

# Welcome to ISPOR 2019!

*Rapid. Disruptive. Innovative:  
A New Era in HEOR*



#ISPORAnnual



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# ISPOR New Professional Event: Career Advice Across the Globe

**“Good Practices for HTA: What is  
out there and how do I use it?”**

ISPOR 2019

Monday, May 20, 2019

5:00-6:00pm CST | Location: Room 292 (2nd Floor)

# Welcome from ISPOR President



**Federico Augustovski, MD, MSc, PhD**

Director of Health Economic Evaluations and  
Technology Assessment  
Institute for Clinical Effectiveness and Health Policy  
Buenos Aires, Argentina

## Objectives & Overview

- This session will provide an opportunity for New Professionals and graduating students to gain experience and learn good practices shared by HEOR experts. The topic discussed will be “Good Practices for HTA: What is out there and how do I use it?”
- The topic was selected through ISPOR Staff’s collaboration with the New Professional Steering Committee members.
- Upon completion of the presentations there will be time for Q&A and Networking.



## Questions this presentation will seek to address

- Review which HTA processes have good practices associated with them and which do not.
- What to do in the absence of good practices? When multiple good practices exist?
- Implications of upcoming policy changes related to HTA approaches in Europe and North America (e.g., centralized HTA in Europe) – what should New Professionals prepare for?

# Agenda

Time	Topic	Presenter
5:00 – 5:05pm	Welcome from the ISPOR President	Federico Augustovski
5:05 – 5:10pm	Objectives, Overview of agenda	Jason Cohen
5:10pm– 5:15pm	Speaker: Elisabeth Oehrlein, PhD	Elisabeth Oehrlein
5:15pm– 5:30pm	Speaker: Dan Ollendorf, PhD	Dan Ollendorf
5:30pm– 5:45pm	Speaker: Michael Drummond, PhD	Michael Drummond
5:45pm- 6:00pm	Q&A / Open Discussion / Networking	ALL

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# ISPOR New Professionals Overview

Presenter:

Elisabeth Oehrlein, PhD

Senior Director, Research and Programs,

National Health Council

Washington, DC, USA &

ISPOR New Professional Steering Committee Chair

## New Professional Overview



- The ISPOR New Professionals Network is composed of recent graduates from HEOR related programs. The membership is available to former ISPOR student members and any new members who join that possess 3 years or less of experience in the HEOR field.
- Members will be eligible to renew for two additional years after they join before becoming standard ISPOR members. Current ISPOR members, paying the \$150 Standard membership, are not eligible to downgrade their membership to New Professional.



# New Professional Steering Committee

## New Professional Steering Committee Chair:

- **Elisabeth Oehrlein, MS, PhD**, Senior Director, Research and Programs, National Health Council, Washington, DC, USA

## New Professional Steering Committee Members:

- **Blythe Adamson, MPH, PhD**, Senior Quantitative Scientist, Flatiron Health, New York, NY, USA
- **Sanket Shah, PhD, MD**, Manager, Stratevi, Boston, MA, USA
- **Ernest Law, RPh, PhD**, Senior Manager, Pfizer Inc., New York, NY, USA
- **Mark Bounthavong, MPH, PharmD**, Investigator, Veterans Affairs Health Economics Resource Center, Menlo Park, CA, USA

## ISPOR Staff:

- **Jason A. Cohen, MPP**, Manager, Member Services (Students & New Professionals), ISPOR, Lawrenceville, NJ, USA



Elisabeth



Blythe



Sanket



Ernest



Mark



Jason

## Member Benefits Overview

- Access to ISPOR *Value & Outcomes Spotlight*, the news journal of the Society;
- Access to the electronic version of *Value in Health*, the peer-reviewed journal of the Society;
- “Career Advice Across the Globe” events during ISPOR conferences;
- Access to online educational opportunities including: “My Career Path” webinars, “My ISPOR Story” webinars, scientific webinars, and thought leadership videos;
- Networking opportunities at ISPOR conferences to meet with professionals and peers;
- Access to the ISPOR Career Center;
- Eligible to participate in special interest groups / task forces;
- Free online access to [FormularyDecisions.com](http://FormularyDecisions.com);
- Eligible to apply for ISPOR Meeting Travel Grants;

# Tips To Get Involved

- Attend Professional Development Webinars and ISPOR Scientific Educational Webinars when promoted;
- Participate as a reviewer on a Special Interest Group;
- Submit an article to *Value in Health*, *Value in Health Regional Issues*, or *Value & Outcomes Spotlight*;
- Visit the ISPOR Booth during conferences to learn more about the ISPOR New Professional Network and benefits;
- Access Dymaxium's FormularyDecisions.com to utilize your free access as part of your membership;
- Email [newprofessionals@ispor.org](mailto:newprofessionals@ispor.org) with questions or suggestions on how we can improve the member experience!



