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# ISPOR CONNECTIONS

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## LETTER FROM THE EDITOR



Another year has come and gone and with it another year of progress for our Society. We recently convened at the 15th Annual European Congress in Berlin and over 3,500 people attended, besting last year's European Congress attendance by nearly 10 percent. ISPOR's other 2012 meetings also set attendance records, with more than 2,900 attending the 17th Annual International Meeting in Washington DC and over 900 attending the 5th Asia-Pacific Conference in Taipei.

This issue of *ISPOR CONNECTIONS* contains a great deal of material from the Berlin meeting, including a summary of the meeting program by our Managing Editor, Stephen Priori, a photo gallery of meeting attendees, and a listing of presentation award recipients. We also publish reports from ISPOR Travel Scholarship Award recipients, who were able to come to Berlin from various outposts in Albania, Bangladesh, Brazil, Ghana, India, Jordan, Pakistan, and The Philippines. In addition, the ISPOR European Congress program Co-Chair, Michael Schlander, contributes an interesting polemic for German health economists, exhorting them to stop complaining about not being listened to in the political process and instead retool their methods to be more in line with public needs.

Techniques of dynamic transmission modeling have been used in the fields of biology and epidemiology to better understand the spread of infection, occurrence of epidemics, and patterns of drug resistance, among other important phenomena. Health economists have begun using dynamic transmission models to ensure that analyses of cost-effectiveness appropriately capture the full costs and benefits of infection spread and control. Analyses of vaccines against communicable diseases, for example, need to capture the direct benefits of immunity provided to vaccine recipients as well as the indirect benefits afforded to non-recipients—the latter benefit from reduced overall infection risk, sometimes referred to as “herd immunity.” A fuller exploration of the use of these techniques in economic evaluation is contained in an article in this issue of *ISPOR CONNECTIONS*.

Also contained in this issue is a fascinating review of multi-criteria decision analysis (MCDA), which as the name implies, is a method for formally incorporating a variety of dimensions into the quantitative analysis of a decision problem. The authors highlight the potential for MCDA to facilitate medical decision making in two areas, marketing authorization (regulatory approval) and reimbursement, and include an interesting discussion of contrasting approaches to these issues in Europe versus the United States. As in other forms of health technology assessment, there appears to be a strong commitment to quantitative rigor in Europe, whereas in the United States less rigorous qualitative approaches appear to be all that can be agreed upon.

Turkey represents a fast-growing market and medical devices an increasingly important area for our field. Another article in this issue addresses both of these topics, providing an overview of the Turkish health care sector, the market for medical devices, registration processes, and reimbursement issues.

All of us at *ISPOR CONNECTIONS* offer you our best wishes for the holiday season and look forward to seeing you at the upcoming meetings in 2013.

See you there!

David Thompson, PhD

Editor-in-Chief, *ISPOR CONNECTIONS*



# Getting Connected: Systems Solutions for Generating Maximal Value from Health Care Resources

Deborah Marshall, PhD, MSHA, 2012-2013, ISPOR President and Canada Research Chair, Health Services and Systems Research; Associate Professor, Department of Community Health Sciences, Faculty of Medicine, University of Calgary; Director, Health Technology Assessment, Alberta Bone and Joint Health Institute, Calgary, AB, Canada

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The world is a connected place and we are, in great leaps, becoming a global population of connectivity junkies, feeling not fully dressed without a mobile device and isolated without a tweet, an email, a text message or a voice message.

Today, if you don't "get connected" you're likely to "not get anything at all."

As I said last November in my welcoming remarks at the ISPOR 15th Annual European Congress in Berlin, Germany, connectivity makes the whole greater than the sum of its parts. Berlin, where the congress was held, is itself proof of this notion. A city once divided, east and west, Berlin is now connected and, as the capital of Europe's strongest economy, has emerged greater than the sum of its former parts.

The name of this publication, *ISPOR CONNECTIONS*, ISPOR's news and technical journal, also says plenty. We know that connecting you with your 12,000 ISPOR colleagues through this news and technical journal helps to make our organization greater than the sum of its members.

In our health research community, connectivity goes much deeper than mobile devices, tweets and emails. Connectivity is at the core of systems thinking. And systems thinking is about understanding at the deepest level the linkages, relationships, interactions and cause-effect behaviours – in other words, the connections – among the different components that make up a system.

*Why is this important?* These connections can expose a seemingly sound decision in one area as disruptive or counterproductive to the system as a whole. In health care, for example, we know that closing operating rooms will reduce hospital costs. But are there unintended consequences? This question can be answered only by examining other components of the system. For example, service delivery: will waiting time for surgery be extended? Money: will patients consume more resources to manage their condition while waiting, and which resources, how many and what will they cost? Workforce: will the best surgeons leave for greater opportunity to practice elsewhere?

Systems thinking requires considering both the upstream points of leverage and the downstream

consequences. It requires anticipating and connecting the full range of effects – both intended and unintended – from a change in the system.

Think about how powerful this approach is for health care researchers and health service planners. It enables health care services to be planned more strategically so that maximal value, in the forms of better care and greater efficiency, can be derived from the resources used.

This is why I have made *research in health care applying systems thinking* one of the two core themes of my tenure as ISPOR President. In the last issue of *ISPOR CONNECTIONS* (September/October 2012), I wrote about the other theme, *knowledge translation*, which involves engaging decision makers and patients to mobilize knowledge.

In this issue, I will address systems thinking in health research – an approach whose time has truly come. Systems thinking is critical because governments around the world are struggling with the dual juggernauts of a crushing debt burden and the rising need for health care. Systems thinking in research offers a solution for managing increasingly expensive and scarce health care resources so that we can do more with and get more from them. A necessary part of this is mobilizing knowledge – promoting rapid translation of research findings so that the best technologies move without delay from the bench to the bed, driving economic growth along the way.

The ultimate objective of systems thinking and knowledge translation is to get the right health services to the right people, in the right order, in the right place to achieve the right outcome combining quality, cost control and innovation.

I think governments would be interested.

Admittedly, change is never simple or easy, and what I am proposing is nothing less than a paradigm shift. But it's also a paradigm shift that ISPOR is ideally positioned to lead. The breadth, depth and reach of our membership give ISPOR the means to bridge systems thinking across continents and embed it in research practice. They give us the opportunity to shine at a time in history when the economic clouds are dark.

Systems thinking is relatively new in health >

care but its power has been understood for centuries. English philosopher and author Sir Thomas More described it this way in *Utopia, Book 1*: “. . . by applying a remedy to one sore, you will provoke another; and that which removes the one ill symptom produces others, while the strengthening one part of the body weakens the rest.” That was 500 years ago.

The manufacturing and engineering industries caught on decades ago, using systems thinking to optimize processes and improve access, effectiveness and efficiency. Systems thinking is also behind the restaurant industry's transformation making it possible for large chains to combine quality control, cost control and innovation while increasing productivity. In his recent *New Yorker* article entitled 'Big Med' [1], Atul Gawande, a surgeon at Brigham and Women's Hospital and professor at the Harvard School of Public Health, writes: “In medicine, too, we are trying to deliver a range of services to millions of people at a reasonable cost and with a consistent level of quality . . . (but) we haven't figured out how. Our costs are soaring, the service is typically mediocre, and the quality is unreliable. Every clinician has his or her own way of doing things, and the rates of failure and complication (not to mention the costs) for a given service routinely vary by a factor of two or three, even within the same hospital.”

Mayo Clinic's recently created Center for the Science of Health Care Delivery focuses on systems engineering as a means of transforming the way health care is delivered and experienced. Mayo Clinic has a team who work on quality improvement using systems modeling. It has applied engineering principles and systems thinking to several initiatives to redesign its practices, particularly in the domains of cardiac surgery and outpatient practice. Mayo Clinic's interest in this approach comes none too soon, according to Dr. Jeanne Huddleston, Director of the Center's Health Care Systems Engineering Program. She says health care delivery in the United States operates the way industry did in the 1970s [2]. “Projects were late, everything came in over budget, nothing was done efficiently, lots of errors and lots of safety problems. So I believe that we can translate those principles that were used to improve manufacturing and make us competitive again in the '70s and '80s, apply those to health care.”

*How do we get there?* We can again look to industry and engineering and the proven operations research methods they employ with great success. One of these methods is system dynamics modeling (SDM), which offers tremendous potential for extracting maximal value from health care resources.

SDM is a mathematics-based method of analyzing complex systems with many connecting and interacting components and using computer applications

to actually simulate the effects of a change in one component on the entire system. It focuses on the internal structure of a system – its underlying flows, accumulations, feedback loops, and cause-effect relationships.

SDM can be used to realistically mimic a real-world health system, demonstrating the dynamic interactions among its components, its behaviour, and the outcomes in response to a single event or multiple events. It can be used to develop system tools that allow health service planners to test various scenarios or effects of a proposed policy without actually having to first implement the policy. SDM is a proactive rather than reactive decision-making tool and can be used to overcome indecision or break down resistance to policy changes in the public sector.


Widely used in industrial operations to optimize manufacturing processes, SDM is relatively new to health care and not commonly used to understand and manage the dynamic complexities of health care systems. Tools like SDM demonstrate vividly the feasibility of using systems thinking to improve resource efficiency and population health outcomes whether managing a single event, such as a virus outbreak, or a large health system.

*So what now?* The world situation demands that we move beyond cost-effectiveness and budget impact analyses – and quickly. It demands connectivity across all the components when planning health services, and it demands using systems thinking to rapidly move the best, most innovative technologies into practice.

Writing in *Science*, Madon et al. [3] made the case that systems-oriented approaches are critical in bridging the gap between innovations in health and their delivery in the developing world. “. . . we need to train a generation of researchers who can effectively bridge the implementation gap. This will require new curricula and interdisciplinary, systems-oriented approaches.”

Now, we need to step forward and mobilize this knowledge and the tools in practice.

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***The deadline for submitting nominations is Friday, January 4, 2013.***

# Understanding and Use of Dynamic Models in Health Economic Analyses

Sonya J. Snedecor, PhD, Director, Health Economics, Pharmerit International, Bethesda, MD, USA



### INTRODUCTION

Models are a quantitative abstraction of reality used in cost-effectiveness analyses to help guide health care decision making and allocation of health care resources. Those commonly used in cost-effectiveness analyses are known as “static” models, which do not allow for interactions among individuals in the population of interest. These interactions may affect estimates of disease transmission and incidence over time, leading to changes in the prevalence of disease within the span of the model horizon.

For diseases such as arthritis, osteoporosis, and various cancers, static model methodology is appropriate because the population’s disease risk is constant and does not increase or decrease with medical intervention of treated individuals. Infectious diseases and their control, however, are associated with externalities, where one person’s actions impose (or mitigate) risks on others. *Dynamic models* have the capacity to incorporate these externalities as well as other demographic and biologic characteristics that may change with time or as a result of an intervention.

### WHAT ARE DYNAMIC MODELS?

Dynamic models employ equations representing populations and their interactions. These equations replicate or “model” a system of interest such as infectious disease transmission. Like static models, the equations represent

an interpretation of the reality of epidemiologic and biologic mechanisms of transmission, progression, and treatment. In the case of an infectious disease, *dynamic transmission models* capture disease transmission among individuals. This transmission is quantified by the *force of infection* – the risk of infection for a susceptible individual – which depends on the number of infected people in the population, the likelihood of contact among those infected, and the individual’s susceptibility of contracting the disease.

### WHEN TO USE DYNAMIC MODELS?

Use of dynamic models in health economics is particularly important when externalities exist. That is, in order to accurately assess the value of an intervention, the benefits to the treated individual as well as to others must be considered. This scenario can arise in the case of an infectious disease whereby vaccination or treatment of one individual can lower the risk of disease transmission to other unvaccinated or untreated members of the population.

Dynamic models can also be used to explore vaccine policies. For example, given a certain efficacy level, transmission models can answer the question: What is the minimum proportion of the population needed to be vaccinated to achieve a desired reduction in disease incidence? Or the converse question: What proportion of people needs to forgo vaccination to cause an epidemic outbreak in disease? Furthermore, dynamic models may also be used for other scenarios >

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such as interventions for smoking cessation where the annual rate of cessation is influenced by changing prevalence rates, demographic trends, and smoking interventions [1]. Other “communicable” public health factors may be modeled dynamically in cases where interventions, geared toward key members of a household or population, produce beneficial externalities to others (e.g., smoking cessation, nutrition counseling, etc.)

