



Preliminary programme



Ladies and Gentlemen,

On behalf of CEESTAHC we invite you heartily to take part in:

10th International Evidence-Based Health Care Symposium titled "Disinvestment by HTA & Pricing How can we better address health needs?"

that will take place in Cracow on December 14-15, 2015.

Every day we observe incredible progress in medicine. People continue discovering more effective methods of diagnostics and treatment, while at the same time the costs of healthcare increase relentlessly. Not only can we cure patients more and more effectively, but we can also treat an increasing number of diseases, including rare and ultra-rare diseases. The patients-taxpayers' awareness increases and thus they demand that more healthcare services are guaranteed without restricting access to basic, highly cost-effective methods of diagnostics and treatment.

A growing number of technologies meet the necessary clinical, economic and financial requirements and become part of the basic benefit package. Many technologies or medical services are included in the package due to social, lobbing and political pressures. As a result the package keeps boosting beyond measure and thus generating immense costs. The burden to the budget becomes increasingly difficult to control, the waiting lists to healthcare services are longer, which is the symptom of a financial deficit, which in consequence may lead to the system collapsing under its own weight.

The solution of choice applied in our country is delaying reimbursement decisions as long as possible and increasing the queues, or waiting lists, both in number and length. We should bear in mind that a queue is a health technology of proven harmfulness, which is particularly unjustified in the case of highly effective and cost-effective healthcare services.

This year during the annual EBHC symposium, CEESTAHC will tackle the issue of excessive burdening of the basic benefit package. The main issue is managing the guaranteed services package in a way in which financial resources indeed guarantee those services. What can be done to control the contents of the package? What can be done to eliminate the deficit understood as the disparity between the contents of the package and the funds allocated to its implementation? What can be done to make the system more fair? Where can we find additional funding for add value medical technologies in order to prevent a deficit and waiting lists to basic healthcare services?

Park Inn Hotel



Manggha Museum of Japanese Art and Technology



The basic benefit package is a tool which, like any other tool, in order to function correctly, requires proper handling, reviews and maintenance. The technologies included in the package should be periodically reassessed and, if need be, replaced by better alternatives. Meanwhile, the Polish quaranteed services package is a walk down the memory lane rather an active area for finding better solutions. When, after undergoing a lengthy assessment process (usually the case of drugs), a technology is included in the package, theoretically it can stay there "forever". New technologies are added to the package and with time actual heaps are created - forgotten, musty, difficult to assess and difficult to remove, as there is no one who would take on that task. The Polish Agency for Health Technology Assessment and Tariff System (AOTMiT) assesses nearly only drug technologies and operates on a thin line between innovative drugs and the quaranteed services package. AOTMiT virtually never deals with non--drug technologies and completely fails to revisit the "guaranteed" service package in order to makes space for new health technologies and relocate funds for innovations. The hope lies with launching the Tariff System Agency – however, will the adopted valuation methods be able to ensure the expected efficiency?

Removing a health technology from the basic benefit package once it is included is very difficult in our country. One problem is the lack of experience in this type of operations, another is the significant risk that the competing political option will use this against the incumbents. Their opponents will not hesitate to horrify the public with their political rivals' "totalitarian" inclinations or to persuade confused patients to appear before the doors of the key authorities as part of "spontaneous social protests". Usually in such cases the situation starts spinning out of control and politically-motivated decisions replace the rational ones.

Despite these difficulties many countries have systems in force allowing for efficient "fine-tuning" of the basic benefit package. It is helpful to learn about these solutions, especially since the right procedures took decades to develop.

We invite you wholeheartedly to participate in the Symposium.



