between 0,1% to 0,6%. However, in addition to the impact on expenditure, the matching rate is also important. We were only able to reach up to 96 % of matching rate. Therefore, for at least 4 % of medicines these ERP models were not suitable.

Our study suggests that ERP models are relatively robust to the changes in the main parameters. Therefore, when setting up or adjusting an already established ERP model, practicality and efficiency should be considered primarily (e.g. access to relevant data sources, matching rates). In addition, the strengths and weaknesses of this or any other model, such as Value Based Pricing model, should also be taken into account in the consideration about future pricing systems.

THE BENELUXA INITIATIVE: AN EXAMPLE OF NEIGHBOURING COUNTRIES COLLABORATION IN HTA PROCESSES

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In April 2015 during an informal meeting of European Ministers the ministers of health of Belgium and the Netherlands announced that they would explore their possible collaboration on pharmaceutical policy. Later that year Luxembourg joined this initiative. In 2016 Austria joined the cooperation initiative which is known by the name Beneluxa. Ireland was the last country to join in 2018. The aim of the Beneluxa initiative is to have sustainable access and appropriate use of pharmaceuticals in the participating countries with a focus on orphan pharmaceuticals. In addition, the participating countries strive to increase patients' access to high quality and affordable treatments. The new pharmaceuticals that were introduced to the market in recent years are not comparable to the pharmaceuticals that were introduced in the past few decades. The new pharmaceuticals are more complex and often developed for a small number of patients with an orphan disease. With these new pharmaceuticals the quality of life of these patients can be dramatically improved and sometimes they can even be cured outright. However, the disadvantage is that these orphan pharmaceuticals are often extremely expensive. This threatens the affordability of care, and will negatively influence the care for other patients. In order to change these developments collaboration is essential and the Beneluxa initiative is a first step towards more collaboration and balance in the pharmaceutical market. Therefore the countries involved in Beneluxa are cooperating in a number of areas, being horizon scanning, information sharing and policy exchange, health technology assessment (HTA) and pricing and reimbursement. In this presentation the focus will be on horizon scanning and HTA. Horizon scanning is used to find out which new find often expensive pharmaceuticals are about to become available in the near future. Horizon scanning will improve national decision making on pricing and reimbursement by identifying pharmaceuticals that might have a large impact on health systems either positive or negative. From 2022 is the International Horizon Scanning Initiative (IHSI) operational for this purpose. Some experience have been gained in the cooperation on performing HTAs. The main goal is to increase the efficiency of the assessment process by exchanging expertise and mutual recognition of HTAs. This is achieved by doing joint assessments that are then used for joint pricing negotiations.

IMPLEMENTATION OF VBHC IN SLOVENIA

Valentina Prevolnik Rupel

OBJECTIVES: In Slovenia, a transformation of health care system based on inputs and processes into an outcome-driven health care is much discussed. The change is imminent due to rising health care costs and the fact that the current payment mechanisms and organization of care are not helpful.
METHODS: As VBHC is foremost a change of values, vision and goals, it is very important to define a proper way of its implementation. Various stakeholders in health care system have started to cooperate and work in a direction of VBHC principles adoptio. Health Insurance Institute of Slovenia started a project *Modernisation of payment models for outpatient healthcare*; Ministry of Health initiated the first few patient-reported outcomes measures to be included in the national hip and knee registry, namely Oxford Hip Score, Oxford Knee Score and EQ-5D; civil initiative set up a working group to start preparing the Guidelines for the implementation of VBHC in Slovenia and several researchers and clinicians started off small-scale projects where outcome measures are being collected. Most of all, various presentations at conferences and articles in scientific journals and daily newspapers are being prepared to widen the knowledge and increase the awareness onVBHC.
RESULTS: The implementation of VBHC in Slovenia has thus far not been comprehensive or systematic and many would claim that nothing has changed yet. From the viewpoint of more demanding customers this is true: the full potential of VBHC has not been unlocked or even touched upon. The rise of quality and savings that can be derived from benchmarking is only visible when at least a few providers or clinicians start to measure the treatment outcomes make their data public and start exhanging good practices. On the other hand, even the most sceptical observers must admit that things are changing. Patients are willing to be more engaged in their treatment, providers are aware that the waste in the system is overwhelming and must be tackled. The payer, a crucial stakeholder, knows that payment by *points performed* only limits the access and does not improve quality.
CONCLUSIONS: it is high time for an orientation towards patients' needs: a breakaway from inefficient technical solutions, an acceptance of patients as active participants in decision-making, measurement of their treatment outcomes, and the adoption of already proven advanced payment models, such as population-based payments. The journey towards value-based healthcare is on the roll.