### Box. Review of health economic models

#### STATIC MODELS

- Typically follow an individual or single cohort over time
- Model natural history of infection and disease
- Do not include transmission
- May underestimate benefits of vaccination
- Allow estimation of cohort-specific variables (e.g., incidence)
- Potentially less complex

#### DYNAMIC MODELS

- Follow multiple cohorts over time
- Model natural history of infection and disease
- Describe transmission of the virus and resulting disease in a population
- Capture direct and indirect “herd immunity” effects of vaccination
- Allow estimation of population-level variables over time (e.g., incidence)
- Potentially more realistic
- May introduce additional uncertainty

### DYNAMIC MODEL COMPONENTS

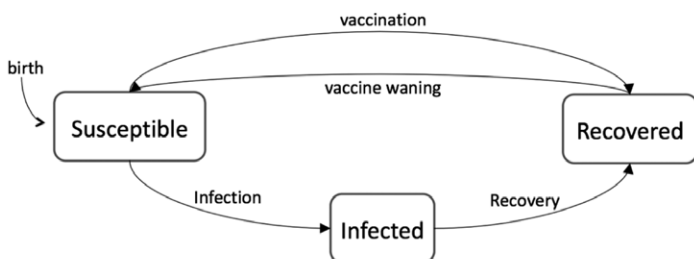
Dynamic models represent the population of interest as a collection of mutually exclusive and exhaustive groups, referred to as “compartments.” These compartments indicate different characteristics of the population such as age, disease risk level, infection state, or a combination of characteristics. Individuals “flow” from one compartment to another at pre-determined rates. Each compartment is represented by an equation parameterized by the populations of any contributing compartments and the “flow” between them.

Figure 1 demonstrates a simple SIR (susceptible – infected – recovered) model with three compartments representing the possible health states and arrows representing the transitions among them. Differential equations are constructed to describe the dynamic relationships among populations. These relationships are predetermined (i.e., modeled) and allow evaluation of continuously changing quantities over a specified period of time. The numerical solution to the system of equations is simply the population of each compartment at every point during the simulation period.

Each of the arrows represents an input to or an output from its respective compartment. These directional arrows correspond to a positive input to or a negative output from the compartment. For example, birth is an input into the **Susceptible** population. Similarly, the infection rate represents an input into the **Infected** population, but an output from the **Susceptible** population.

**Figure 1. SIR model**

Uninfected individuals are born into the **Susceptible** compartment. Vaccination transitions individuals from **Susceptible** to **Recovered**, and vaccine waning (or changes in infectious agent) causes those in the **Recovered** compartment to become **Susceptible**.



For infectious diseases, the infection rate is dependent on the number of infected individuals in the population – if the population of **Infected** is small, the risk of infection is also small. Therefore, the infection rate represents the probability of an infectious contact between **Infected** and **Susceptible** individuals. The rate of recovery is often dependent on some level of treatment that could vary over time. In the case of vaccination, a proportion of **Susceptibles** are vaccinated which is represented as a direct “flow” to the **Recovered** (i.e., immune) population. The effectiveness of the vaccine could be modeled to wane over time representing temporal immunity and/or changes in the infectious agent such that it evades vaccine protection.

### REQUISITE DATA FOR DYNAMIC MODELING

Static and dynamic models both quantify factors influencing individuals’ disease status (age, disease incidence, recovery, etc.). Dynamic models also capture population-level factors including probability of interactions among individuals and probabilities of disease transfer. This component of the models is the most data-intensive.

Understanding intra-population interactions among individuals and how the disease process is affected by these interactions is difficult to ascertain. Functionally, these data are incorporated into a dynamic model via the contact matrix, or the *WAI/W* (*Who Acquires Infection From Whom*) matrix. Often, empirical data necessary to populate a contact matrix are not available and model calibration methods to existing epidemiologic data are necessary.

### USE OF DYNAMIC MODELS IN COST-EFFECTIVENESS ANALYSIS


To use dynamic models in cost-effectiveness analyses, the costs and quality-adjusted life years (QALYs) over time can be estimated using the calculated proportions of patients within each of the health states over the model horizon. That is, the total cost at any time represents the disease costs for each health state multiplied by the proportion of the population in that health state. The total QALYs at any time are calculated similarly. To compute overall costs and QALYs for a fixed period of time, one must discount and integrate (find the area under the curve) these curves. The area under the curves represents the total costs and QALYs, which can then be used to determine the incremental cost-effectiveness ratio (ICER) of a vaccine program.

Static models estimate the benefits to the vaccinated individual, but not the external benefits to others in the population. Dynamic models are best to fully assess indirect benefits of a vaccine. For this reason, the estimated ICER with a dynamic model will always be lower than with a static model since the dynamic model captures more benefit (i.e., more disease reduction and QALYs gained) for the same amount of intervention costs. It is possible, however, to “adjust” the ICER of a static model to incorporate indirect benefits. To approximate the ICER of a dynamic vaccination model within a static framework, one can multiply the cost of disease averted and the QALYs gained calculated from the static model by  $1 + \frac{1}{R_0 - 1}$ , where  $R_0$

is the basic reproduction number, the expected number of disease cases one infectious individual will cause within a fully susceptible population over the course of his/her infectious period. This approximation is closer to that of the dynamic model but overestimation of the ICER remains.

Therefore, static ICERs – even when adjusted – will fundamentally underestimate the population benefits of the vaccine and are mathematically independent of vaccine coverage. That is, the economic benefit to the population of interest is constant, regardless of the level of vaccine coverage. Conversely, the ICER of a dynamic model retains dependence on coverage. In this case, when vaccine coverage is low, disease transmission among those unvaccinated is largely unchanged and the ICER will approximate that of the static model. However, when vaccine coverage is higher, unvaccinated individuals will incur some level of indirect protection and reduced disease incidence, leading to a lower ICER. >

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## DISCUSSION

If dynamic models are more accurate in predicting ICERs of vaccines or other interventions with externalities, then why are they not more common? For one, there is no standard software to produce and compute these models, and numerical integration routines are often manually programmed with programming languages or software with which few are familiar. Additionally, dynamic modeling is a relatively more complex analysis, where adoption may be slower due to unfamiliarity of the mathematical techniques, uncertainty in how to interpret the models' results, and possibly resistance to modeling with less than complete data (e.g., contact matrix). These models could be considered by some to be a "black box" where familiar epidemiologic variables enter to be inexplicably transformed into curves and ICERs using methods not easily understood.

Unfamiliarity of dynamic modeling methods is understandable, as it is not a technique routinely learned in the field of pharmacoeconomics. Clear and informative communication by modelers to unfamiliar users of the results of dynamic models is important to facilitate understanding. Regardless of the complexity of any analysis, it is important that modelers take care to create effective model communications appropriate for the end user and decision maker as understanding the models and their results ultimately leads to familiarity and acceptance.

Neither is there a standard reference or journal dedicated to dynamic modeling. For more information regarding dynamic modeling techniques and guidance, we guide readers to some useful references [2-8]. Additionally, the ISPOR and SMDM professional societies offer guidance in the form of a joint task force working group on dynamic transmission modeling with publications and meeting workshops [9].

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# Does the Future Belong to MCDA?

Kevin Marsh, MA, DrPH, BA, UBC, Hammersmith, UK; J. Jaime Caro, MD, UBC, Lexington, MA; and Noemi Muszbek, MSc, BSc, UBC, London, UK



## INTRODUCTION

A key challenge for health care decision makers is balancing the multiplicity of medical, social, and economic factors that have a bearing on their choices. These factors, and the importance attached to them, often vary from one decision to another and between the stakeholders. Ensuring accountability requires that the process for determining these factors and their relative importance is transparent. Multi-criteria Decision Analysis (MCDA) is one approach to this end that has recently received much attention.

MCDA covers a range of methods that structure decision problems such that the relevant evaluation criteria and their relative importance are explicit. In doing so MCDA can better inform decisions. Since the first attempts in the 1960s [1], MCDA has been applied in many settings, including transport, environmental protection, construction, defence and finance [2]. To date, however, formal application in health care has been limited [3, 4].

This article provides a brief introduction to MCDA, outlines current proposals for its use in health care, and spotlights related challenges and opportunities for industry.

## WHAT IS MCDA AND WHY DOES IT INTEREST DECISION MAKERS?

The term 'MCDA' is used to refer to a range of different methods, and it is important to be clear about which definition of MCDA is being adopted. One definition of MCDA is a method used to structure group decision making [5]. This approach is concerned with eliciting and making transparent the judgements made in the decision making process. An alternative, broader definition of MCDA is the set of methods that seek to score, weight and ultimately aggregate the various criteria into an overall composite measure of benefit [6]. The second definition is inclusive of the first, but also includes a range of alternative approaches to weighting criteria, such as stated preference techniques. In the remainder of this paper, the latter definition of MCDA is adopted.

MCDA can inform a range of health care decisions – such as manufacturers' judgements to invest in compounds, regulatory approvals, reimbursement decisions, health authority resource allocation decisions, and clinicians' prescription decisions. MCDA can support these decisions in a number of ways, including [6,7]:

1. Improving the transparency, predictability and consistency of decisions.
2. Facilitating the incorporation of patients' values in decision making.
3. Supporting the communication of the benefits, risks, and costs of treatments.
4. Informing the design of data collection.
5. Understand differences in viewpoints between stakeholders.
6. Sharpening signals to industry about what matters to decision makers.

The following four steps are common to all MCDA methods: identifying options, defining and weighting relevant criteria, and scoring each option on each criterion. Each of the steps in MCDA presents methodological challenges: Which options should be considered? How should the criteria be selected? How should weights be assigned and who should be responsible for this? How should options be scored on the criteria? How should uncertainty be assessed? These questions have been addressed in many different ways by the various MCDA methods [2], but two key differences are often used to distinguish methods. First, whether the result of the MCDA is a quantitative overall score, or whether the MCDA stops

short of such a score and a structured deliberation of the data is undertaken instead. Second, if a quantitative score is produced, what method is used to estimate the weights required to combine criteria to generate this score.

The next two sections consider how MCDA is being considered for two areas of health care decision making – authorisation and reimbursement.

## MCDA AND MARKETING AUTHORISATION

High profile withdrawals of drugs over the past decade have led to a renewed focus on drug safety [7]. These concerns about safety are only heightened by a drug assessment process that “does not include an explicit, consistent, transparent, and aggregate quantification of the risks and benefits and lacks clarity pertaining to the role of specific factors in the recommendations” [7]. As a consequence both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are considering new ways to weigh the benefits and risks of drugs, including, notably, MCDA.

In 2006, the Institute for Medicine Report on Drug Safety recommended that the Centre for Drug Evaluation and Research (CDER) at the FDA develop a systematic approach to benefit-risk assessment (BRA) [8]. As a consequence, enhancing BRA in regulatory decision-making is now one of the Prescription Drug User Free Act's (PDUFA) Reauthorisation Performance Goals (<http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf>). The precise nature of the BRA method that will be adopted is not yet known; but this is expected to be announced in early 2013. Early communications suggest that the FDA's preferred approach will be more qualitative than quantitative [9]. Data is collected to populate a grid designed to standardise the way that benefits and risks are described, but no weighting of these data are undertaken to generate an overall benefit-risk score.

The EMA has provided more detail on how it proposes to undertake BRA. The Committee for Medicinal Products for Human Use (CHMP) was set up to provide recommendations on ways to improve the methodology, transparency, consistency and communication of BRA. It advised that a structured, but mainly qualitative, approach be used [10]. It also recommended further research to develop BRA methods. Accordingly, the EMA initiated five work packages to develop tools and processes for balancing multiple benefits and risks to support informed, science-based regulatory decision making about medicinal products [11]. Work Packages 1 to 3 reviewed BRA practice within the EU regulatory network; assessed the applicability of relevant frameworks and quantitative approaches; and field-tested preferred methods [11]. The conclusions were that decision analysis provides a sound theoretical basis; that the so-called ProACT-URL (Problem formulation, Objectives, Alternatives, Consequences, Trade-Offs, Uncertainties, Risk Attitude and Linked Decisions) framework should be employed; and that a quantitative model could be developed to support decisions [11].

Work Package 4 re-emphasised the importance of the ProACT-URL framework and identified the EMA's preference for effect tables that draw on reviews of relevant studies in order to score interventions, and quantitative MCDA for more contentious cases where the benefit-risk balance is marginal [11]. Work package five will pilot these tools and processes, and provide for relevant training.