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# ISPOR New Professional Event: Career Advice Across the Globe

## “Good Practices for HTA: What is out there and how do I use it?”

**Presenter:**

**Dan Ollendorf, Ph.D.**

Director, Value Measurement & Global Health Initiatives,  
Center for the Evaluation of Value and Risk in Health

Assistant Professor of Medicine

Tufts Medical Center

Boston, MA, USA

## Summary of Involvement with ISPOR

- Member of ISPOR since 1996
- Faculty, Regional HTA training curriculum
- Member, HTA Council Working Group on good practices in HTA
- Member, Medication compliance and persistence Special Interest Group

# Evolution of Health Technology Assessment in the US

- At federal level, a tortured and difficult history
  - The rise (and fall) of the OTA
  - AHRQ's PR and budget woes
  - PCORI's authorizing legislation
- Severe limitations on public payers' ability to use and apply HTA
- Commercial payer HTA
  - Nonexistent in small plans
  - Large national players conduct HTA to varying degrees
  - Increased citation of foreign HTA in coverage decisions

## Recent Developments in US HTA

- Shift in PCORI's funding priorities from patient engagement to full-on comparative effectiveness research
- Cost-effectiveness and budget impact increasingly part of conversation
- Development and refinement of value frameworks

# Value Frameworks in the USA

	ACA/AHA	ASCO	ICER	Sloan Kettering	NCCN
Clinical benefit	X	X	X	X	X
Toxicity/safety	X	X	X	X	X
Treatment novelty			X	X	
Condition rarity and condition burden			X	X	
Budget impact			X		
Cost-effectiveness	X		X		
Decision Context	Treatment guidelines and pathways	Clinical shared decision making	Coverage and reimbursement	Shared decision making and pricing	Treatment guidelines and shared decision making



# Value Frameworks in the USA

- “New wine in old bottles”
- Some (ASCO, NCCN) intended to inform patient decisions
- Few (e.g., ACC/AHA, ICER) explicitly mention cost-effectiveness and thresholds
- Others not listed (e.g., NPC, FasterCures) really a set of principles to judge value frameworks by

## Emergence of



- Institute for Clinical and Economic Review
- Founded in 2006, but visibility grew in 2015 with pivot to focus on emerging biopharmaceuticals
- Process and components of HTA (transparency, evidence review, CEA, BIA) aligned with international HTA community
- Discussion of evidence, economics, other considerations all done in public
- Work products freely available as public goods

# So What Has Changed?

- ICER's visibility and press coverage
  - Some high-profile examples of manufacturer, payer/PBM, and ICER collaboration on pricing
  - Increased citation of ICER by commercial payers
- Small movements by public payers
  - Price transparency laws with "teeth" to support NY and MD Medicaid
- Increased calls (by some) for public, independent HTA body in US receiving government appropriations

# What Does the Future Hold?

- Near term
  - Current administration: no formal HTA
  - Proposed pricing reform: in a way, indirect HTA
  - Continued tension between price, innovation, and affordability
    - Patients and families at major financial risk
- Longer term
  - Whether and how CMS adopts HTA/CEA for pricing dependent on whether payer structure drastically changes
  - More price visibility and payer restrictions on access should change industry behavior on pricing
    - But will it affect innovation pipeline? And should it?

# Advice for U.S. Manufacturers

- Treat US HTA like any other jurisdiction
- Centralize your HTA function
  - Don't depend on brand teams to re-invent the wheel each time
- Engage with ICER and major payers early and often
  - Be proactive in helping shape scope
  - Share data
  - Suggest experts/patients/other stakeholders
  - Participate in calls and public meetings
  - Conduct empiric exercises to inform your comments

# Advice for New Professionals

- US HTA has arrived, be prepared!
- Be aware of ICER's processes (and others who may join in the fold)
  - All are available on organization website
- Understand relevant methods development as applied to the US
  - 2<sup>nd</sup> Panel on Cost-Effectiveness in Health & Medicine
  - ICER reference case
  - New techniques for evidence synthesis
- Opportunities in industry, academia, and especially PBMs/payers

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“Good Practices for HTA: What is  
out there and how do I use it?”

