

12th International Symposium Evidence-Based Health Care

December 11th-12th, 2017 | Kraków, Poland

HTA

**Evidence and value
in decision-making
paradigm**



Preliminary programme

Ladies and Gentlemen,

On behalf of CEESTAHC we are pleased to invite you to take part in the

12th International Evidence-Based Health Care Symposium
titled

„HTA: evidence and value in decision-making paradigm“

which will take place in Cracow, on 11–12 December 2017.

Venue: Hotel Park Inn, Kraków, ul. Monte Cassino 2.

Evidence-based health care is becoming a dominant direction for development of health care systems around the world. At the same time, thanks to greater awareness and increasing problems with interpreting results of studies and reviews, basic questions tend to be asked again. After so many years of EBHC development, we pose the question: what is evidence, anyway? We are searching for answers by starting with a single patient (e.g. in the case of rare diseases) and are going up to the level of the entire system – with emphasis on what values and effects we want to achieve.

We wish to invite you to yet another edition of our Symposium, which is intended as a starting point for a discussion on solutions created both in Poland and elsewhere in the world. Currently, many countries are either analysing phenomena or are already taking actions in areas which we discuss in our sessions:

- Developing value-based health care systems,
- Changing our approach towards obtaining marketing authorisations for drugs based on adaptive pathways; challenges faced by payers in Europe,
- Comprehensiveness and integration of care in the health care system,
- Introducing new medical devices and methods of their financing,
- Clinical guidelines – how they are created, implemented and how do they impact the system,
- The situation and role of rare diseases – including in particular the active attitude of patients and the solutions they prefer.

The market of medicinal products, medical devices and all health services is becoming more and more complicated. In this multilevel structure we encounter both cooperation and competition, and conflicts of interest are not always easy to identify. It seems obvious that the primary objective of health care should be meeting the health needs of the society, which can be done by way of prophylaxis, treatment and monitoring. Each country searches for optimal solutions which would keep up with the ever-changing surroundings and possibilities (and costs) brought about by new solutions.

The aim of this Symposium is to ask: what should the shape of the system be? how should it be financed? – and most of all: what should serve as the basis for its evaluation: costs, effects, values, or political objectives? We will also attempt to find an answer to these questions together. Furthermore, we will consider whether these questions can be used as a long-term indicator for the correct direction of development and when should they be adjusted?

A hand-picked panel of experts from Poland and other countries will present the results of their studies and will suggest proposals of solutions in 6 sessions:



1. Directions of change in health care systems – **fee free session**
2. Adapt or not to Adapt? Adaptive Pathways: a lifecycle approach in a sustainable way – **fee free session**
3. New solutions in rare diseases
4. Is it necessary to regulate medical devices in the healthcare system?
5. Patient care integration – management, financing evidence
6. Evidence – synthesis and translation

Representatives of the Polish and Belgian Ministries of Health have been invited to take part in the opening session. They will present their strategic goals and changes planned for the months and years to come. Belgium was one of the first countries in Europe to introduce a value-based systems several years back, therefore we are counting on honest reflections and first-hand experience.

A broad group of stakeholders has been invited to participate in the session on adaptive pathways, including patients, representatives of registration offices and the European Medicines Agency in order to discuss problems and challenges faced by payers.

The Symposium also has the goal of supporting and educating the invited patient associations dealing with rare diseases. The session on rare diseases will present methods for measuring patients' preferences and practical solutions developed in France which ensure comprehensiveness of treatment.

The session on synthesis of evidence and creating guidelines will present the latest concepts. This session will demonstrate the latest Polish and Czech solutions and the years-long engagement of Cochrane, an international organisation, in the creation of credible methodology for systematic reviews.

We are convinced that, despite many years of reform, it is necessary to continue the discussion on financing of services. Especially in view of such dynamic positive changes regarding the network of hospitals, medical devices, or integrated patient care. We hope that Polish and foreign examples of system solutions presented during the Symposium will constitute good starting points for an exchange of opinions. At the same time, in the session on medical devices, we will hold a panel discussion between representatives of the pharmaceutical industry, the public payer, experts in health care and clinicians.

We want to treat our meeting at the 12th International Evidence-Based Health Care Symposium on 11-12 December 2017 as a chance for an exchange of views and a great opportunity to obtain information on detailed solutions in Poland and abroad.

Join us at the Symposium!