The EMA has gone a long way to specify how MCDA can be used to support BRA. In essence, it believes MCDA should be employed where decisions are contentious, that it should be based on a quantitative assessment of drugs against multiple >

criteria, and that this assessment should form the basis for scoring and weighting by workshop participants. Even so, the agency's recommendations leave several questions unanswered. For example, who sets the criteria? How should users ensure criteria meet MCDA requirements, such as preference independence – the idea that an option's score on one criterion can be determined independently of its score on other criteria? What methods are appropriate for populating effect tables? Exactly how should weights be elicited? Furthermore, EMA's recommendations differ from some practice currently employed by industry. For instance, while EMA seem to prefer expert-based weights generated through workshops, there are examples of industry eliciting patients' weights via surveys [12]. Furthermore, a range of alternative quantitative approaches have been identified by the ISPOR Risk-Benefit Management Working Group [7].

Partly motivated by the need to answer these questions, a number of initiatives have been launched to further develop BRA methods. These often involve collaboration between industry, regulator, and academia. Examples of such initiatives include the Innovative Medicines Initiative's (IMI) Pharmacoeconomic Research on Outcomes of Therapeutics in a European Consortium (PROTECT) programme [13], the work of the Benefit Risk Action Team (BRAT) [14], and the CASS work [15]. These initiatives hold out the promise of greater standardisation in the use of MCDA to inform BRA, which will allow the industry to better plan their investments and the corresponding evidence generation.

### MCDA AND HEALTH TECHNOLOGY ASSESSMENT (HTA)

As with BRA, HTA faces the challenge of weighing the various costs, risks, and benefits of a drug. To date, the formal evidence generation undertaken to inform HTA has focused on only a portion of the risks and benefits that stakeholders consider relevant for this setting. In the UK, for instance, NICE's reference case requests a cost-effectiveness analysis that quantifies the health benefits of a drug as far as these can be captured by the quality-adjusted life year (QALY). Stakeholders, however, are often interested in other, very different, sources of value [16]. As a consequence, it has been argued that MCDA should be adopted to ensure HTA takes an appropriate account of all relevant factors in reaching judgements [17].

The EVIDEM Collaboration (<https://www.evidem.org/>) was launched to respond to this increasing demand for MCDA in HTA. Having reviewed decision-making processes in 20 jurisdictions, EVIDEM identified 15 criteria relevant to HTA and was designed to fulfil MCDA requirements [18]. These criteria were used as the basis for an MCDA framework to inform HTA. The framework specifies that each criterion needs to be weighed by experts using a five-point scale. The scores for each alternative are then quantified using best practice synthesis methods. Once the criteria have been quantified, experts use this data to score the criteria on a four-point scale. These quantitative criteria are supplemented with qualitative contextual criteria intended to focus decision-makers' attention on "colloquial" forms of evidence.

The authors of the EVIDEM framework highlight drawbacks within the framework, including a weighting and scoring system with potentially low discriminatory power, and the violation of the requirement for non-redundancy by the inclusion of cost-effectiveness as a criterion even though its components are themselves included as separate criteria [18]. Despite such limitations, pilots of the framework have concluded that it can support deliberations as part of the appraisal of technologies [19].

The EVIDEM framework adopts the structured decision making definition of MCDA. Whether this is the appropriate form of MCDA for HTA, or whether, for instance, patient or public values should be used to weight criteria, is currently the subject of a consultation by NICE [6]. The debate about MCDA and HTA in the UK tends to be framed around the question of how to broaden the benefits considered in HTA beyond the health gains captured in the QALY. Others, such as the Institute for Quality and Efficiency in Health Care (IQWiG) in Germany and the Patient-Centred Outcomes Research Institute (PCORI) in the U.S., have rejected the QALY. The challenge of weighing the benefits and risks of technologies

still remains, and similar methodological questions inform the debate in these countries. For instance, IQWiG has explored conjoint analysis and the analytic hierarchy process as methods to prioritize and weigh patient-centred outcomes [20]. IQWiG has not committed to either of these methods. Rather the Federal Joint Committee may request that manufacturers employ one of these methods where health economic analysis is submitted.

In recognition of the call for HTA with a broader perspective, a number of recent initiatives and studies have explored the possibility of incorporating several criteria into decision making, and will influence the nature of any MCDA incorporated into HTA. Emblematic of these is the value-based pricing (VBP) initiative in the UK [21], which plans to formally assess drugs based on their innovative nature, broader social value, and the severity of the illness being considered, as well as their cost-effectiveness. Similar concerns in Sweden led the National Pharmaceutical Strategy to emphasize that health investments should be judged against criteria relating to environmental sustainability, world class medical outcomes, equitable care and innovativeness. The UK's VBP initiative would have important implications for MCDA methods. Following NICE's preference for weighting endpoints based on general public preferences [22], the UK Department of Health has commissioned various academic institutions to undertake population surveys to generate cost-effectiveness weights for different severities of disease.

### CONCLUSION

There is increasing support for using MCDA to support health care decisions to ensure these are more structured, consistent and transparent. It is not clear; however, which MCDA methods will become standard in the BRA and HTA processes. In this regard, the existing literature provides some indications as to the MCDA methods that may eventually be requested by decision makers, but much more detail is required before we can be sure what these methods will be. Further research and consultation is required in this area.

Ultimately, different approaches to MCDA will probably be adopted to support BRA and HTA. This assumption reflects the fact that the aims, and thus the criteria relevant to these processes differ, with HTA being concerned, for example, with a broader set of values, including equity and innovation. Also, while the EMA's current framework suggests that BRA might lead to appraisal-specific weights, it seems likely that weights generated for HTA will be applied across appraisals and even across therapy areas.

The uncertainty surrounding the precise role of MCDA in BRA and HTA presents both a challenge and an opportunity to industry. Without clarity on the methods and processes, it is difficult to plan for the emergence of MCDA. Industry cannot know, for example, what data to collect; when these might be needed; how to process them; what weighting and scoring methods might need to be followed; and what pitfalls to avoid. These unknowns, however, also provide opportunities for industry to influence which MCDA methods are adopted and to research the implications of alternative methods. MCDA even holds out the ground-breaking possibility of moving away from the QALY, or at least using more transparent and appropriate weighting of its components, as well as other factors to formulate a new, better composite measure.

Since similar debates about MCDA methods are ongoing for both BRA and HTA, there are opportunities to identify and take advantage of synergies between the evidence required for both these decision points. In particular, alignments between these processes to produce efficiencies in the evidence-generation process are increasingly desirable as it becomes clearer that market authorisation can no longer exist in isolation from reimbursement decisions, and cooperation between regulators and HTA bodies is already on the rise [23]. One example of this – a pilot program in Sweden between the national medicines agency (MPA) and the reimbursement body (TLV) – was judged as a step in the right direction; however, it was insufficiently co-ordinated such that processes happened more in parallel than with close integration [24]. The interest in MCDA provides an opportunity to progress this agenda further, improving the transparency, rigour and consistency of BRA and HTA, but also to bring these processes closer together.

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# Medical Device Policies & Market Access in Turkey

*Güvenç Koçkaya, MD, MSc, Health Economics and Policy Association, Ankara, Turkey; Pelin Kılıç, PharmD Turkish Medicines and Medical Device Agency, Ankara, Turkey; Ismail Güler, Social Security Institution, Ankara, Turkey; and Adem Ünal, PhD, Directorate of Health Researches, Ankara Turkey*



The Health Transformation Program was started by the Ministry of Health in the year 2003. The program changed all health sector directions, laws and rules. Since that all stakeholders, decision makers, health care providers and third party bodies changed in recent years. For example, there was not any family physician system in Turkey. Now family physicians are serving health care in all cities and towns for free to all population. There were different health insurance institutions like SSK (for private sector employers), Bag-Kur (for private sector owners), Emekli Sandığı (for government employers), not a national based health insurance institution like now as Social Security Institution (SGK) that covers all population [1]. The aim of the article is to understand Turkish medical device sector policies and market access in the light of new directions which were published with the Health Transformation Program by the Ministry of Health in recent years.

## TURKEY'S GENERAL HEALTHCARE SECTOR

Turkey is a Euroasian country with a population of 74 million inhabitants – 71% living in urban areas – and a founding member of the Organisation for Economic Co-Operation and Development (OECD) and G-20 major economies. The gross domestic product (GDP) of Turkey was calculated as \$35 billion (US) by the World Bank in 2010. The health revolution has been in process since 2002. Public health expenditure percentage within the GDP, however, rose from 4.9% to 6.1% from 2000 to 2008 ([www.tuik.gov.tr](http://www.tuik.gov.tr)). Turkey is last in the list of health expenditures per person among the OECD countries, with \$624 (US) in 2008. Additionally, 73% of the total health expenditure has been covered by the government. It was reported that 58% of the total health expenditure of the Social Security Institute (SGK) was for hospital care in 2011.

## TURKEY'S MEDICAL DEVICE SECTOR

Medical devices are a promising component of health care. When we look at Turkey, we see that it holds its place among the top 30 markets of the world, with its medical device numbers being at constant and gradual growth, the 2010 figures for Turkey's medical equipment and disposables/reusables market suggest a capacity exceeding \$2 billion (US). Moreover, this capacity is expected to reach \$3 billion (US) by 2015 [2]. With this foreseen dramatic increase, the Turkish Medicines and Medical Devices Agency (TITCK) has developed legislative documents in line with the European Union (EU) for the management of medical device

regulations. In other words, the Turkish laws for medical devices comply with that of the EU.

## REGISTRATION OF MEDICAL DEVICES

Turkey's medical device regulations are a perfect match with the directions of the European Union. Established in 2011 as a transition from the former Directorate-General of Pharmaceuticals and Pharmacy, TITCK is responsible for all regulatory processes dealing with human medicinal products, cosmetics and medical devices. In addition, TITCK is responsible for approvals, investigations and applications of notified bodies in Turkey. While there was, however, a medical device management office under different directorates, this is the first time a medical device sector of Turkey has been named an institution. The institution will be recruiting up to 100 device inspectors in the next year for its base office as currently, there are only about 20 device inspectors in the base office today. In addition, more inspectors will be recruited to add to the 43 device inspectors in the field. This shows that the Ministry of Health (MoH) supports the good regulation of medical devices as well as pharmaceuticals. Turkish pharmaceutical regulations are very elaborate, and rules are well set [3].

TITCK is responsible from medical devices products, to registration to the "Turkish National Information Database for Medicines and Medical Devices (TITUBB)," to monitor the availability in the market, to provide appropriate patient access, to monitor all phases of the value chain from production, to follow importing and distribution to the market. Pricing is not one of the responsibilities of TITCK. There are free pricing schemes for medical devices.

In this regard, medical device manufacturers and importers based in Turkey have the freedom to circulate their products inside the country. They are obliged, however, to notify TITCK in order to be able to attain the designation: "registered from the health authority." This happens in such a manner that manufacturing and importing companies based in Turkey are required to register their medical devices, retailers and/or technical service providers into TITUBB. In addition, manufacturing and importing companies and their franchises should be registered to TITUBB as medical device companies. Otherwise, the companies cannot participate in the government auctions.

The Turkish Medicines and Medical Devices Agency (TITCK) is the regulatory and processing body of

the registration of a medical device to TITUBB. All medical devices need to be approved by TITCK. Once registration is fulfilled, medical device companies can launch the device and deliver it to the market with the price that is settled by themselves.

## REIMBURSEMENT OF MEDICAL DEVICES

The Social Security Institution (SGK) is responsible for establishing reimbursement schemes for all medical devices with a settled reimbursement price. All medical devices need to make an application to SGK for reimbursement.

Newly published directions and guidelines will be put into practice in 2013. These directions and guidelines are similar to those of the reimbursement of pharmaceuticals. There will be two scientific commissions in the assessment of the reimbursement dossiers. The first is the Clinical and Economic Evaluation Commission (CEEC). The CEEC assesses all applications prior to declaring its decision. The other scientific commission is the Reimbursement Commission (RC). The RC finalizes the decisions declared by the MEEC. The MEEC and RC consist of the Ministry of Health, the SGK, and the Ministry of Finance. Since the constitution of the commission, the decision is from the population point of view, not only from the payer's point of view. Positive lists for the reimbursement of the medical devices exists in the area of expertise, such as cardiovascular, orthopedic and general surgery, etc. Should the commissions accept to list the device in the positive list, the Health Service Pricing Commission under the SGK determines a reimbursement price.

The reimbursement price is dependent on the state hospital tender price. The SGK considers the lowest prices (5 for private hospitals, 3 for foundation university hospitals, and there is no price ceiling or floor for governmental hospitals) of the state hospital tender price from the last year. The class of the medical device in question is also considered for the reimbursement price. If there is a similar product already on the market, the reimbursement margin of that particular product is set for the product in question. In addition, the SGK can claim to pay back to hospitals for each package. If a similar product does not exist, in accordance with the new regulations, the company should present the cost-effectiveness and the budget impact reports for negotiating the reimbursement margin. The SGK will then include the product with its determined margin in the positive list for reimbursement. Once devices

are included in the list, hospitals can buy and use those devices on their patients. While hospitals are using the devices in the positive lists, they can get extra payment over the reimbursement coverage of the disease related package payment system.