**Presenter:**

**Michael Drummond, PhD**

Professor of Health Economics  
University of York,  
York, UK

# Summary of Involvement with ISPOR

- Member of ISPOR since 1996
- Board Member
- President, 2006-7
- Served on a number of Task Forces
- Co-Editor-in-Chief of Value in Health, from 2010 to present



# Landscape for HTA in Europe

- Long history of conducting and using HTA, dating back to the 1980s
- A wide variety of HTA organizations, conducting HTAs for a range of purposes
- Growth in the use of HTA in pricing and reimbursement of health technologies, from the late-1990s
- Pan-European collaboration in HTA, through EUNetHTA, since 2008
- Recent proposals by the European Commission for more regulation of HTA within the EU

# HTA for Pricing and Reimbursement in Europe

- Two broad approaches have developed
  - (a) Assessment of the clinical data to determine the level of innovation, of 'value added' associated with the technology; use in price negotiations  
eg France, Germany
  - (b) Estimation of the incremental cost-effectiveness ratio (ICER) of the new technology compared with current standard of care; comparison of the ICER with an implicit or explicit decision-making 'threshold'  
eg Netherlands, Sweden, United Kingdom

# Guidelines for HTA in Europe

- EUR-ASSESS Project (1997)
- HTA 'Core Model' (EUNetHTA) (2009)
- Various national methods guidelines, especially in the context of HTA for reimbursement decisions

## Issues for Discussion

- Implications of the recent proposals for more regulation of HTA within the EU
- Dealing with an absence, or many conflicting, guidelines for HTA
- Navigating the politics and perspectives of multiple stakeholders
- Keeping up to speed with evolving HTA practices
- Impact on pharmaceutical discovery and innovation due to HTA

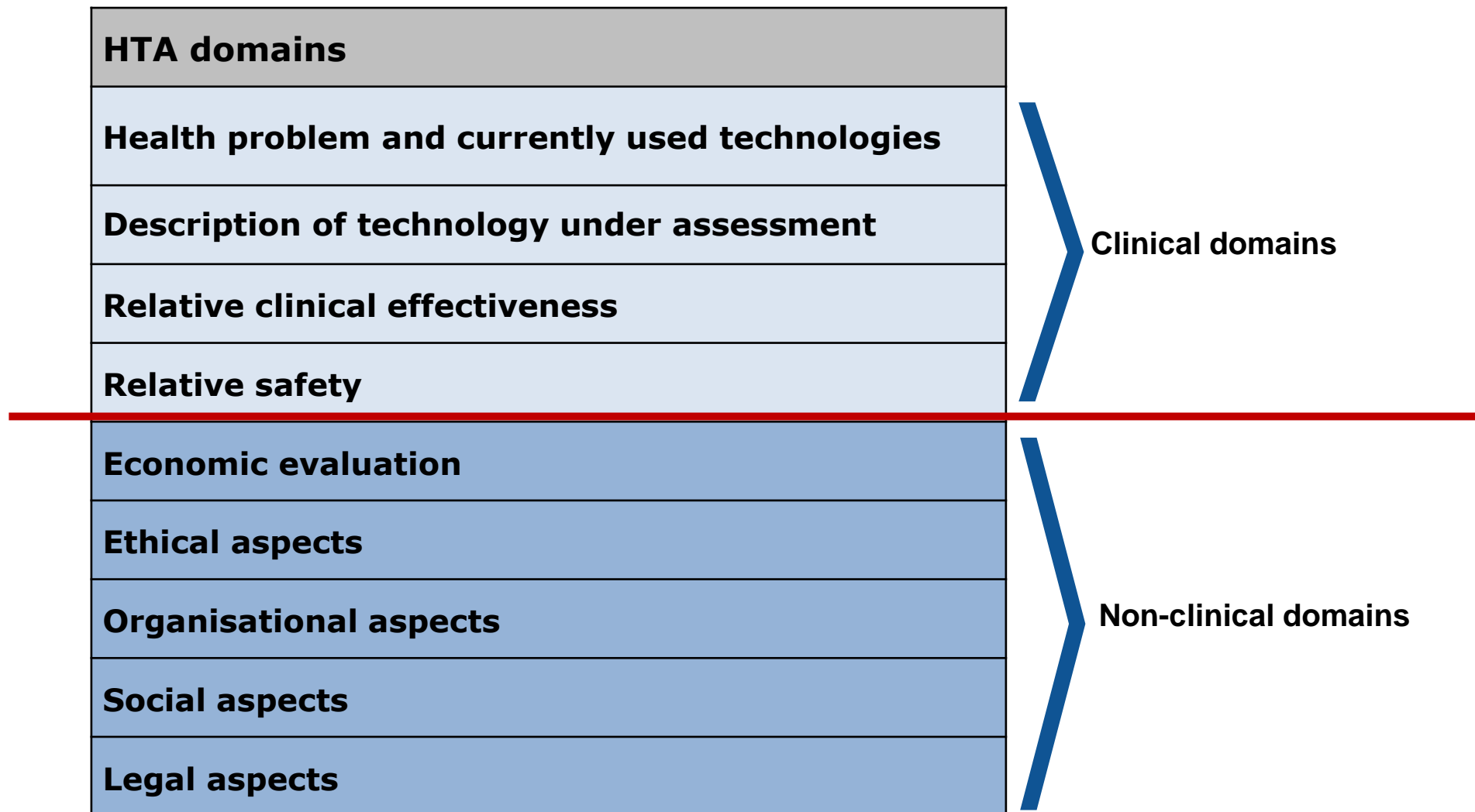
# Implications of the Recent Proposals for More Regulation of HTA within the EU