Hotel
Park Inn

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

Magdalena Władysiuk
Małgorzata Bała
Maria Libura
Ad R. Schuurman
Mitchell Sugarman
Brian Godman

Local Organizing Committee

Maciej Dziadyk
Tomasz Jan Prycel
Izabela Kukła
Piotr Miazga
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Poniedziałek, 11 grudnia 2017 / Monday, December 11th, 2017

9:30 – 15:50

Numer i tytuł sesji, temat wykładu / <i>Session, lecture topic</i>	Zaproszeni prelegenci <i>Invited speakers</i>	
<p>Sesja 1 / Session 1 Kierunki zmian w systemach ochrony zdrowia Directions of change in health care systems</p> <p> Wstęp wolny! / Fee free session!</p> <p>Moderator: Magdalena Władysiuk</p>	<p>Czas trwania / <i>Duration</i>: 9.30 - 11.10</p>	
<p>Otwarcie Sympozjum / <i>Opening of the Symposium</i></p>	Magdalena Władysiuk	5 min.
<p>Polityka lekowa państwa – w kierunku większej przewidywalności systemu / <i>The national drug policy – towards the system's greater predictability</i></p>	Marcin Czech	20 min.
<p>Rola i znaczenie programów pilotażowych, taryfikacji oraz procesu zmiany technologii medycznej w tworzeniu wykazu świadczeń gwarantowanych / <i>The role and significance of pilot programmes, tariff-setting and the process of adapting health technologies in creating the list of guaranteed benefits</i></p>	Zbigniew Król	20 min.
<p>Międzynarodowa współpraca w zakresie pricingu i refundacji leków: inicjatywa BeNeLuxA jako proof of concept <i>International collaboration on pricing and reimbursement of pharmaceuticals: the BeNeLuxA Initiative as proof of concept</i></p>	Francis Arickx	30 min.
<p>Wartość jakości w systemie ochrony zdrowia – zadania AOTMiT / <i>The value of quality in the healthcare system – tasks of AOTMiT, the Polish HTA Agency</i></p>	Roman Topór-Mądry	15 min.
Przerwa kawowa / <i>Coffee-break</i>		15 min.
<p>Sesja 2 / Session 2 Adaptować czy nie adaptować? Adaptive Pathways: jak w trwały sposób uwzględnić cykl życia leku? / Adapt or not to Adapt? Adaptive Pathways: a lifecycle approach in a sustainable way</p> <p> Wstęp wolny! / Fee free session!</p> <p>Moderator: Ad Schuurman</p>	<p>Czas trwania / <i>Duration</i>: 11.25 - 13.15*</p>	
<p>Przegląd programu adaptive pathways oraz platformy Adapt Smart / <i>Overview of adaptive pathways and Adapt Smart</i></p>	André Broekmans	20 min.
<p>Przemyślenia z perspektywy prawodawczej <i>Reflections from a regulatory perspective</i></p>	Csilla Pozsgay	10 min.

Poniedziałek, 11 grudnia 2017 / Monday, December 11 th , 2017		
9:30 – 15:50		
Numer i tytuł sesji, temat wykładu / Session, lecture topic	Zaproszeni prelegenci Invited speakers	
Adaptive pathways – perspektywa decydenta i płatnika publicznego / Adaptive pathways – decision maker and public payer perspective	Marcin Czech	10 min.
Przemyślenia z perspektywy HTA Reflections from an HTA perspective	Magdalena Władysiuk	10 min.
Adaptive pathways jako „zrównoważone podejście do cyklu życia leku oraz perspektyw pacjenta” – wizja Europejskiego Forum Pacjentów / Adaptive Pathways „a balanced approach to life-cycle and patient Perspectives” the vision of European Patients Forum	Michał Rataj	10 min.
Panel dyskusyjny / Discussion panel: André Broekmans, Marcin Czech, Vinciane Pirard, Csilla Pozsgay, Michał Rataj, Ad Schuurman i Magdalena Władysiuk		40 min.
	Lunch	45 min.
Sesja 3 / Session 3 Nowe rozwiązania w chorobach rzadkich New solutions in rare diseases Moderator: Maria Libura	Czas trwania / Duration: 14.00 - 15.50*	
12 lat strategii na rzecz chorób rzadkich we Francji: co nowego? czego możemy się nauczyć? / A perspective from 12 years of strategy for rare diseases in France: what's new? what's inspirational?	Myriam de Chalendar	20 min.
Wspólnoty pacjentów jako wspólnoty wiedzy. Jak wykorzystać je jako motor innowacji w chorobach rzadkich? / Patient communities as communities of knowledge. How can we use them to drive innovation in rare diseases?	Maria Libura	20 min.
Znaczenie doboru punktów końcowych w badaniach klinicznych – onkologia i hematologia / The significance of endpoint selection for clinical trials – oncology and hematology	Anna Kordecka	20 min.
Value assessment (ocena wartościująca) leków sierocych w chorobach rzadkich / Value assessment of orphan drugs for rare diseases	Steven Simoens	20 min.
Finansowanie leków sierocych w Europie / Financing of orphan drugs in Europe	Robert Plisko	20 min.