The SGK has divided medical device applications into three groups:

- A) Medical devices lacking the devices field definition within the List of Medical Devices Prices of Which are Under Reimbursement, in which the medical device is to be included, and therefore demanded to be included within the list by means of a new device field definition – innovative devices -;
- B) Medical devices to be included in the medical device field definition within the Lists of Medical Device Prices of Which are Under Reimbursement by the Institution - me-too devices -;
- C) Barcode renewal applications regarding the medical devices included within the Lists of Medical Devices Prices of Which are Under Reimbursement by the Institution.

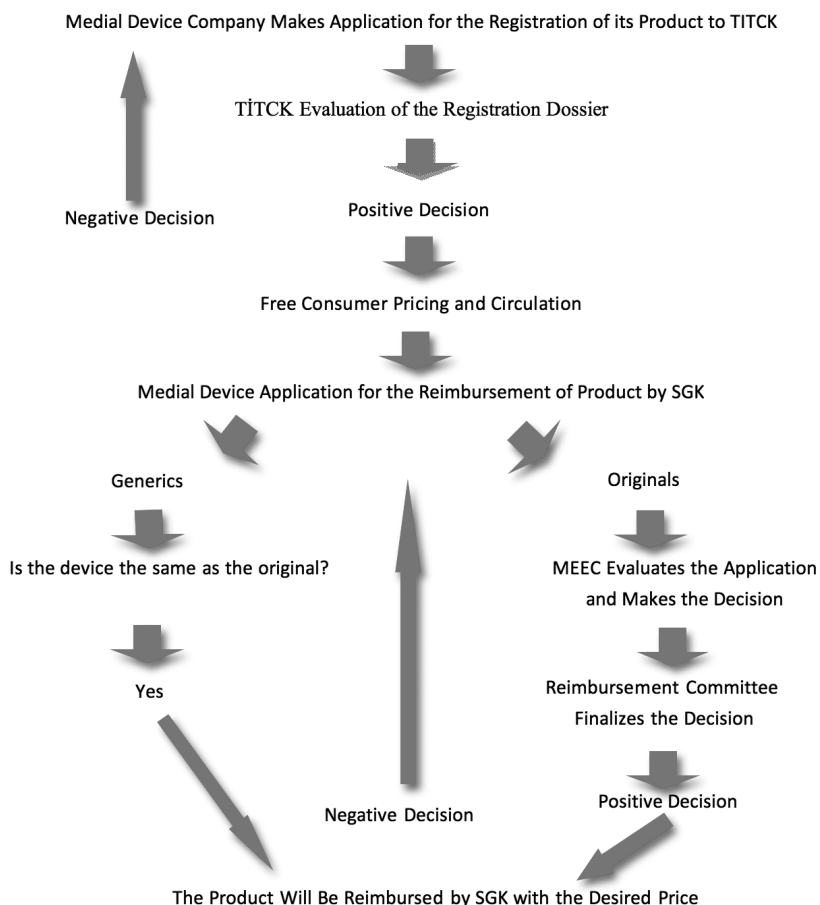
The SGK accepts reimbursement applications up to 4 times a year for A class, 6 times for B class and 12 times for C class medical devices. Economic evaluation dossiers have been deemed mandatory for the application process for innovative devices. Innovative or original devices must justify cost-minimization, cost-effectiveness, cost-utility and budget impact analysis. They need to choose one of the cost-minimization, cost-effectiveness and cost-utility depending on the technology, disease areas, etc. In addition, budget impact analysis must be in the reimbursement dossier. If necessary, generics need to present only budget impact analysis and have to have the same effectiveness and safety profile as original devices.

Cheaper products such as gloves, gauze bandages, medical cotton, etc., are not covered by the reimbursement scheme of the SGK. Their fees are paid in the disease related package payment system to hospitals. The rest of the medical devices are reimbursed as an add on to the disease related package payment system. There are positive lists of medical devices depending on the disease area.

### SOME ADDITIONAL HURDLES FOR MARKET ACCESS OF MEDICAL DEVICES

There is another hurdle for market access of medical devices: If the medical device is reimbursed within the package payment, hospitals will buy cheaper medical devices. If the medical device is paid by the SGK outside of the package payment, the hospital buys the most optimal medical devices depending on the responsibility of the attending physician recruited in that hospital. For hospital sales, hospitals bid on contracts and companies sell the products at a lower price set by the SGK. The hospital may add 15% of institutional profit onto the buying price, and then bill the goods thereafter.

**Figure 1. Overview of Licensed Product Market Access in Turkey**



The unity of state hospital unions was established at the end of 2011. The new hospitals unions will be responsible from all activities of hospitals in the regions like human resource, services, auctions, etc. Even if it is not currently active, it will be running in 2013. At that time there will be 88 unions in Turkey, 5 in Istanbul, 3 in Ankara and 2 in Izmir. The rest of the 78 provinces will belong to one union. In addition, university hospitals in those provinces which have a population of under 850k will be governed by unions in each of the provinces. In light of this information, it could be said that the unity of state hospital unions is going to have more power on the tender price of medical devices and pharmaceuticals due to the collectivity. Price decreases and margin loss can be expected for medical devices within 2013.

On the other hand, MoH is aiming to initiate the DRG system for the reimbursement of health care in 2013. The SGK already makes use of the package payment system, which is similar to DRG but not exactly the same. It is an unknown point for the health care sector how and when to implement DRG. Disease related package payment costs are not updated for a while. If DRG costs are calculated with updated cost of hospitals, there may be an increase in the hospitals' reimbursement payments for health care service.

### SUMMARY

Reimbursement is the fundamental driver of the

Turkish medical devices sector. An overlook of the market access of medical devices in Turkey is mentioned in Figure 1. It was published that the biggest impact on the physicians' behavior for buying a device is reimbursement [4]. If a device is listed in the positive lists, physicians and hospitals may want to buy and use it. Otherwise, if a medical device is found unnecessary or is considered expensive when compared with the package procedure payment, physicians and hospital managements will not want to buy or use such devices.

### USEFULL LINKS

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## Why Do Health Economists Complain that Health Politicians Don't Listen to Them? A Perspective from Germany

*Michael Schlander, PhD, MD, MBA, ISPOR 15th Annual European Congress Co-Chair and Professor of Health Economics and Health Care & Innovation Management, Universities of Heidelberg and Ludwigshafen, Germany, and Chairman and Scientific Director, Institute for Innovation and Valuation in Health Care (InnoVal<sup>HC</sup>), Wiesbaden, Germany*



A long-standing complaint among health economists is that politicians do not listen to them – or at least, many scholars believe so [1]. After all, aren't health systems across the globe plagued by budget constraints? Isn't there an increasing recognition of the need to strive for more efficiency in service delivery? If members of the discipline are seen as experts in the allocation of scarce resources, these should be golden times for health economists.

Quite obviously, this has not yet been the case in Germany, the host country for this year's ISPOR Annual European Congress. A few hours before the official opening of the meeting in Berlin, news broke that the German coalition government had decided to abandon the so called "Praxisgebühr," a patient cost sharing schedule stipulating a co-pay of 10€ for the first visit to a doctor's office each quarter. Other co-payments (per inpatient day, for prescription drugs, etc.) shall remain unchanged, like the caps in place for maximum annual patient co-pays on social grounds. The main argument put forward by the federal minister for health affairs was the lack of a measurable impact of the fee on the overall number of visits, which remain relatively high in Germany. The German Society for Health Economics (DGGÖ) issued critical comments and proposed a uniform fee of 5€ for each visit as an alternative that would have been easier to administer and probably more effective – but the professional organization failed to accomplish more than some media coverage. One cannot help but wonder whether the findings of the RAND Health Insurance Experiment [2] (or any of the numerous smaller studies on the effects of cost-sharing policies) were taken into account by politicians. After all, we are talking here about major findings from one of the most important prospective randomized studies ever conducted in economics, and even in the broader social sciences.

Apparently, there are forces at work that do not neatly fit into the conventional framework of economic theory. The realities of political decision-making establish powerful constraints on the use of rationality as conceptualized by economists. Any democratic government depends on the support by a majority of voters (and in about 12 months' time there will be federal elections in Germany), hence it will often be tempted to act as a maximizer of votes [3]. No less powerful than the voters themselves are certain key interest groups, such as the medical professionals, who have repeatedly used their influence on patients to exert pressure on political parties. Likewise, lobbying efforts of the pharmaceutical industry and of payers – in particular, the statutory health insurance, which covers 85% of the German population, have all been paying dividends in the political process. (As an aside, most patient advocacy groups have been comparably weak in German politics.) The impact of cohesive, well-informed interest groups may then produce outcomes more in their particular group interest than in the public interest [4]. Rent-seeking behaviors, the frequent inability of democratic governments to make long-term commitments, coalition forming and bargaining among political players are among the reasons cited for suboptimal outcomes [5].

In light of this, it is all the more remarkable that it took a health minister from the traditionally market-friendly liberal party in Germany to launch a pharmaceutical market reform ("AMNOG") that introduced the near-equivalent of a fourth hurdle for new products while in effect simultaneously sidelining any role for systematic economic evaluation in the health sector. At the same time, the over-regulation of the German pharmaceutical market has not been reduced. Analysts believe


that more than half of the approximately 30 individual regulation instruments could be removed without any negative effects. Not surprisingly, in this situation – which may well be described as a form of "polypharmacy" [6] – some of these instruments provide inconsistent or even outright contradictory incentives – not to mention the bureaucratic burden they collectively place on health care providers.

Against this background, it is unfortunate that the most visible professional associations of health economists in our nation allowed themselves to be maneuvered into an unsustainable position. Their political stance was characterized by fierce opposition against IQWiG's early attempts to develop alternative evaluation methodologies, a perceived lack of appropriate distance from industry groups by some of their key proponents, and an almost dogmatic insistence on the use of quality-adjusted life years as a presumably universal and comprehensive measure of health-related benefits. Public statements were issued that largely ignored the increasing international recognition that the QALY maximization hypothesis is "descriptively flawed" [7], thus in effect abolishing any empirical foundation for universal cost per QALY benchmarks, with far-reaching policy implications [8]. As a consequence, normative health economics has remained isolated and without political impact in Germany.

The profound neglect of health economic expertise during enactment of the recent pharmaceutical market reform ("AMNOG") speaks for itself in this regard. To improve on this truly unsatisfactory situation, scholars will need to do more than complain about politicians who do not listen to them. There is an undeniable need to pay more attention to the social preferences of the public, i.e., what people really expect from their health systems.

*(Michael Schlander has been a co-founder of the German Society for Health Economics (Deutsche Gesellschaft für Gesundheitsökonomie, DGGÖ, in October, 2008), and was a member of the federal expert council on health affairs of the German liberal party (FDP), until mid-2010.)*

### REFERENCES

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# ISPOR 15th Annual European Congress–Allo' Deutschland!

Stephen L. Priori, Director, ISPOR Publications and Communications

The ISPOR 15th Annual European Congress was held on 3-10 November 2012 at the ICC Berlin, Berlin, Germany. This was ISPOR's first visit back to Germany since the ISPOR 7th Annual European Congress in 2004 in Hamburg. The 15th Congress offered another record-breaking ISPOR attendance of over 3,500 attending this year's Congress, more than any other European Congress or International Meeting!

For this year's Congress, Wolfgang Greiner, PhD, MSc, Professor & Director, Department of Health Economics and Health Management, University of Bielefeld, Bielefeld, Germany, and Michael Schlander, MD, PhD, MBA, Professor, Health Care and Innovation Management, University of Heidelberg and Chairman & Scientific Director, Institute for Innovation & Valuation in Health Care (InnoVal), Wiesbaden, Germany, served as Congress Program Co-Chairs and, along with the Program Committee, provided Congress attendees with another high-level program. This year's theme was, "Challenging Times for Health Care Decisions in Europe: Changing Models of HTA, Price Referencing and Integrating Social Preferences."