HOW CLINICAL EFFICACY OF HIP IMPLANTS RELATES TO LONG TERM COSTS FOR PAYOR - AN CROATIAN EXAMPLE

Damir Detić

Objective: to asses yearly cost implications for payor on difference in clinical efficacy of hip implants measured as revisional arthroplasty rate in period of 10 years post primary total hip arthroplasty
Methods: using publicly available 2021. CEZIH data on DRG volume, DRG values and ACHI volume related to primary and revisional hip arthroplasty assess yearly cost implications for payor (HZZO) in period of 10 years post primary implantation at 2021. DRG values.
Results: at sample of 4246 total hip arthroplasties in 2021. difference in clinical efficacy of 1 percentage point (variance from standard efficacy of 90% iimplant survivorship/functionality n 10 years) is equivalent to cost (related to revisional surgery) at value of 1,23 million kuna/163 thousands €.
Conclusion: clinical efficacy of hip implants impacts long term costs for payor therefore it would make sense for payor to require from providers delivery of medical service at established standard of 10% 10y revisional rate for total hip arthroplasty. Requiring meeting that level of clinical outcome will encourage providers to use hip implants with well documented record of meeting standard requirement of 90% implant survivorship 10 years post implantation.

HEALTH ECONOMIC AND OUTCOMES RESEARCH STUDIES OF PRIORITIZED DISEASE AREAS

CHALLENGES IN DIABETES MELLITUS TREATMENT: POLYPHARMACY

Jurij Fürst, Vita Samaluk, Anita Strmljan

Background: In the last 15 years, two new classes of glucose-lowering medicines have come on the market with many new oral and subcutaneous pharmaceuticals which are used mostly as ad-on therapies. Glucose-lowering medications account significantly to the polypharmacy. Polypharmacy, defined as regular use of at least five medications, is common in older adults and increases the risk of adverse medical outcomes. The aim of this study was to analyse polypharmacy in Slovenia and to find out with how many glucose-lowering active ingredients are treated patients with diabetes.

Methods: The analysis was performed in the Health Insurance Institute's Prescriptions database on the whole Slovenian insured population in 2017 - 2021. Number of active ingredients was defined for all medications. For every person, active ingredients in every of the quarters of a year was summed up and divided by four to calculate the average. The results of the analysis of the population of patients with glucose-lowering drugs are shown only for the last quarter of the year 2021. For both analyses, every person was counted only once.

Results: In Slovenia in 2021 (population of 2,1 million), 70 % of the population has received at least one prescription; 10,6 % of the population has received 5-9 active ingredients and 2,4 % of the population has received 10 or more active ingredients. In the population with glucose-lowering drugs (102.372), 46,5 % received one active ingredients, 31,9 % two, 16,3 % three. Four active ingredients and more received 5,3 % of diabetic population (5.431 patients). In average, every patient received 1,8 glucose-lowering active ingredients. In the whole population, the average number of active ingredients per patient was 7,1 and in the diabetic population it was 10,8.

Conclusions: We found out that in Slovenia, 5,3 % of diabetic population has "diabetic polypharmacy", which may be defined by ≥ 4 glucose-lowering active ingredients. Diabetics have more medications than non-diabetic population. There is lack of data to compare these results. To manage polypharmacy, are recommended regular reviews of necessity of all medication, whether all medication is taken, age- and quality of life adjusted intensity of the treatment and consultations with clinical pharmacist.