* w czasie sesji wliczono czas dyskusji: 10 min. / discussion time included: 10 min.

Wtorek, 12 grudnia 2017 / Tuesday, December 12th, 2017

9:00 – 15:25

Numer i tytuł sesji, temat wykładu / <i>Session, lecture topic</i>	Zaproszeni prelegenci <i>Invited speakers</i>	
Sesja 5 / Session 5 Integracja opieki nad pacjentem – zarządzanie, finansowanie, evidence / Patient care integration – management, financing evidence Moderator: Magdalena Władysiuk	Czas trwania / <i>Duration</i> : 9.00 - 10.30*	
Wczesna interwencja – prezentacja wyników projektu międzynarodowego / <i>Early Intervention – presenting results of an international model</i>	Magdalena Władysiuk	20 min.
Rehabilitacja lecznicza w Polsce – kierunek zmian i rozwoju systemu / <i>Medical rehabilitation in Poland – the direction of changes and system development</i>	Dominik Dziurda	20 min.
Wydatki, których nie widać – analiza kosztów pośrednich na przykładzie przewlekłego wyprysku rąk / <i>Expenses we do not notice – an indirect cost analysis on the example of chronic hand eczema</i>	Paulina Rolska	20 min.
Międzyresortowa koordynowana opieka zdrowotna, propozycje rozwiązań na przykładzie SM / <i>Interministerial coordinated care – proposed solutions on the example of MS</i>	Andrzej Śliwczyński	20 min.
Przerwa kawowa / <i>Coffee-break</i>		10 min.
Sesja 6 / Session 6 Evidence – synteza i zastosowanie Evidence – synthesis and translation Moderator: Magdalena Władysiuk	Czas trwania / <i>Duration</i> : 10.40 - 12.25*	
Opracowywanie, adaptowanie i przyjmowanie wytycznych klinicznych: zastosowanie metodyki GRADE: Evidence-to-Decision / <i>Development, adaptation and adoption of clinical practice guidelines: Application of the GRADE Evidence-to-Decision framework</i>	Wojtek Wiercioch	20 min.
Projekt narodowego centrum ds. wytycznych praktyki klinicznej w Czechach. Wykorzystywanie danych z przeglądów systematycznych w opracowywaniu wytycznych praktyki klinicznej / <i>Project of national centre for Clinical Practice Guidelines in the Czech Republic; data from Systematic Reviews in development of Clinical Practice Guidelines</i>	Miloslav Klugar	20 min.
Wytyczne dla wytycznych praktyki klinicznych w Polsce / <i>Guidelines for creating clinical guidelines in Poland</i>	Dominik Dziurda	20 min.

Wtorek, 12 grudnia 2017 / Tuesday, December 12th, 2017 9:00 – 15:25		
Numer i tytuł sesji, temat wykładu / <i>Session, lecture topic</i>	Zaproszeni prelegenci <i>Invited speakers</i>	
Making sense of the evidence – a programme for developing enhanced HTA expertise in CEE / <i>Jak korzystać z dowodów naukowych – udoskonalenie oceny technologii medycznych w Europie Środkowo-Wschodniej</i>	Alan Haycox	15 min.
Ocena błędu systematycznego w syntezie danych naukowych / <i>Risk of bias assessment in evidence synthesis</i>	Małgorzata Bała	20 min.
Lunch		45 min.
Sesja 4 / Session 4 Czy konieczne jest uregulowanie wyrobów medycznych w systemie ochrony zdrowia? <i>Is it necessary to regulate medical devices in the healthcare system?</i> Moderator: Mitch Sugarman	Czas trwania / <i>Duration:</i> 13.10 - 15.25	
Value-Based Health Care z perspektywy przemysłu <i>Value-Based Health Care – an industry perspective</i>	Mitch Sugarman	20 min.
Wyroby medyczne – dokąd zmierzamy <i>Medical devices – where are we headed?</i>	Ewa Warmińska Krzysztof Łanda	30 min.
Finansowanie, refundacja, współpłacenie – jak rozwiązać ten węzeł gordyjski? / <i>Financing, reimbursement, co-payment – how can this Gordian Knot be disentangled?</i>	Katarzyna Sabiłło	20 min.
Wpływ potencjalnych zmian finansowania wyrobów medycznych stosowanych w ramach świadczeń gwarantowanych na jakość, dostępność i bezpieczeństwo / <i>The impact of potential changes in financing of medical devices applied as part of guaranteed benefits on quality, availability and safety</i>		20 min.
Panel dyskusyjny / <i>Discussion panel:</i> Krzysztof Łanda, Katarzyna Sabiłło, Mitch Sugarman, Wojciech Szeffe, Bartosz Świdrak, Ewa Warmińska	30 min.	