## MONDAY 5 NOVEMBER

After pre-Congress Short Courses on Saturday and now full-day on Sunday, the Congress opened its sessions with a welcome and Presidential address from 2012-2013 ISPOR President Deborah Marshall, PhD, MHSA, 2012-2013 ISPOR President and Associate Professor, University of Calgary and University of McMaster, Director, HTA, Alberta Bone and Joint Health Institute & Canada Research Chair, Health Services and Systems Research Centers, Calgary, AB, Canada. The session also included an opening speech by Andrzej Rys, MD, Director of Public Health, Directorate-General-Health and Consumer Protection, European Commission, Brussels, Belgium. Congress Co-Chair Wolfgang Greiner, PhD, MSc moderated the first **Plenary Session** entitled, "Converging or Diverging Models of HTA in Europe." In this session, the role of HTA, as well as future trends and methodological requirements was discussed by key leaders of health authorities and HTA agencies in Germany, France and the UK. Speakers included Jürgen Windeler, MD, Director, Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany, Carole Longson, PhD, Director, Centre for Health Technology Evaluation and Executive Director, National Institute of Health & Clinical Excellence (NICE), London, UK, and Jean-Luc Harousseau, President and Chairman of the Board, Haute Autorité de Santé (HAS), Saint-Denis La Plaine, France.

**Issue Panels Session I, Contributed Podium Sessions I & II, Workshops Session I & II and Forum Session I** were also held on Monday, as well as **Poster Sessions I & II** and the **Exhibitors Open House Reception**.

## TUESDAY 7 NOVEMBER

The second **Plenary Session**, moderated by Andrew Jack, Reporter, Financial Times, London, UK, entitled, "International Price Referencing – Is There A "Right" Way To Perform It?," offered attendees an overview of current practices within European markets, reasons for international price differentiation, common policy patterns in this field and current trends in the methods to compare prices on an international level from three speakers: Kees de Joncheere, PharmD, MBA, MSc, Director, Department of Essential Medicines and Health Products, World Health Organization (WHO), Geneva, Switzerland, Thomas B. Cueni, Secretary General, Interpharma, Basel, Switzerland, and Ulrich Kaiser, PhD, MSc, Professor, Department of Business Administration – Entrepreneurship, University of Zürich, Zürich, Switzerland.

Congress attendees had an opportunity to attend **Poster Sessions III & IV, the Exhibitors' Wine and Cheese Reception, Contributed Podium Session III**, as



*ISPOR President Deborah Marshall, PhD, MHSA presenting Wolfgang Greiner, PhD, MSc (l) and Michael Schlander, MD, PhD, MBA, with a distinguished service awards as ISPOR 15th European Congress Program Co-Chairs.*

well as **Issue Panels Session II, Workshop Session III, and Forum Session II**. Later in the evening, the ISPOR Social Event, "An Evening at Wasserwerk," gave attendees a chance to enjoy the unique atmosphere of this venue, a historic converted waterworks, while enjoying a taste of Berlin, DJ and dancing!

## WEDNESDAY 7 NOVEMBER

The third day included **Workshop Sessions IV, V, & VI**, and **Poster Session V**. The Third **Plenary Session** titled, "Fairness First? Social Versus Individual Preferences," featured speakers Erik Nord, PhD, Senior Researcher, Norwegian Institute of Public Health, Oslo, Norway, Jeff Richardson, PhD, Professor, Department of Business and Economics and Foundation Director of the Centre for Health Economics, Monash University, Melbourne, Australia, and Christian Affolter, PhD, MBA, Head of Foundations, santésuisse, Solothurn, Switzerland. The session discussed the nature of social preferences, how can they be measured appropriately, and if social preferences can be incorporated in formal health technology assessments and allocation of scarce health care resources. The session was moderated by Congress Co-Chair Michael Schlander, MD, PhD, MBA.

ISPOR will gather again on May 18-22, 2013 in New Orleans, Louisiana, USA for the ISPOR 18th Annual International Meeting. We hope to see you there and thanks for attending the ISPOR meetings this year!

### Program Committee Co-Chairs

Wolfgang Greiner, PhD, MSc, Professor & Director, Department of Health Economics and Health Management, University of Bielefeld, Bielefeld, Germany  
Michael Schlander, MD, PhD, MBA, Professor, Health Care and Innovation Management, University of Heidelberg and Chairman & Scientific Director, Institute for Innovation & Valuation in Health Care (InnoVal), Wiesbaden, Germany

### Research Review Committee Co-Chairs

Dominik Golicki, MD, PhD, MA, Research Leader, HealthQuest sp z o.o., Warsaw, Poland  
Luciana Scalone, PhD, PharmD, ScD, Researcher, Research Centre on Public Health, University of Milan-Bicocca, Monza, Italy

Mondher Toumi, MD, MSc, PhD, Professor & Chair, Market Access, and Professor, UFR d'Odontologie, University Claude Bernard Lyon 1, Lyon, France

### Workshop Review Committee Co-Chairs

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Koen Torfs, MSc, Vice President, Health Economics & Market Access, Janssen, Neuss, Germany

### Issue Panel Review Committee Co-Chairs

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Carolyn Miltenburger, PhD, Senior Director, Global Health Economics & Reimbursement, Medtronic, Tolochenaz, Switzerland

### Decision-maker Case Study Review Committee Chair

Alric Ruether, MD, PhD, Head, Department of Health Care Quality, International Affairs, Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany 

# PHOTOGRAPHIC HIGHLIGHTS FROM THE



*The ISPOR 15th Annual European Congress venue:  
The ICC Berlin*



*Third Plenary Session, "Fairness First? Social Versus Individual Preferences," panel  
(l-r): Christian Affolter, PhD, MBA, Jeff Richardson, PhD, and Erik Nord, PhD*



*First Plenary Session speaker  
Jürgen Windeler, MD*



*ISPOR 15th European Congress Welcome*



*ISPOR 15th Annual European Congress Exhibitors*



*ISPOR Methods Of Financing And Decision Making In Health Care In Central & Eastern Europe In Times Of Limited Funds: Revolution Or Evolution? Forum  
(l-r): Guenka Petrova, MPharm, MEcon, PhD, DSc, John Yfantopoulos, PhD, Assena Stoimenova, PhD, and Josip Culig, PhD*



*Second Plenary speaker Kees de  
Joncheere, PharmD, MBA, MSc*



# ISPOR 15TH ANNUAL EUROPEAN CONGRESS



*ISPOR 15th Annual European Congress Program Co-Chairs Wolfgang Greiner, PhD, MSc (l) and Michael Schlander, MD, PhD, MBA*



*Second Plenary Session panel (l-r): Ulrich Kaiser, PhD, MSc, Thomas B. Cueni, MSc, Kees de Joncheere, PharmD, MBA, MSc, and moderator Andrew Jack*



*ISPOR 15th Annual European Congress Poster Sessions*



*Networking at the ISPOR Lounge at the ISPOR 15th European Congress*



*ISPOR Health Evidence for Decision Making: Assessment Tool for Prospective and Retrospective Observational Studies Forum Speaker Bradley Martin, PhD, RPh, PharmD*



*ISPOR Implementation of HTA to Support Pricing and Reimbursement Decisions in Emerging Market Countries: More Academic, More Pragmatic or “Nicer” Approach? Forum speaker Vlad Zah, PhD*



*Early Modelling In Medical Product Development and Market Access workshop discussion leader Maarten J. IJzerman, PhD*



*Introduction to Modeling Short Course*

# ISPOR 15th Annual European Congress Scientific Awards Recipients

Stephen Prior, Director, ISPOR Publications and Communications

The ISPOR Best Research Podium and Poster Presentation Awards were established in 1998 to recognize the scientific merit of podium and poster presentations of the ISPOR Annual International Meetings, Annual European Congresses, and Asia-Pacific Conferences. At this year's European Congress, the ISPOR Awards Committee evaluated 60 podium presentations and over 1,400 poster presentations.

Evaluations of scientific merit were based upon the following criteria:

- Background provides appropriate perspective/context for the subject
- Objectives/research questions are clearly stated
- Research design/methods/modeling is appropriate and transparent (scores on this will determine winners in case of ties)
- Data sources and/or sampling procedures are clear and appropriate
- Data analyses are appropriate
- Research objectives are met/addressed
- Implications of findings are discussed
- Factual information is kept separate from interpretations or implications
- Abstract is presented in an unbiased manner
- Clarity of presentation

The recipients are:

## BEST PODIUM RESEARCH PRESENTATION AWARDS

### UT4: HEALTH UTILITY SCORES IN CHILDREN AND ADOLESCENTS WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER: RESPONSE TO STIMULANT TREATMENT

Setyawan J<sup>1</sup>, Banaschewski T<sup>2</sup>, **Hodgkins P**<sup>3</sup>, Lecendreux M<sup>4</sup>, Johnson M<sup>5</sup>, Zuddas A<sup>6</sup>, Bloomfield R<sup>7</sup>, Coghill DR<sup>8</sup>, <sup>1</sup>Shire Development LLC, Wayne, PA, USA, <sup>2</sup>University of Heidelberg, Mannheim, Germany, <sup>3</sup>Shire Pharmaceuticals LLC, Wayne, PA, USA, <sup>4</sup>CHU Hospital Robert-Debré, Paris, France, <sup>5</sup>Queen Silvia Children's Hospital, Gothenburg, Sweden, <sup>6</sup>University of Cagliari, Cagliari, Italy, <sup>7</sup>Shire Pharmaceutical Development Ltd., Basingstoke, United Kingdom, <sup>8</sup>Newells Hospital, Dundee, United Kingdom

### NI2: THE USE OF OFF-LABEL COMPARATORS IN NICE APPRAISALS – AN INDIRECT ENDORSEMENT?

**Kusel J**, Wong GK, Costello Medical Consulting Ltd., Cambridge, UK

### CV3: OUTCOMES AND COSTS OF CONCOMITANT AORTIC VALVE REPLACEMENTS ASSOCIATED WITH A NEW SUTURELESS AND COLLAPSED VALVE IN ITALY, FRANCE, GERMANY, AND THE UNITED KINGDOM

**Pradelli L**<sup>1</sup>, Zaniolo O<sup>1</sup>, Giardina S<sup>2</sup>, Ranucci M<sup>3</sup>  
<sup>1</sup>AdRes HE&OR, Turin, Italy, <sup>2</sup>Sorin Group, Saluggia, Italy, <sup>3</sup>IRCSS Policlinico San Donato, San Donato Milanese, Italy

## BEST NEW INVESTIGATOR RESEARCH PRESENTATION PODIUM AWARDS

### CV2: IS IT WORTH SPENDING ANY MONEY TO DEVELOP A BIOMARKER TEST TO OPTIMIZE STATIN TREATMENT FOR INDIVIDUALS WITH AN INTERMEDIATE CARDIOVASCULAR RISK?

**Burgers LT**<sup>1</sup>, Nauta ST<sup>2</sup>, Deckers JW<sup>2</sup>, Severens JL<sup>1</sup>, Redekop WK<sup>1</sup>, <sup>1</sup>Erasmus University Rotterdam, Rotterdam, The Netherlands, <sup>2</sup>Erasmus Medical Center, Rotterdam, The Netherlands

### NI3: PATIENT ACCESS SCHEMES IN THE NEW NHS

**Spoors J**, Brown C, Johnson N, Rietveld A, R.J.W. & Partners, Royston, Hertfordshire, UK

### UT3: ESTIMATING PREFERENCE-BASED INDEX FROM CANCER-SPECIFIC QUALITY OF LIFE MEASURES FOR USE IN COST-UTILITY-ANALYSIS

**Teckle P**, Peacock/Stuart S

Canadian Centre for Applied Research in Cancer Control, BC Cancer Agency, Vancouver, BC, Canada

## BEST STUDENT RESEARCH PRESENTATION PODIUM AWARDS

### QL4: THE IMPACT OF DISEASE INFORMATION ON GENERAL PUBLIC PREFERENCES FOR HEALTH STATES: COMPARING LABELING, DISEASE-SPECIFIC, AND ADAPTATION INFORMATION

**Butt T**, Morris S, Orr S, Rubin G, University College London, London, UK

### NI4: ANALYSIS OF STAKEHOLDERS INVOLVED IN HTA DECISION MAKING PROCESS IN THE UNITED KINGDOM

**Kalbasko A**<sup>1</sup>, Andreykiv M<sup>2</sup>, Van Engen A<sup>3</sup>, Zorzi O<sup>2</sup>, <sup>1</sup>Erasmus University Rotterdam, Rotterdam, The Netherlands, <sup>2</sup>Quintiles, Hoofddorp, The Netherlands, <sup>3</sup>Quintiles Global Consulting, Hoofddorp, Noord-Holland, The Netherlands

### MO2: IMPACT OF STRUCTURAL ASSUMPTIONS ON COST-EFFECTIVENESS OUTCOMES: TOWARDS A STANDARDIZED COST-EFFECTIVENESS MODEL FOR ADJUVANT BREAST CANCER THERAPIES