CARDIOVASCULAR MORBIDITY AND MORTALITY IN PATIENTS WITH TYPE 2 DIABETES USING NOVEL ANTIDIABETIC MEDICINES AS ADD-ON THERAPY IN SLOVENIA

Spela Zerovnik, Mitja Kos, Igor Locatelli

Objective: To evaluate the effect of sodium-glucose co-transporter 2 inhibitors (SGLT2i) and glucagon-like peptide-1 receptor agonists (GLP-1RA), compared to dipeptidyl peptidase-4 inhibitors (DPP-4i) as add-on therapy on cardiovascular (CV) morbidity and mortality in real-world patients with type 2 diabetes (T2D).

Methods: We conducted a nationwide retrospective cohort study comparing patients on SGLT2i and GLP-1RA with patients on DPP-4i. We linked data from three Slovenian healthcare databases: outpatient prescription claims data, hospitalisation claims data and death registry data. T2D patients with newly introduced DPP-4i, GLP-1RA or SGLT2i as add-on therapy between June 2014 and June 2018 were included in the study. We assessed the risk of MACE (composite clinical outcome of CV death, myocardial infarction and ischaemic stroke), CV death and hospitalisations due to heart failure (HF). We calculated adjusted hazard ratios (aHRs) for each outcome under study using covariate-adjusted Cox regression models. We used both the intention-to-treat and on-treatment approaches. In the latter, discontinuation of a novel antidiabetic medicine or initiation of a comparator medicine were treated as censored events.

Results: The study population consisted of 3817 new users of DPP-4i, 2851 new users of SGLT2i and 855 new users of GLP-1RA. During a median follow-up of 2.8 years (interquartile range, IQR: 1.9–3.8 years), 437 MACE events, 234 CV deaths and 205 hospitalisations due to HF were observed. In the intention-to-treat analysis, SGLT2i add-on therapy, when compared to DPP-4i was associated with a statistically significant 1.5-fold lower risk of MACE (aHR=0.66; 95% CI: 0.50–0.85; p=0.002) and a 2.2-fold lower risk of CV death (aHR=0.46; 95% CI: 0.30–0.73; p=0.001). In the on-treatment analysis, SGLT2i add-on therapy was also associated with a lower risk of hospitalisation due to HF compared with DPP-4i add-on therapy (aHR=0.54; 95% CI: 0.30–0.99; p=0.047). In the intention-to-treat analysis, GLP-1RA add-on therapy was associated with a 1.6-fold lower risk of MACE when compared with DPP-4i (aHR=0.64; 95% CI 0.43 to 0.97; p=0.034). In the GLP-1RA group, we observed a lower incidence of CV death and a higher incidence of hospitalisation due to HF compared with the DPP-4i group, but the differences between groups were not statistically significant for any of these outcomes.

Conclusion: SGLT2i and GLP-1RA improved CV morbidity and mortality in real-world patients with T2D compared to DPP-4i as add-on therapy. The results of this study may help inform treatment decisions when selecting an optimal add-on antidiabetic medicine in order to reduce CV morbidity and mortality in patients with T2D.

THE IMPORTANCE OF COST-EFFECTIVENESS PRINCIPLES IN TIMES OF A GLOBAL PANDEMIC

Bertalan Németh

Introduction: Health technology assessment (HTA) is one of the most commonly used tools to judge the clinical and economic value of new health technologies in order to support pricing and reimbursement decisions. The COVID-19 pandemic introduced a great urgency to make these decisions without relying on robust evidence, despite enormous health, economic and societal implications. This happened due to the tremendous pressure coming from the general public and the media as well. However, the opportunity cost of decisions still exists and can seriously affect the use of public funds and, finally, patients' access to essential medicines.

Areas Covered: Based on our professional experience and our understanding of the core principles of Health Economics, we compiled a set of recommendations. For example, that emerging evidence about effectiveness and safety of new or repurposed technologies should be considered not only a public good, but a global public good. We believe that even under extreme circumstances, decision-makers should adhere to the key principles of what is considered to be the good practice of evidence-based decisions. Future decisions should build on the experiences of previous decisions. Coverage with evidence development (CED) schemes offer an opportunity for reducing uncertainty by allowing temporary reimbursement while additional data are collected, thereby facilitating final reimbursement decisions at a later stage without delaying patient access to therapies or vaccines.