10th International EBHC Disinvestment by HTA & Pricing

Poniedziałek, 14 grudnia 2015 / Monday, December 14 th , 2015 9:30 – 17:00			
Numer i tytuł sesji, temat wykładu / Session, lecture topic	Prelegent / Speaker	(1)	
Czas trwania / Dur Priorytety i plany strategiczne Ministerstwa Zdrowia / Priorities and strategic plans of the Ministry of Health		ation:	
Otwarcie Sympozjum / Opening of the Symposium	Magdalena Władysiuk	15 min.	
Wystąpienie przedstawiciela Ministerstwa Zdrowia - Podsekretarz Stanu Krzysztof Łanda Lecture of the representative of the Ministry of Health - Undersecretary of State Krzysztof Łanda			
Przerwa kawowa / Coffee-break		10 min.	
Sesja 2 / Session 2 Perspektywa analiz oceny technologii medycznych The perspective of health technology assessment analyses Moderator: Magdalena Władysiuk	Czas trwania / Dur 10.40 - 12.20		
Perspektywa społeczna w ocenie ekonomicznej: teoria prostsza od praktyki / Societal perspective in economic evaluation: easier said than done	Mark J. Sculpher	40 min.	
Analizy Oceny Technologii Medycznych: perspektywa Szkocji / Health Technology Assessment Analyses: A Scottish perspective	Angela Timoney	25 min.	
Kierunki rozwoju polskiej Agencji Oceny Technologii Medycznych / Directions for development of the Polish Health Technology Agency	Wojciech Matusewicz	25 min.	
	Lunch	60 min.	

^{*} w czasy sesji wliczono czas dyskusji / discussion time included



At the request of the company providing simultaneous interpretation you will be asked to deposit your ID card when receiving your audio set-up.

The time for panel discussion with the speakers will be provided within each session. Simultaneous translation of all speeches into Polish and English.



Poniedziałek, 14 grudnia 2015 / Monday, December 14 th , 2015 9:30 – 17:00			
Numer i tytuł sesji, temat wykładu / Session, lecture topic	Prelegent / Speaker	(1)	
Sesja 3 / Session 3 Sesja diagnostyczna: Debata nad stanem polskiego systemu ochrony zdrowia Diagnostic session: A debate on the condition of the Polish healthcare system Moderator: Magdalena Władysiuk	Czas trwania / Dur 13.20 - 14.35		
Czy polski system ochrony zdrowia da się uzdrowić? Analiza trendów długoterminowych / Can the Polish healthcare system be healed? An analysis of long-term trends	Stefan Bogusławski	25 min.	
Debata / Debate: Krzysztof Łanda, Anna Janczewska-Radwan, Stefan Bogusławki, Magdalena Władysiuk, Jacek Siwiec, Jakub Szulc			
Przerwa k	Przerwa kawowa / Coffee-break		
Sesja 4 / Session 4 Sesja "terapeutyczna: Jak zrobić porządek z koszykiem świadczeń gwarantowanych? Therapeutic session: How can some order be introduced to the basic benefits package? Moderator: Robert Plisko	Czas trwania / Dur 14.50 - 17.00		
Polski system ochrony zdrowia z perspektywy Paryża The Polish Health-Care System: A View From Paris	Peter Jarrett		
Zakres gwarancji państwa, publiczne wydatki na zdrowie a rynek prywatnych ubezpieczeń zdrowotnych The scope of state guarantees, public spending on health and the private health insurance market	wotnych g		
Czy system ochrony zdrowia odpowiada na potrzeby pacjentów z chorobami rzadkimi? / Does the healthcare system address the needs of patients suffering from rare diseases?	care		
Praktyka kodowania świadczeń medycznych w ramach jednorodnych grup pacjentów (JGP) w Polsce Healthcare service coding practices in the diagnosis- -related group (DRG) system in Poland	Agnieszka Wojtecka	20 min.	
Debata / Debate: Wojciech Matusewicz, Wojciech Wysoczański, Peter Jarrett, Stefan Bogusławski, Magdalena Władysiuk, Jakub Szulc, Maria Libura, Agnieszka Wojtecka			