**Frederix GW**<sup>1</sup>, van Hasselt JG<sup>2</sup>, Schellens JH<sup>3</sup>, Hövels AM<sup>4</sup>, Huitema AD<sup>2</sup>, Raaijmakers JA<sup>5</sup>, Severens JL<sup>6</sup>, <sup>1</sup>Netherlands Cancer Institute, Amsterdam, The Netherlands, <sup>2</sup>Slotervaart Hospital & Netherlands Cancer Institute, Amsterdam, The Netherlands, <sup>3</sup>Netherlands Cancer Institute & Utrecht University, Amsterdam, The Netherlands, <sup>4</sup>Utrecht University, Utrecht, The Netherlands, <sup>5</sup>Utrecht University & GlaxoSmithKline, Utrecht, The Netherlands, <sup>6</sup>Erasmus University Rotterdam, Rotterdam, The Netherlands

## BEST RESEARCH PRESENTATION POSTER AWARDS

### PMD76: THE EFFECT OF INSULIN PUMP THERAPY ON HEALTH STATUS AMONG THOSE WITH TYPE 1 DIABETES

**Pignot M**<sup>1</sup>, Eichmann F<sup>2</sup>, DiBonaventura MD<sup>3</sup>, <sup>1</sup>Kantar Health, München, Bavaria, Germany, <sup>2</sup>Kantar Health GmbH, München, Germany, <sup>3</sup>Kantar Health, New York, NY, USA

### PMH2: INTERIM RESULTS FROM THE "AUTOR" STUDY, A EUROPEAN OBSERVATIONAL STUDY IN PEDIATRIC PATIENTS WITH ATTENTION DEFICIT/HYPERACTIVITY DISORDER: PATIENT CHARACTERISTICS AND 1-YEAR COSTS

**Haynes V**<sup>1</sup>, Quail D<sup>2</sup>, Lorenzo M<sup>2</sup>, Deix C<sup>3</sup>, Anand H<sup>2</sup>, <sup>1</sup>Eli Lilly and Company, Indianapolis, IN, USA, <sup>2</sup>Eli Lilly and Company, Surrey, UK, <sup>3</sup>Eli Lilly and Company, Vienna, Austria

### PSU7: SEASONAL PERIODICITY OF SECONDARY HIP REPLACEMENT AFTER FEMORAL NECK FRACTURES WITH REDUCTION INTERNAL SCREW FIXATION AGED OVER 60

**Sebestyén A**<sup>1</sup>, Gajdáczi J<sup>2</sup>, Patzai B<sup>3</sup>, Molics B<sup>4</sup>, Varga S<sup>4</sup>, Sándor J<sup>5</sup>, Boncz I<sup>4</sup>, <sup>1</sup>National Health Insurance Fund Administration, South-Transdanubian Regional Office, Pécs, Hungary, <sup>2</sup>National Health Insurance Fund Administration, Budapest, Hungary, <sup>3</sup>Department of Traumatology and Hand Surgery, University of Pécs, Pécs, Hungary, <sup>4</sup>Institute for Health Insurance, University of Pécs, Pécs, Hungary, <sup>5</sup>Department of Preventive Medicine, University of Debrecen, Hungary

## BEST STUDENT RESEARCH PRESENTATION POSTER AWARDS

### PCN47: COST-OF-ILLNESS OF COMMON CANCER TYPES - RESULTS OF A HEALTH INSURANCE CLAIMS DATA ANALYSIS

**Damm O**, Leppert F, Greiner W, School of Public Health, Bielefeld University, Bielefeld, Germany

### PCN4: DECISION-ANALYTIC MODEL FOR THE FIRST-LINE THERAPY OF CHRONIC MYELOID LEUKEMIA

**Rochau U**<sup>1</sup>, Sroczynski G<sup>2</sup>, Wolf D<sup>3</sup>, Schmidt S<sup>4</sup>, Conrads-Frank A<sup>2</sup>, Jahn B<sup>2</sup>, Saverno KR<sup>5</sup>, Brixner D<sup>6</sup>, Gastl G<sup>7</sup>, Radich J<sup>8</sup>, Siebert U<sup>9</sup>, <sup>1</sup>UMIT; Oncotyrol - Center for Personalized Cancer Medicine, Hall i.T.; Innsbruck, Tyrol, Austria, <sup>2</sup>UMIT - University for Health Sciences, Medical Informatics and Technology; Oncotyrol - Center for Personalized Cancer Medicine, Hall i.T.; Innsbruck, Tyrol, Austria, <sup>3</sup>University of Bonn, Medical University Innsbruck, Bonn/Innsbruck, Austria, <sup>4</sup>Internal Medicine V, Hematology and Oncology, Medical University, Innsbruck, Austria, <sup>5</sup>UMIT- Univ. for Health Sciences, Medical Informatics and Technology, Hall i.T., Austria; Univ. of Utah, Salt Lake City, USA, Hall i.T.; Innsbruck, Tyrol, Austria, <sup>6</sup>University of Utah, College of Pharmacy, Salt Lake City, UT, USA, <sup>7</sup>Medical University Innsbruck, Innsbruck, Austria, <sup>8</sup>Fred Hutchinson Cancer Center, Seattle, WA, USA, <sup>9</sup>UMIT/ Oncotyrol/ Harvard University, Hall i.T.; Innsbruck, Tyrol, Austria

### PCN30: TREATMENT PATTERNS AND OUTCOMES OF BREAST CANCER PATIENTS IN A PATIENT-CENTERED RETROSPECTIVE RESEARCH REGISTRY

**Saokaew S**<sup>1</sup>, Cai B<sup>1</sup>, Kuo KL<sup>2</sup>, Bauer H<sup>2</sup>, Albright F<sup>2</sup>, Brixner D<sup>2</sup>, Stenehjem D<sup>1</sup>, <sup>1</sup>University of Utah, Salt Lake City, UT, USA, <sup>2</sup>University of Utah, College of Pharmacy, Salt Lake City, UT, USA

## BEST NEW INVESTIGATOR RESEARCH PRESENTATION POSTER AWARDS

### PIN79: HEPATITIS C VIRUS INFECTION INCREASES THE RISK OF ALZHEIMER'S DISEASES

**Chiu WC**<sup>1</sup>, Chen PC<sup>2</sup>, <sup>1</sup>Cathay General Hospital, Taipei, Taiwan, <sup>2</sup>College of Public Health, National Taiwan University, Taipei, Taiwan

### PIN84: TRENDS IN PREVALENCE OF ANTIBACTERIAL DRUG USE AMONG DUTCH CHILDREN FROM 2005 UNTIL 2010


**Joosten SGL**<sup>1</sup>, Houweling LMA<sup>2</sup>, Penning FJA<sup>2</sup>, <sup>1</sup>Utrecht University, Utrecht, The Netherlands, <sup>2</sup>PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands

### PCN90: COST EFFECTIVENESS ANALYSIS OF BENDAMUSTINE AS FIRST LINE TREATMENT FOR CHRONIC LYMPHOCYTIC LEUKAEMIA IN THE NETHERLANDS

**Vandekerckhove S**<sup>1</sup>, Holtzer-Goor K<sup>2</sup>, Van Den Steen D<sup>1</sup>, van Megen Y<sup>3</sup>, Huijgens P<sup>4</sup>, Lamotte M<sup>1</sup>, Uyl- de Groot C<sup>5</sup>, <sup>1</sup>IMS Health, Vilvoorde, Belgium, <sup>2</sup>iMTA, Rotterdam, Zuid Holland, The Netherlands, <sup>3</sup>Mundipharma Pharmaceuticals, Hoewelaken, The Netherlands, <sup>4</sup>VU University Medical Center, Amsterdam, The Netherlands, <sup>5</sup>Erasmus University, Rotterdam, The Netherlands

A special thanks goes to all the judges, the ISPOR Annual European Congress Research Presentation Awards Chairs as well as the ISPOR Awards Committee Chairs who volunteered their time and efforts in selecting the recipients.

## ISPOR 15<sup>TH</sup> ANNUAL EUROPEAN CONGRESS RESEARCH AWARDS CHAIRS:

Podium: **Axel Mühlbacher, PhD**, Professor, Health Economics and Health Care Management, Hochschule Neubrandenburg, Neubrandenburg, Germany, and Poster: **Luciana Scalone, PhD, PharmD, ScD**, Researcher, Research Centre on Public Health, University of Milan-Bicocca, Monza, Italy 

## WEB CONNECTIONS

The World Health Organization (WHO) is always an excellent resource of robust data, including health and health care data. WHO has established the Global Health Observatory (GHO), to provide access to health-related statistics from around the world. GHO provides country data and statistics as well as analysis on global, regional and country trends. All country statistics and health profiles available within WHO are included in GHO, which also issues analytical reports on priority health issues, global burden of disease, as well as current topics of interest. Visit GHO, which is easily accessible at: <http://www.who.int/gho/about/en/index.html> and explore all the rich health related data WHO is making available to the public.

Do you know of any websites that you would like to share with the ISPOR community? If so, contact **Bonnie M. Korenblat Donato, PhD**, at: [bonnie.donato@bms.com](mailto:bonnie.donato@bms.com).

## ISPOR CALL FOR NOMINATIONS

The ISPOR Awards Committee is seeking nominees for:

### ISPOR Research Excellence Awards

ISPOR Award for Excellence in Methodology in Pharmacoeconomics and Health Outcomes Research  
ISPOR Award for Excellence in Application of Pharmacoeconomics and Health Outcomes Research

• • •

### ISPOR Bernie J. O'Brien New Investigator Award

Recipients of these awards will be announced at the 18th Annual International Meeting,  
Sheraton Orleans Hotel, New Orleans, LA, USA, May 18-22, 2013

For awards descriptions, criteria, selection process, nature of award, and past recipients, go to:

<http://www.ispor.org/awards/index.html>.

Please submit nominations materials via email to [awards@ispor.org](mailto:awards@ispor.org)

**THE DEADLINE FOR SUBMITTING NOMINATIONS IS FEBRUARY 8, 2013**



**FACULTY POSITION IN CLINICAL PHARMACY (ESAS) AT THE  
ASSISTANT/ASSOCIATE/FULL PROFESSOR LEVEL  
UNIVERSITY OF CALIFORNIA, SAN DIEGO  
SKAGGS SCHOOL OF PHARMACY & PHARMACEUTICAL SCIENCES**

The University of California, San Diego Skaggs School of Pharmacy & Pharmaceutical Sciences (SSPPS) (Web: <http://pharmacy.ucsd.edu>) is seeking applicants with expertise in the Economic, Social and Administrative Sciences (ESAS) (e.g., patient reported outcomes, pharmacoepidemiology, comparative effectiveness research, health services research) who are qualified for appointment at the assistant, associate, or full professor level. The final rank and series will be based on skills and qualifications.

The successful candidate will be expected to instruct and mentor Pharm.D. and Ph.D. students and post-doctoral trainees at the didactic and experiential levels. The candidate will develop clinical research programs focusing on translational research, improvement of therapeutic outcomes, and/or cost-effective care. Applicants should have a doctoral degree in a clinical and/or research field, experience in teaching and obtaining research funding, and a record of accomplishment and promise for further academic advancement.

SSPPS is the newest health professions school in the University of California system. The School accepts only post-baccalaureate students, has a joint curriculum with the UC San Diego School of Medicine and is competitive nationally for the very top tier of pharmacy school applicants. Current enrollment is 240 Pharm.D. students, 60 Ph.D. students, and 30 residents. The School is ranked within the upper echelon of pharmacy schools in its research endeavors and grant funding. SSPPS has excellent opportunities for faculty interaction with the vibrant pharmaceutical industry in San Diego, as well as our partners such as the UCSD Rady School of Business, the Moores Comprehensive Cancer Center, The Scripps Research Institute, the Salk Institute, the UCSD Global Health Initiative, and the UCSD joint doctoral program in Public Health with San Diego State University.

Salary is commensurate with qualifications and based on University of California pay scales.

Review of applications will begin 11/01/12 and continue until the position is filled.

The application should include detailed resume/curriculum vitae; a cover letter describing clinical, teaching, and research interests/efforts; names and addresses of three references; and a separate statement summarizing past or potential contributions to diversity (see <http://facultyequity.ucsd.edu/Faculty-Applicant-C2D-Info.asp> for further information).

Submit applications to: <https://apol-recruit.ucsd.edu/apply/>.