- What is being proposed ?
- What are the potential advantages?
- What are the objections?

## EC proposal on the Regulation of HTA (Amending Directive 2011/24/EU)

- Makes a distinction between 'clinical' and 'non-clinical' domains
- Argues for more collaboration in horizon scanning, early joint scientific advice and systematic reviews of the clinical literature, plus continued voluntary collaboration on other aspects of HTA
- Proposes that there will be a '**Joint Clinical Assessment**' of all pharmaceutical products, medical devices class IIb and III, and some in vitro diagnostics

# Clinical and Non-Clinical Domains of (HTA)



# Use of Joint Clinical Assessments

## Member States shall

- apply joint clinical assessment reports in their health technology assessments at Member State level
- not carry out a clinical assessment or an equivalent assessment process on a health technology included in the *List of Assessed Health Technologies* or for which a joint clinical assessment has been initiated

**Appraisal (i.e. conclusions on added value) remains at Member States level**



# European Commission Proposals: Arguments For and Against

- ***For***

- may avoid some duplication in the use of HTA resources  
(eg multiple systematic reviews of the clinical evidence)
- may help some of the smaller, or less well-resourced, member states get up to speed with HTA

- ***Against***

- even the clinical domains of HTA can be context-specific  
(eg differences in current standard of care)
- this approach takes away the rights of member states to assess health technologies as they see fit

## **Dealing with an Absence, or Many Conflicting, Guidelines for HTA**

- In general, HTA is less well-developed in Southern Europe
- No all guidelines are equal; some of the methods guidelines are quite old and do not reflect the current state of the art
- Give more attention to those guidelines of jurisdictions with more experience of conducting and using HTAs
- In many cases, a relevant ISPOR Task Force would be a good source of information on current methods

# Keeping up to speed with evolving HTA practices

- Make sure you are aware of all the recent HTA guidelines and ISPOR Task Force reports
- Make use of your time at ISPOR meetings to find out what is going on in various countries

# Navigating the Politics and Perspectives of Multiple Stakeholders

- Need to recognize that HTA comprises a mixture of 'assessment' (the scientific part) and 'appraisal' (the decision-making part)
- HTA can therefore be inherently 'political' so be mentally prepared for that; a well-conducted piece of analysis may not always be the most influential factor in the decision
- Often, individuals' career decisions reflect their desire for alignment with the stakeholders they feel most comfortable with; the great thing about HTA is that there are always lots of opinions!

# Impact on Pharmaceutical Discovery and Innovation due to HTA in Europe

- Over time we have seen a change in the mindset of industry R&D to search for 'added value'
- In many European countries the percentage of health care expenditure on pharmaceuticals has remained fairly constant, HTA is about how best to spend your resources, not about cutting expenditure
- It's still the case that the countries applying HTA more rigorously are not the biggest sources of pharmaceutical company income (eg the UK represents 3%)
- However, if added value is not adequately rewarded where it exists, there may be less funds available for further research

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## Q&A Period

Monday, May 20, 2019  
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