^{*} w czasy sesji wliczono czas dyskusji / discussion time included





10th International EBHC Disinvestment by HTA & Pricing

Wtorek, 15 grudnia 2015 / Tuesday, December 15 th , 2015 9:30 - 15:10			
Numer i tytuł sesji, temat wykładu / Session, lecture topic	Prelegent / Speaker	(1)	
Sesja 5 / Session 5 Rola agencji taryfikacji Role of a tariff system agency Moderator: Wojciech Matusewicz	Czas trwania / Duration: 9.30 - 11.35*		
Agencja Taryfikacji – rola i miejsce w polskim systemie The Tariffs Agency – its role and place in the Polish system	Gabriela Ofierska-Sujkowska	20 min.	
Ocena technologii medycznych w publicznym systemie szpitalnym AP-HP we Francji i Europie (narzędzie dla decydentów oparte na dowodach naukowych) Hospital-based Health Technology Assessment at AP-HP in France and in Europe (A tool for decision-making based on evidence)	Alexandre Barna	25 min.	
Wycena i ustalanie cen świadczeń w ramach Społecznego Ubezpieczenia Zdrowotnego w Niemczech Valuation and pricing in the framework of the Social Health Insurance in Germany	Bertram Häussler	25 min.	
Wycena nowych leków w podejściu HTA: doświadczenia z Litwy / Valuing of new medicines with HTA approaches: Lithuanian experience			
Zmiany w systemie informacji w ochronie zdrowia – skutki dla władzy, lekarzy i obywateli Changes in the information system in healthcare – their impact on authorities, doctors and citizens	Tomasz Pęcherz	25 min.	
Przerwa kawowa / Coffee-break			

^{*} w czasy sesji wliczono czas dyskusji / discussion time included



Wtorek, 15 grudnia 2015 / Tuesday, December 15 th , 2015 9:30 - 15:10			
Numer i tytuł sesji, temat wykładu / Session, lecture topic	Prelegent / Speaker	(1)	
Sesja 6 / Session 6 Fundusz Walki z Rakiem Innovative Oncological Care Fund Moderator: Jakub Szulc	Czas trwania / Duration: 11.50 - 12.45*		
Koncepcja i podstawy organizacyjne Funduszu Walki z Rakiem w Polsce / The concept behind the Innovative Oncological Care Fund in Poland and its organisational bases	Anna Kordecka	15 min.	
Dostęp do diagnostyki i leczenia w ramach Funduszu Walki z Rakiem / Access to diagnostics and treatment under the Innovative Oncological Care Fund	Cezary Pruszko	15 min.	
Rozwój dodatkowych ubezpieczeń zdrowotnych a źródła finansowania Funduszu Walki z Rakiem / Development of additional health insurance and sources of financing the Innovative Oncological Care Fund	Robert Plisko	15 min.	
	Lunch	60 min.	
Sesja 7 / Session 7	Czas trwania / Duration: 13.45 - 15.10*		
Real World Evidence Moderator: Nowicki Maciej	13.45 - 15.10	*	
11000	Joanna Lis Maciej Niewada	* 20 min.	
Moderator: Nowicki Maciej Rola RWE w podejmowaniu decyzji w ochronie zdrowia	Joanna Lis	I	
Moderator: Nowicki Maciej Rola RWE w podejmowaniu decyzji w ochronie zdrowia The role of RWE in decision-making in healthcare Źródła danych dla pozyskiwania RWE – praktyczne rozwiazanie Early Access Program w leczeniu WZW typu C w Polsce / Source of Data for Real World Evidence Practical solution – Early Access Program	Joanna Lis Maciej Niewada	20 min.	
Moderator: Nowicki Maciej Rola RWE w podejmowaniu decyzji w ochronie zdrowia The role of RWE in decision-making in healthcare Źródła danych dla pozyskiwania RWE – praktyczne rozwiazanie Early Access Program w leczeniu WZW typu C w Polsce / Source of Data for Real World Evidence Practical solution – Early Access Program in HCV management in Poland	Joanna Lis Maciej Niewada Maciej Nowicki	20 min. 20 min.	