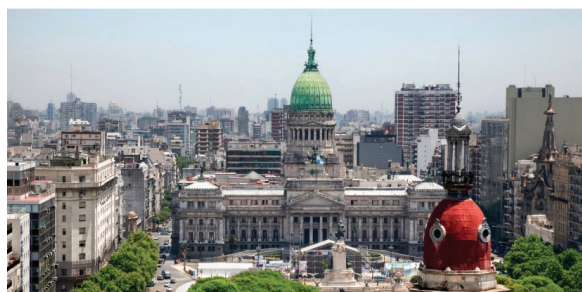
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# ISPOR 4TH LATIN AMERICA CONFERENCE

12-14 SEPTEMBER 2013 • HILTON BUENOS AIRES • BUENOS AIRES, ARGENTINA

*Challenges for Health Care Systems in Latin America: Changing Models of HTA, Priority Setting, and Health Rights*



## CALL FOR ABSTRACTS

**ORGANIZED BY:** International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and the ISPOR Latin America Consortium, in coordination with the ISPOR Argentina Regional Chapter

### CONFERENCE PROGRAM PLANNING COMMITTEE

#### Planning Committee Co-Chairs

**Federico Augustovski, MD, MSc, PhD**, Director, Economic Evaluations and HTA Department, Institute for Clinical Effectiveness and Health Policy (IECS), Professor of Public Health, University of Buenos Aires and Staff Physician, Family and Community Medicine Division, Italian Hospital of Buenos Aires, Buenos Aires, Argentina

**Guillermo Williams, MD**, Director, National Board of Health Regulation and Quality Health Care, Ministry of Health, Buenos Aires, Argentina

#### Issue Panel Review Committee Co-Chairs

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**Pedro Lovato, MD, MPH**, Medical Affairs Manager, Pfizer Central America & the Caribbean, San José, Costa Rica

#### Workshop Review Committee Co-Chairs

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**Alarico Rodríguez, MD**, Medical Benefits Manager, Uruguayan National Agency for Highly Specialized Medical Procedures, Montevideo, Uruguay

#### Contributed Research Review Committee Co-Chairs

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**Manuel Espinoza, MD, MSc, PhD**, Health Economist, Department of Public Health, School of Medicine – Papan University of Chile, Santiago, Chile

**ABSTRACT SUBMISSION BEGINS:  
21 JANUARY 2013**

**ABSTRACT SUBMISSION DEADLINE:  
21 MARCH 2013**

**EARLY REGISTRATION DEADLINE:  
23 JULY 2013**

### SUPPORT & PROMOTIONAL OPPORTUNITIES

#### Corporate Support

ISPOR provides opportunities for organizations to financially support the ISPOR 4th Latin America Conference. *For information, please email [laconsortium@ispor.org](mailto:laconsortium@ispor.org).*

#### Event Support

*Increase your visibility!* Give your company increased prominence. *For information, please email [eventsponsor@ispor.org](mailto:eventsponsor@ispor.org).*

#### Exhibit

*Over 475 attendees in 2011!* Present your products and services to key outcomes researchers and health care decision-makers in pharmaceutical, medical device & diagnostics, biotechnology industries, clinical practice, government agencies, academia, and health care organizations. *For information, please email [exhibit@ispor.org](mailto:exhibit@ispor.org).*

#### Educational Symposia

These sponsored presentations are open to all delegates. The host organization chooses a subject of interest and arranges suitable speakers for the presentation. *For information, please email [symposia@ispor.org](mailto:symposia@ispor.org).*

**FOR FURTHER INFORMATION VISIT:  
[WWW.ISPOR.ORG](http://WWW.ISPOR.ORG)**

# ISPOR 4TH LATIN AMERICA CONFERENCE

12-14 SEPTEMBER 2013 • BUENOS AIRES, ARGENTINA

## SHORT COURSES • 12 SEPTEMBER 2013

**\*\* Separate Short Course Registration Required • See Registration Form for Details \*\***

### ALL DAY SHORT COURSES (9:00-18:00)

#### INTRODUCTION TO HEALTH ECONOMICS (HEALTH ECONOMICS FOR DECISION MAKERS)

**Track:** Economic Methods

**Level:** *Introductory*. This course is suitable for those with little or no experience with pharmacoeconomics.

**Course Description:** This course is designed to teach clinicians and new researchers how to incorporate pharmacoeconomics/health economics into study design and data analysis. Participants will learn how to collect and calculate the costs of different health care or health care economic evaluation alternative treatments, determine the economic impact of clinical outcomes, and how to identify, track and assign costs to different types of health care resources used. The development of economic protocols and data collection sheets will be discussed. Different health economics models and techniques will be demonstrated with case studies. These include: cost-minimization, cost-of-illness, cost-effectiveness, cost-benefit and cost-utility analysis. Decision analysis, sensitivity analysis and discounting will also be demonstrated and practiced. Participants will learn to compare and evaluate interventions such as drugs, devices and clinical services.

#### INTRODUCTION TO MODELING

**Track:** Modeling Methods

**Level:** *Introductory*. This introductory course requires a basic familiarity with decision analysis.

**Course Description:** This course includes a review of Markov models, discrete event models, and other modeling techniques and their appropriate applications, including a review of the ISPOR Principles of Good Practice for Decision Analytic Modeling in Health Care Evaluations, as well as the recent ISPOR-SMDM guidelines (*Value in Health*, 2012). Using a series of related examples, the course will carefully review the practical steps involved in developing and using these kinds of models. Instructors will cover the practical steps involved in the selection and modeling of data inputs and practical aspects related to the determination of when, why and how to handle stochastic (i.e., first order Monte Carlo Simulations) and probabilistic uncertainty (i.e., second order Monte Carlo Simulations). Issues related to the selection of model input parameters and their distributions for use in probabilistic sensitivity analyses will be considered.

### MORNING SHORT COURSES (9:00-13:00)

#### EXTRACTING COST DATA FOR ECONOMIC ANALYSIS IN LATIN AMERICA

**Track:** Economic Methods

**Level:** *Intermediate*. This course is designed for those with some experience with pharmacoeconomic analysis.

**Course Description:** This course will focus on practical aspects of cost development for pharmacoeconomic studies. The objective is to help the participant bridge the gap between understanding pharmacoeconomic theory and the practice of developing cost estimates. Factors to consider when costing pharmacoeconomic analyses, such as perspective, data sources, data classification systems, developing resource use profiles, obtaining unit costs, and making cost adjustments will be presented. Examples of issues encountered when identifying and extracting cost data will be discussed.

### HEALTH-RELATED QUALITY OF LIFE / UTILITY MEASURES

**Track:** Patient-Reported Outcomes/Preference Methods

**Level:** *Introductory/Intermediate*. This course is for those with some experience with quality-of-life measures in health economic evaluation.

**Course Description:** Conceptual, methodological, and practical methods for measuring quality of life, health status and other types of health outcomes will be presented. Utility measurement, a method of determining an individual's preference for a certain outcome represented by a quantitative score (utility), will also be reviewed. Methods for measuring preference-based outcomes like the standard gamble, time trade-off, and visual analogue scale will be demonstrated. Additionally, utility-based instruments such as the EQ-5D, HUI, QWQ and SF-36 will be briefly discussed. Utility measurement however is not only about mastering these techniques; it is about using them in such a way that health care decision-makers can apply the results, for instance in cost per QALY-analyses. For this purpose, one needs to be aware of shortcomings of the available utility measures and potential solutions. Furthermore one should be aware of the decision-making context and the way results are interpreted. To equip participants with expertise in the field of utility measurement, the most important issues will be discussed, such as potential insensitivity of generic instruments for particular disease specific problems, and to what extent adaptation of generic or disease-specific quality of life instruments may offer a solution. Also the issue of "whose values count: patient values or values from the general public?" will be discussed. Finally we turn to the interpretation in the context of resource allocation.

### AFTERNOON SHORT COURSES (14:00-18:00)

#### APPLIED MODELING

**Track:** Modeling Methods

**Level:** *Advanced*

**Prerequisite:** This course is suitable for those who are familiar with modeling methods and/or those who have previously taken the ISPOR Short Course, "Introduction to Modeling".

**Course Description:** This course is a hands-on introduction to the use of software in the creation and analysis of cost-effectiveness decision models. The basics of cost-effectiveness decision making, building and analyzing a simple decision tree will be discussed. Markov modeling and Monte Carlo simulation will be introduced. All participants must bring a Windows laptop computer with a copy of TreeAge Pro Suite installed and running. You will be provided download and installation instructions when you pre-register for the course.

#### BUDGET IMPACT ANALYSIS

**Track:** Economic Methods

**Level:** *Intermediate*. This course is designed for those with some experience with pharmacoeconomic analysis.

**Course Description:** This course will describe methods to determine the costs associated with a health condition and the budget impact of new technologies for that condition. The course will present incidence- and prevalence-based costing strategies. Treatment algorithms and event-based approaches will be demonstrated for disease-specific costs from different decision-maker perspectives. Both static and dynamic methods for estimating the budget impact of adding a new drug to a health plan formulary will be presented. Issues related to imputing missing data will also be discussed.

# ISPOR 4TH LATIN AMERICA CONFERENCE

12-14 SEPTEMBER 2013 • BUENOS AIRES, ARGENTINA

## CALL FOR ABSTRACTS

**ABSTRACT SUBMISSION BEGINS: 21 JANUARY 2013 / ABSTRACT SUBMISSION DEADLINE: 21 MARCH 2013**

### SUBMISSION INSTRUCTIONS

**All abstracts and proposals MUST be submitted through ISPOR's online abstract submission system by 21 March 2013.**

Abstracts accepted for other ISPOR meetings can NOT be submitted.

Research published or presented at other national or international meetings is discouraged.

**Abstracts will be accepted in Spanish, English & Portuguese.**

#### RESEARCH ABSTRACTS

Outcomes research on all health care interventions (including drugs, devices, behavioral modification programs, surgery, disease prevention, gene therapy, screening, diagnostic procedures and health education) on all diseases or health disorders are considered. Research abstracts (except for conceptual papers) must be organized by OBJECTIVES, METHODS, RESULTS, CONCLUSIONS. All accepted research abstracts are published in *Value in Health* as submitted. Accepted research is presented as a 15 minute podium presentation or poster presentation (with a poster author discussion hour). Abstracts are evaluated on the quality of the study (or concept) and quality of the abstract presentation.

*Research topics include: Clinical Outcomes Studies, Cost Outcomes Studies, Patient-Reported Outcomes & Patient Preference Studies, Health Care Use & Policy Studies, Research on Methods, Conceptual Papers.* See the ISPOR website for research subtopics, diseases and health care treatments.

#### WORKSHOP PROPOSALS

Workshop proposals should show novel and innovative experiences in the conduct of outcomes research (including, but not limited to, experiences with conjoint analysis, large database analysis, modeling, observational studies, record review, surveys, sensitivity analysis and patient registries) or novel and innovative experiences in the use of outcomes research (clinical, economic, or patient-reported/preference-based outcomes) in health care policy development. Workshop proposals must be organized by DISCUSSION LEADERS, PURPOSE, DESCRIPTION. Accepted workshops are one hour in duration with a minimum of 2 and maximum of 4 discussion leaders (more than one organization must be represented). An audience interactive element must be included in the proposal and during the workshop.

*Workshop topics include: Clinical Outcomes Research, Economic Outcomes Research, Patient-Reported & Patient Preferences Outcomes Research, Use of Real World Data, Health Policy Development Using Outcomes Research.* See the ISPOR website for workshop subtopics.

#### ISSUE PANEL PROPOSALS

Issue panel proposals should show real debate on new or controversial issues in health economic/pharmacoeconomics and outcomes research or real debate on the use of outcomes research in health care decision-making. Issue panel proposals must be organized MODERATOR, PANELISTS, ISSUE, OVERVIEW. An accepted issue panel is one hour in duration with a moderator and 2-3 panelists. Panelists should be from different institutions and/or work environments representing different perspectives on the debate.

*Issue Panel topics include: Clinical Outcomes Research Issues, Economic Outcomes Research Issues, Patient-Reported Outcomes & Patient Preferences Research Issues, Health Policy Development Using Outcomes Research Issues.* See the ISPOR website for issue panel subtopics.