* w czasie sesji wliczono czas dyskusji: 10 min. / *discussion time included: 10 min.*

Price table

Price table (nett prices 23% VAT)	Private sector	Public institutions, NGOS, students and PhD students
registration till November 30th 2017		
1 day	570 €	60 €
2 days	645 €	85 €
registration from November 30th 2017 & during Symposium		
1 day	600 €	145 €
2 days	685 €	200 €

Conditions of participation

1. Variants of participation in the Symposium:
 - 1 day
 - 2 days
 - two fee free sessions on December 11th only
2. 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 2017” + invoice ID
7. Cancellation. If participation is cancelled no later than December 4th, 2017, the cost of cancellation will be 30% of the fee; after that day the fee will not be returned.
8. The organisers reserve the right to change the Symposium programme.

Join us at the 'Meet the Experts' gala dinner and board the „Alrina”

Theme of the meeting: **Ahoy, sailors!**

When: Monday, 11 December 2017, 8 pm

Where: Kurlandzki boulevard next to Father Bernatek Footbridge, Cracow

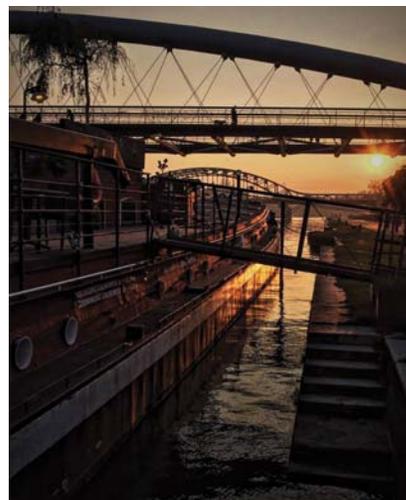


The heart of Cracow, on the Vistula River, where Father Bernatek's Footbridge connects two districts, Kazimierz and Podgórze, is where „Alrina” – a nineteenth century Dutch barge – is moored. It is the oldest, the largest and the only barge of this kind

in Poland. There are only three such vessels in the entire Europe. It is a real gem. Thanks to people who shared a passion for it, Alrina has been expertly renovated, and thus became special and one of a kind.

Alrina, built in 1889, is truly unique. It is 53 meters long and has a very interesting past. Only three barges that size were built in Europe, and the Dutch felt that „Alrina” is so unique that it should be presented on their postage stamps.

That is why when in 2003, after having been sold to a Polish company, and „Alrina” was leaving Rotterdam, a scandal broke out in the Netherlands and there was outrage that this precious historical specimen was being let out of the country. However, it was too late for controversies – the antique barge already had a new owner and set off for a nearly 10-month (as it later turned out, bumpy) inland cruise towards Poland. One of such bumps included a situation at the Polish-German border, where the previous captain of the barge refused to disembark.





„Alrina” has undergone several years of renovation and was adapted for new purposes. The barge’s traditional appearance was maintained – with the beautiful curves of its sides and raised bow which is a rarity among other inland vessels. A roof was built over two holds, which were transformed into two rooms: a conference room and a restaurant, which is where a unique, sandbank-inspired bar is located. The original space division, with an elevated poop deck and a central platform was maintained on the main deck. The only change included added roofing, thanks to which the deck can be enjoyed even during winter.

The highlight of the evening, as legendary as the „Arlina” (although not as old), will be **Mirek „Koval” Kowalewski** – a lovable Polish shantyman (who prefers the phrase „swamp and marsh song performer”, as he sings about inland, rather than marine sailing). Koval, along with the „Zejman & Garkumpel” band, are the authors of numerous sailing-themed songs and promoters of sailing among the young ones. Despite his notorious tendency to belittle his accomplishments and experiences, Mirek is also the author of columns in sailing magazines and an experienced sailor who, among others, sailed around **Cape Horn**.





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