^{*} w czasy sesji wliczono czas dyskusji / discussion time included





Speakers

- 1. Alexandre Barna, France
- 2. Stefan Bogusławski, Poland
- 3. Robert Dewor, Poland
- 4. Jolanta Gulbinovič, Lithuania
- 5. Bertram Häussler, Germany
- 6. Anna Janczewska-Radwan, Poland
- 7. Peter Jarrett, Canada
- Anna Kordecka, Poland 8.
- 9. Maria Libura, Poland
- 10. Joanna Lis, Poland
- 11. Krzysztof Łanda, Poland
- 12. Wojciech Matusewicz, Poland
- 13. Maciej Niewada, Poland
- 14. Maciej Nowicki, Poland
- 15. Gabriela Ofierska-Sujkowska, Poland
- 16. Tomasz Pecherz, Poland
- 17. Robert Plisko, Poland
- 18. Cezary Pruszko, Poland
- 19. Mark Sculpher, UK
- 20. Jacek Siwiec, Poland
- 21. Mitch Sugarman, USA
- 22. Jakub Szulc, Poland
- 23. Angela Timoney, UK
- 24. Magdalena Władysiuk, Poland
- 25. Agnieszka Wojtecka, Poland
- 26. Wojciech Wysoczański, Poland



Session 2 | The perspective of health technology assessment analyses

Health is one of the greatest values both for the individual and for society as a whole, and its protection is inextricably linked with the State's responsibilities. In the past few years there has been an intense discussion on the healthcare policy model, the scope of financing services and decision-taking in healthcare. Implementation of goals set out for the State is becoming increasingly difficult due to:

- demographic changes, including changes resulting in a reduction of the working population,
- changes on the labour market,
- growing needs and expectations of the society related to healthcare,
- lack of coordination of actions taken between different sectors which would reduce consequences of civilisation diseases, increasing disability and growing public spending.¹

In the context of challenges faced by decision-makers in the field of health policy, data on indirect costs generated due to reduced productivity of patients constitutes valuable information, which so far has been underestimated. Analyses extended by assessments of lost productivity make it possible to view a disease not only as an issue affecting the patient directly, but also help see the negative consequences of the disease to the society as a whole.

This session is devoted to a further discussion on the social perspective – its constraints, scope of data and the possibility of being applied in health technology assessment. You will learn in particular about the experiences of Great Britain and Scotland.



¹ Indirect costs in health technology assessment. Methodology, pilot study and recommendations. Warsaw, December 2014. http://hta.pl/cmsd/uploads/upload_54883d3d95e082.82536106.pdf



Session 4 | Therapeutic session: How can some order be introduced to the guaranteed benefits package?

In Poland, the guaranteed benefits package has been discussed by experts since the late 1990s. At the same time the "benefits package" is a popular political slogan which is supposed to be an antidote to the problems suffered by the Polish healthcare system. This slogan keeps being used by political parties in their policy programmes, however no details or suggestions for changes are actually given. So what can a basic benefit package be? A positive list, a negative list or a combination of both these types? Have we created a closed list of guaranteed technologies which allows us to precisely determine what a patient is entitled to in the Polish healthcare system? Is it possible to define it through specifications related to a health technology? If so, in what timeline and scope?

Some elements of the system are subject to change, but the key problem – deficit in healthcare – remains the same. In other words, it's not like we have too little money on health care, nor are there few benefits in the package. The problem is that we have to determine what is most necessary from the society's perspective and introduce conditions which would ensure access to healthcare services. Firstly, it must be determined which services are needed the most.

Foreign guests invited to participate in this session have specialised in the issue of guaranteed packages for many years, and the Polish speakers take part in shaping the final form of the package in Poland. We might witness a very interesting confrontation.



Session 5 | Role of a tariff system agency

Since 1 January 2015, pursuant to the Act of 27 August 2004 on health care benefits financed from public funds (Journal of Laws 2015, item 581, as amended), the scope of activities of the Polish Agency for Health Technology Assessment also includes valuation of health care services.

Before that date, entities applying for inclusion of a health technology into the guaranteed benefits package were required under applicable provisions of law to provide a cost analysis conducted from the perspective of the payer and sometimes also from the social perspective. Cost analyses (micro-costing) were performed primarily for reimbursement, and not pricing decisions. That is why they concern mainly expensive innovative technologies compared with alternative technologies.

The Agency's new responsibilities will include the following tasks:

- · Determining tariffs of healthcare services,
- Proposing recommendations on the cost accounting standard,
- Developing, verifying, collecting, sharing and disseminating information on principles of determining tariffs,
- Creating a methodology of determining tariffs for services,
- Providing opinions on health policy programmes.