Conclusions: We believe that making procurement and reimbursement decisions in urgent times without insisting on collecting data and developing new evidence creates a lost opportunity. As a reasonable and scientifically sound compromise, CED schemes, for example, offer an opportunity for reducing uncertainty in these situations. We believe that the role of health economists is to respond to the new situations created by the pandemic and come up with proposals on how decision-making frameworks can be improved.

RECONSIDERING THE ROLE OF DRUG REPURPOSING IN THE POST-COVID ERA

Zsuzsanna Petykó

Introduction: Pharmaceutical research and development (R&D) of new molecules entails extremely high costs, and only a minority of patients can access innovative medicines due to affordability constraints in Central and Eastern European countries for example. Drug repurposing can offer a wide range of benefits at significantly lower R&D costs, providing accessible treatment options to patients.

Areas covered: Repurposed medicines are developed by incremental innovation of off-patent drugs. They may address different health care needs and problems, including medicine shortages, off-label use of medicines, poor patient adherence, harmful polypharmacy, need for home or personalized health care services, etc.. However, several barriers prevent societies from realizing the benefits of incremental innovation. First, generic manufacturers have a limited budget and experience to demonstrate the value of repurposed medicines. Second, current market exclusivity options do not efficiently prevent free ridership and do not guarantee a return on investment for innovators. Third, value propositions of repurposed drugs are limitedly consistent with current HTA frameworks, consequently, incremental innovation is not acknowledged nor rewarded with differential pricing by payers.

Conclusion: Current policy practices need to be reconsidered internationally to exploit the full societal benefit of drug repurposing, which was also highlighted by the desperate drug repositioning attempts during the COVID-19 pandemic. A more receptive pharmaceutical policy environment needs to include efficient policies to guarantee market exclusivity for incremental innovation, acknowledgment of fair rewards proportional to the added value, and the acceptance of low-cost evidence generation methods.

INTRAVENOUS IMMUNOGLOBULIN (IVIg) IN HOSPITALISED COVID-19 PATIENTS – THROWING MONEY DOWN THE VEIN?

Robert Mačec, Vinko Michael Dodig, Robert Likić

The coronavirus disease 2019 (COVID-19) has caused a worldwide pandemic with more than 519 105 112 confirmed cases and 6 266 324 deaths, as reported by the WHO. Early in the pandemic, and even today almost 3 year later, physicians were faced with a complex clinical problem: the number of hospitalised patients was significant and there were no proven, widely available, and affordable therapeutic options for treating COVID-19 patients. Consequently, various already available drugs were repurposed to treat the new disease, on a more or less sound pharmacological rationale. One such example is the use of intravenous immunoglobulin (IVIg) in hospitalised COVID-19 patients. Although the logic behind the use of immunoglobulins is sound, as they have the potential to target the disease pathophysiology through two distinct mechanisms: direct antiviral antibody neutralisation and immunomodulation of the host response; the results of reported studies exploring IVIg's efficacy are contradictory. With this in mind, we conducted a systematic review and meta-analysis, in which we included a total of 13 studies (of which were 7 retrospective) on the topic. Our findings suggest that IVIg had no impact on patient mortality, or the length of hospital stay. In conclusion, although the rationale behind IVIg treatment in hospitalised COVID-19 patients was sound, current evidence does not support its use. Furthermore, a relatively large number of published retrospective studies imply that IVIg was extensively used in COVID-19 patients despite a lack of clear evidence supporting its use which certainly resulted in unnecessary financial consumption alongside no proven clinical benefit.

IMPACT OF COVID-19 PANDEMIC ON UTILISATION OF HEALTHCARE SERVICES IN CROATIA

Tereza Šarić

Objective: The COVID-19 pandemic notably altered the delivery of healthcare services in 2020 and 2021. There were several reasons for declining healthcare use during the pandemic, including the public's fear of becoming infected while visiting health facilities, the suspension or cancellation of non-COVID-19 care as well as barriers imposed by lockdown policies (for example, curfews, transport closures and stay-at-home orders). To determine the extent and nature of changes in utilisation of healthcare services during COVID-19 pandemic an analysis has been performed.

Methods: The research is a retrospective, comparative analysis of the all outpatient services delivered and hospital admission rate across all Diagnosis Related Group (DRG) classes before and during the pandemic. It is based on DRG data from all hospitals in Croatia, as well as on data from the Croatian Institute of Public Health (CIPH) and Croatian Health Insurance Fund (CHIF).

Results: Different sectors of the health system have been affected by the services reduction to different degrees. At the level of primary health care patient examinations declined by 20% in 2020, although contacts with patients (physical and virtual) even increased. Total specialist outpatient visits declined by 27% by the end of 2020. Preliminary data for 2021 indicate that disruptions likely persisted. Hospital admission rate show a 20% decrease in the total number of admissions for non-specialized acute hospitals in 2020 and remained lower than in 2019 by 15% in 2021. Other components of care like prescription drugs and others remained the same or rose marginally. These changes had the economic implications, as well.

Conclusion: Healthcare utilisation decreased notably during the pandemic, with considerable variation, and with greater reductions among people with less severe illness. Further research is needed to examine the consequences of disruption to healthcare services in Croatia.

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Srdačan pozdrav,

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glavna urednica

Viktorija Erdeljić Turk
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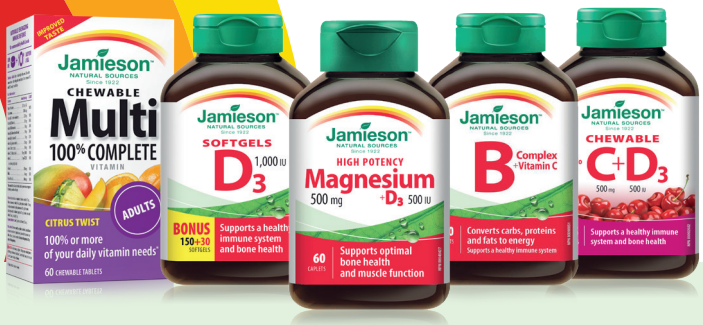

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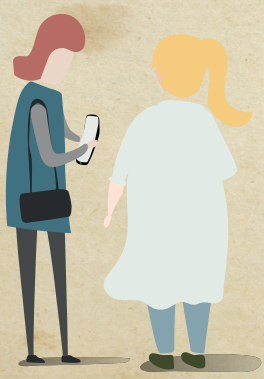

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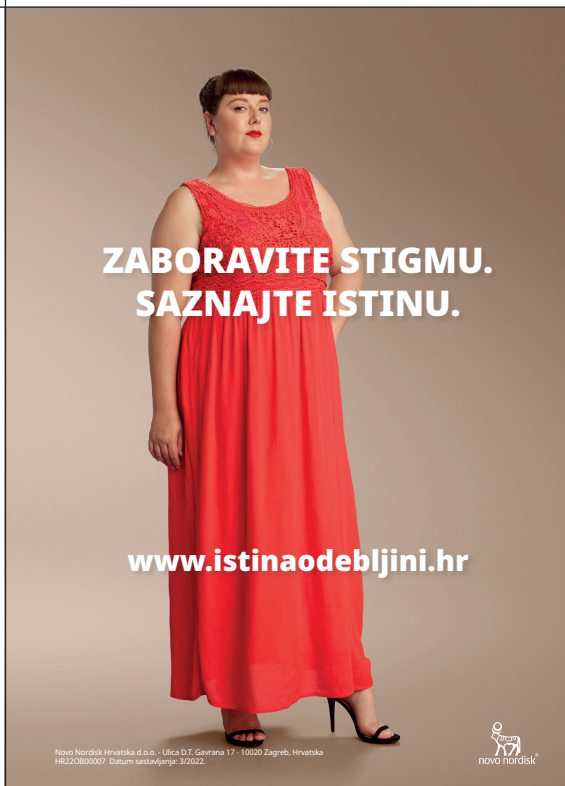

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