According to experts, ensuring actual, reliable valuation of health services could reduce queues to doctors and promote the most cost-effective services or forms of care which are scarce. The central question is whether valuation of services carried out only on the basis of historical data will prove to be an effective tool. Taking into account only retrospective data results in the process disregarding some important elements, such as queues, actual needs, and most of all, the need to shape the scope and form of healthcare in the future. This fits into the real-world data trend which more and more countries start to take into account when planning actions to be taken in their healthcare systems.

During this session we want to show examples of activities taken by tariff system agencies from other countries (i.a. Germany), their scope of responsibilities, methodology and potential problems with valuation.





Session 6 | Innovative Oncological Care Fund

The guaranteed benefits package in Poland becomes increasingly less open to new technologies, including actual innovations. There are still over 250 innovative drug technologies and approximately 1000 innovative non-drug technologies not included in the Polish guaranteed benefits package. This situation particularly affects cancer patients who are fighting a hopeless battle, knowing that there is a drug out there which could save their life, but which they can't afford.

In the years to come, more and more newly-created health technologies will remain outside the financial capacities of public funds. The main impediments are budget shortages, intensified by the global crisis and complicated legal regulations governing management of the guaranteed benefits package. Other Central and Eastern European Countries and middle-income countries worldwide struggle with similar problems. The main barrier is lower GDP per capita than in the case of high-income countries and its consequence: a smaller GDP percentage spent on healthcare. Innovative technologies first enter the wealthiest and largest markets in the world. And therefore their pricing, which constitutes the basis for economic analyses, becomes a significant barrier which makes them beyond reach. In many cases it takes several years for an innovative drug to be granted reimbursed, until its price erodes. In the meantime, Polish oncological patients do not have access to health technologies which constitute latest achievements of modern medicine and which could help them.



In order to improve this situation, the idea of the Innovative Oncological Care Fund (Polish: Fundusz Walki z Rakiem; FWR) was created, which aims at ensuring the availability of innovative methods for treatment and diagnosis of neoplastic diseases. The Innovative Oncological Care Fund will make it possible to bypass the inefficient financial system and, thanks to its independence from central regulations, will be free to operate in line with evidence-based healthcare (EBHC). However, this is not supposed to be "luxury insurance for the chosen ones". It is based on several principles which set out its direction for development and regulate its activity:

- the principle of solidarity some of the funds from operations of complementary health insurance are to be allocated to financing of the Innovative Oncological Care Fund, and the Fund covers the costs of innovative oncological technologies for all Poles,
- the rule of precedent if one person with a given disease characteristics and form receives treatment, all other patients in the same demographic and clinical situation would receive treatment somewhat automatically,
- full access not only to modern drugs, but also to non-drug therapeutic and diagnostic technologies.

Many experienced policymakers of the Polish healthcare will cry out: "Counterrevolution!", but such solutions are already being used worldwide. Funds created to improve access to oncological innovations have been established in the UK and Australia – whose healthcare systems are among the best ones.





Session 7 | Real World Evidence

All over the world there is a growing awareness that randomised trials, which for many years had been treated as the only "absolute assessment" of a therapy's efficacy, do not reflect the full spectrum of a health technology's use. The aim of a real-world evidence analysis is to supplement the process in order to help make better economic decisions, in particularly in a long-time horizon – like in the case of reimbursement.

Interest in the new approach is getting stronger not only due to the possibility of determining actual effectiveness, but also the method of studying types of populations, types of doctors' behaviour, the degree of adherence or compliance, the profile of adverse effects or costs.

The definition of real-world data (or real-life data) varies, but in its broadest scope it covers all studies apart from phase III of trials (in line with the ISPOR definition) and is currently implemented with regard to relative effectiveness or comparative effectiveness. And thus each payer, when analysing its databases, can publish data related not only to effectiveness, but also processes and costs. All observations made in the heal-thcare system may be treated as real-life data.

In this session we want to discuss the possibilities of using new analytical methods. We will demonstrate what methodological problems are related to the implementation of specific types of solutions. We will present data which can be collected in the following areas:

- existing databases in healthcare systems (data of payers and hospitals, registers),
- periodic examinations in specific diseases, e.g. costs of the disease, epidemiological data,
- observational studies in terms of health technology assessment, patient management adverse effects,
- · registers,
- pragmatic clinical trials,
- risk-sharing agreements.

Join us at the "Meet the Experts" gala dinner

Manggha Museum of Japanese Art and Technology

Theme of the meeting: Cultures of the world Time: Monday, 14 December 2015, 8.00 pm

About the Manggha Museum

- The Manggha Museum of Japanese Art and Technology was created on the initiative of Andrzej Wajda and opened in 1994 as the Manggha Centre of Japanese Art and Technology.
- It was a branch of the National Museum in Kraków for ten years and at the same time the venue of the proactive activities of Andrzej Wajda and Krystyna Zachwatowicz's Kyoto-Krakow Foundation.
- On 11 July 2002, the Manggha Museum was visited by the Japanese Emperor Akihito and Empress Michiko, which was a great honour for the institution and a sign of recognition for its efforts.
- In 2005, the Manggha Museum was granted the status of a state cultural institution.
- Since 2007 it has operated as a museum. In accordance with the Founders' idea, a special place was created in Kraków as "a home for the collection of Japanese art" amassed mostly by Feliks 'Manggha' Jasieński, who donated it to the National Museum in 1920.
- The collection of Far Eastern Art of the National Museum in Kraków was ultimately deposited with the Manggha Museum in 2009.





Price table

Duize table	Representatives of		
Price table (nett prices)	public institutions	private sector	Students and PhD students
registration till November 13th 2015			
1 day	140,00€	430,00€	70,00€
2 days	200,00 €	545,00 €	115,00€
registration till November 27th 2015			
1 day	185,00 €	545,00 €	85,00 €
2 days	245,00 €	630,00 €	145,00€
registration from November 28th 2015 and during Symposium			
1 day	215,00 €	570,00 €	85,00 €
2 days	270,00 €	685,00 €	145,00 €



Conditions of participation

- 1. Variants of participation in the Symposium:
 - 1 day
 - 2 days
- The cost of participation of one person depends on the time of declaration and the selected variant of participation (see the Price table for details).

The number of places is limited.

- 3. The following participants are entitled to discounted fee:
 - representatives of public institutions: a certificate must be produced on demand
 - students and postgraduate students: based on the school's letter of reference (with official stamps)
- 4. The fee includes: participation in scientific sessions, educational materials, coffee breaks and the lunch.
- 5. Declaration may be submitted by:



E-procurement system on our website



Printed application form send by fax

6. Payment should be made within 7 days following acceptance of declaration (no later than 5 working days before commencement of the Symposium) to the following account:

Bank PKO S.A O/Krakow

Rynek Glowny 47, 30-960 Krakow, POLAND

PL 97 1240 4689 1111 0000 5142 0745

Swift code: PKOPPLPW

Payment title: "EBHC Symposium 2015"

- Cancellation. If participation is cancelled no later than December 4th, 2014, the cost of cancellation will be 175€; after that day the fee will not be returned.
- 8. The organisers reserve the right to change the Symposium programme.







Boehringer Ingelheim



























Medtronic















Central and Eastern European Society of Technology Assessment in Health Care (CEESTAHC)

The Society was founded in Krakow in 2003.

We associate professionals in the fields of HTA, economic and cost evaluations, EBM and quality assurance in clinical trials.

Our main aim is development and progress of standards and methods of assessment of drug and non-drug health technologies in Central and Eastern Europe. Our additional goal is to develop and promote a common understanding and vocabulary, which allows various parties in the health care system to communicate: physicians, representatives of health insurance, medical societies, pharmaceutical companies, politicians, economists, hospital managers and other specialists who deal with financial aspects of medical services and assessment of both health care system quality and effectiveness of health technologies.

Our further aim is to promote HTA and EBM in our part of Europe.

We help especially those who has just begun with HTA – we consult, organize training and offer other forms of support.

Scientific Program Committee

Wojciech Matusewicz Zbigniew Szawarski Krzysztof Łanda Mitchell Sugarman Brian Godman

Local Organizing Committee

Magda Władysiuk Maciej Dziadyk Tomasz Jan Prycel Izabela Kukla Piotr Miazga

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