**OVER 500 ATTENDEES ANTICIPATED!**

### PRELIMINARY PROGRAM

#### THURSDAY, 12 SEPTEMBER (8:00-20:00)

**SHORT COURSE PROGRAM** (*Separate Short Course Registration Required • See Registration Form for Details*)

\*Introduction to Health Economics \*Introduction to Modeling \*Extracting Health Care Data for Economic Analysis \*Budget Impact Analysis \*Applied Modeling \*Health-Related Quality of Life

**Plus!** \*EDUCATIONAL SYMPOSIA \*WELCOME RECEPTION

#### FRIDAY, 13 SEPTEMBER (9:00-21:00)

**FIRST PLENARY SESSION: ASSIGNING REGIONAL PRIORITIES & THE USE OF HTA IN ECONOMIC EVALUATIONS IN LATIN AMERICA: HOW FAR HAVE WE COME?**

Various initiatives currently exist in Latin America and the Caribbean at a regional level dedicated to promoting the appropriate use of health care technologies. Some of these initiatives focus on the incorporation of economic evaluations using common tools for health care decision-making at the country-level (Pan American Health Organization (PAHO) ProVac (Promotion of Evidence-Based Decision Making for the Introduction of New & Underutilized Vaccines) initiative, dedicated to new and underutilized vaccines). Others bring together various health technology assessment (HTA) agencies and institutions throughout the Americas to work together as a network in advancing the diverse aspects of HTA (RedETSA-Latin America HTA Network). Still others concentrate on the importance of interactions between the health care system and the judicial system, since the majority of countries in Latin America guarantee health care as a universal right within their national Constitutions (World Bank Institute Priority Setting and Constitutional Mandates in Health initiative). In this session, speakers will discuss the achievements and challenges of each of these regional initiatives.

**Plus!** \*EDUCATIONAL SYMPOSIA \*ISSUE PANELS \*WORKSHOPS \*RESEARCH POSTER & PODIUM PRESENTATIONS \*EXHIBITS

#### SATURDAY, 14 SEPTEMBER (9:00-14:00)

**SECOND PLENARY SESSION: HTA AS A TOOL TO INFORM PRICING AND COVERAGE POLICIES IN THE NATIONAL CONTEXT: CASE STUDIES FROM BRAZIL, CHILE, COLOMBIA, MEXICO AND URUGUAY**

During this plenary session, speakers will review successful case studies from select Latin America countries regarding the use of health technology assessment (HTA) at the public/government level. These countries are considered to be among those successfully advancing towards systems where economic considerations (i.e., economic evaluations, budget impact analysis, etc.) are routinely utilized in public health care decision-making. Issues discussed will include: the incorporation of health technologies into the health care system; pricing negotiations for the incorporation of new health care technologies; and the design and revision of public health care benefit packages.

**Plus!** \*EDUCATIONAL SYMPOSIA \*ISSUE PANELS \*WORKSHOPS \*RESEARCH POSTER & PODIUM PRESENTATIONS \*EXHIBITS

# ISPOR 4TH LATIN AMERICA CONFERENCE

12-14 SEPTEMBER 2013 • BUENOS AIRES, ARGENTINA

## CONFERENCE REGISTRATION

FIRST NAME	LAST NAME	DEGREES	MEMBER ID#
POSITION		ORGANIZATION	
MAILING ADDRESS			
CITY	STATE	ZIP	COUNTRY
TELEPHONE	FAX	EMAIL	

### PRE-CONFERENCE SHORT COURSES THROUGH 23 JULY 2013

AFTER 23 JULY 2013

FEE

**12 SEPTEMBER 2013** (Short Course registration is optional and is in addition to Conference Registration fee.)

**ALL DAY SHORT COURSES (9:00-18:00)** Regular: \$200 (ARS 948) Student: \$100 (ARS 473) Regular: \$400 (ARS 1896) Student: \$200 (ARS 948)

INTRODUCTION TO HEALTH ECONOMICS (HEALTH ECONOMICS FOR DECISION MAKERS) \$ \_\_\_\_\_

INTRODUCTION TO MODELING \$ \_\_\_\_\_

**MORNING SHORT COURSES (9:00-13:00)** Regular: \$100 (ARS 473) Student: \$50 (ARS 237) Regular: \$200 (ARS 948) Student: \$100 (ARS 473)

EXTRACTING COST DATA FOR ECONOMIC ANALYSIS IN LATIN AMERICA \$ \_\_\_\_\_

HEALTH-RELATED QUALITY OF LIFE / UTILITY MEASURES \$ \_\_\_\_\_

**AFTERNOON SHORT COURSES (14:00-18:00)** Regular: \$100 (ARS 473) Student: \$50 (ARS 237) Regular: \$200 (ARS 948) Student: \$100 (ARS 473)

APPLIED MODELING \$ \_\_\_\_\_

BUDGET IMPACT ANALYSIS \$ \_\_\_\_\_

### CONFERENCE REGISTRATION

THROUGH 23 JULY 2013

AFTER 23 JULY 2013

FEE

**13-14 SEPTEMBER 2013**

**STANDARD** US \$400 (ARS 1896) US \$500 (ARS 2375) \$ \_\_\_\_\_

**CLINICAL PRACTITIONERS** (Clinical Practice, Hospital) US \$400 (ARS 1896) US \$500 (ARS 2375) \$ \_\_\_\_\_

**FULL-TIME GOVERNMENT AND ACADEMIA** US \$200 (ARS 948) US \$300 (ARS 2375) \$ \_\_\_\_\_

**FULL-TIME STUDENTS** (must provide current enrollment docs) US \$80 (ARS 380) US \$100 (ARS 473) \$ \_\_\_\_\_

### ISPOR MEMBERSHIP (OPTIONAL)

FEE

**MEMBER** \$ \_\_\_\_\_

USD \$275 – includes 1-year subscription to Value in Health (online & hard copy, including access to all past issues) and a 1-year-bi-monthly subscriptions to *ISPOR CONNECTIONS* (online and print).

USD \$140 – includes 1-year online subscription to Value in Health (online access to all past issues) and a 1-year-bi-monthly subscriptions to *ISPOR CONNECTIONS* (online and print).

**STUDENT MEMBER** \$ \_\_\_\_\_

USD \$120 – includes 1-year subscription to Value in Health (online & hard copy, including access to all past issues) and a 1-year-bi-monthly subscriptions to *ISPOR CONNECTIONS* (online and print).

USD \$35 – includes 1-year online subscription to Value in Health (online access to all past issues) and a 1-year-bi-monthly subscriptions to *ISPOR CONNECTIONS* (online and print).

### AMOUNT DUE

Short Course fee + Conference Registration Fee = **TOTAL FEE** \$ \_\_\_\_\_

### PAYMENT INFORMATION

*Note: Exchange rate as of November 2012. The ARS rates should be used as a reference only. All credit card payments to ISPOR are charged in USD\$ at the exchange rate prevailing at the time of the transaction. Due to this exchange, credit card statements may vary slightly.*

Please enclose a check payable in US dollars to: International Society for Pharmacoeconomics and Outcomes Research or ISPOR and send to the ISPOR address below.

Charge to:  VISA  MasterCard  American Express Account Number: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

Name: \_\_\_\_\_ Authorized Signature: \_\_\_\_\_

**MAIL DETAILS:** If not paying by credit card online, send registration form and payment to: International Society for Pharmacoeconomics and Outcomes Research, 505 Lawrence Square Blvd South, Lawrenceville, NJ 08648 USA • Tel: 609-586-4981 • Fax: 609-586-4982 • E-Mail: info@ispor.org • Internet: www.ispor.org

**PAYMENT DETAILS:** Payment can be made by check, bank transfer (\$40USD additional charge) or credit card (Visa, MasterCard, American Express). All credit card payments will be charged in USD. Phone charges will NOT be accepted. If payment is being made by your company, please make sure your name is indicated on the check stub or correspondence for bank transfer.

**CANCELLATION DETAILS:** Cancellation fee before April 9, 2013 is US \$100. **No refunds given after 23 July 2013.**

For more information: [www.ispor.org](http://www.ispor.org)

Register Online @ [www.ispor.org](http://www.ispor.org)



# ISPOR Meeting Travel Scholarship Award Reports

The ISPOR Meeting Travel Scholarship Award was established in 2006 to support travel to ISPOR meetings or regional conferences for ISPOR members residing in economically disadvantaged countries or regions of the world and to contribute to the development of pharmacoconomics and outcomes research or the use of outcomes research in health care decisions in these countries or regions.

After the ISPOR Meeting Travel Scholarship Award experience, recipients submit a report outlining how they contributed to the development of pharmacoconomics and outcomes research or the use of outcomes research in health care decisions in their own country/region based on this experience. The following are reports from Meeting Travel Scholarship recipients from the ISPOR 15th Annual European Congress, held in Berlin, Germany, from 3-7 November, 2012, and the ISPOR 5th Asia-Pacific Conference in Taipei, Taiwan, from 2-4 September 2012 (*Previous reports from recipients from the Taiwan Conference appeared in the September/October 2012 issue of ISPOR CONNECTIONS.*)

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## Pharmacoconomics and Capacity Building in Jordan

**Abeer Ahmad Al Rabayah, BSc Pharmacy, MBA, Pharmacoconomist, King Hussein Cancer Center, Center for Drug Policy and Evaluation (CDPE, Amman, Jordan)**



I was honored to receive an ISPOR Meeting Travel Scholarship Award to attend the ISPOR 15th Annual European ISPOR Congress. This award was a great chance for me to explore the area of pharmacoconomics and health outcomes research in other countries. Furthermore, I attended four courses that were directly related to my work in Jordan. I think ISPOR meetings represent an invaluable opportunity to health care providers, researchers and policy makers to exchange ideas and share experiences with experts on the international level.

The Congress' theme for this year tackled important points that are challenging for many countries. Even though the level of complexity of health technology assessment models differs from country to country, there are many similarities in term of challenges. I think during the coming years a transition in health technology assessment (HTA) models will take place through new regulations that emphasize the culture of using evidence-based medicine to better inform about the reimbursement and pricing decision-making process.

Pharmacoconomics and health outcomes research is moving forward in the Middle Eastern region and it is predicted to gain even more acceptance from policy makers in the future due to economic challenges from one side and the commitment towards quality of care due to health care accreditation standards from the other. I believe that improving access to education in this important area is a key factor in improving access to medicine and providing citizens with high quality, safe and cost-effective medication.

During previous years, my colleagues in Jordan worked on creating awareness

regarding Pharmacoconomics and its importance through lectures and workshops. I think now we reached a stage where we need to move into more focused education and capacity building in order to be ready for the future.

The building capacity of a young generation that is passionate about pharmacoconomics/ health economics is an important mission that I will personally focus on delivering. In my beloved country Jordan, where people represent our main asset and investing in them is the most cost-effective strategy to improve the use of medication.

Furthermore, advocacy and changing regulations that support evidence-based decision making is also an important aspect that needs further attention and focused effort. This represents a long-term goal that builds on the availability of a supporting culture and politics to improve the medication selection process and efficiency, with an ultimate goal to improve access to medicine.

ISPOR is playing a major international role in developing the science of pharmacoconomics and health outcomes research all over the world. It is investing in people by providing scholarships and awards that are beneficial and add to any participant's experience. I would like to thank ISPOR for all the amazing work that it is doing; it serves as a reference for anyone who is interested in pharmacoconomics. It was my pleasure to participate and enrich my knowledge from such a meeting, and I am looking forward for my next participation --hopefully with a team of young Jordanian pharmacoconomists.

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## Pharmacoconomics and Outcomes Research: The Vision, Mission and Scope of ISPOR In Developing Countries

**Muhammad Akhtar, RPh, Mphil, Lecturer, Department of Pharmacy, The Islamia University of Bahawalpur, Bahawalpur, Pakistan**



First of all, I congratulate the organizers of ISPOR's 15th Annual European Congress, held 3-7 November 2012, Berlin, Germany, for the successful and remarkable commencement of this mega event. For me, the organization of the Congress throughout the event was impressive and all credit goes to ISPOR staff and other committees of this Congress. I am also very grateful to ISPOR for granting me an ISPOR Meeting Travel Scholarship Award. This gave me an opportunity to present my research presentation poster, "Evaluation of Prescribing Practices of Clinicians in Government Teaching Hospital in Pakistan," and to learn new ideas and methods about pharmacoconomics and outcomes

research by attending three short courses, productive and informative plenary sessions, workshops, educational symposia, five poster sessions, as well as other sessions. In first two days of the Congress, I participated in three short courses. The first day short course I attended was "Introduction to Health Economics/ Pharmacoconomics Evaluations," which took place the entire day. The second day of the Congress, I attended two short courses titled, "Patient Registries" and the other was "Network Meta-Analysis in Relative Effectiveness Research". All three courses were very informative, productive and fulfilled my expectations. >

More than 3500 registered participants from over 75 countries participated in this mega event. As this was my first ISPOR Congress, I wanted to utilize every opportunity available. The experts and research scholars from around the world attended the Congress and I learned and shared new ideas in the area of health economics and outcomes research with them. After attending the Congress, I realized how outcomes research is a powerful tool for rational health care decision making in countries with resource-limited settings like Pakistan.

Overall, the Congress provided many advantages to all participants. ISPOR's support to the researchers from the financially disadvantaged countries is, however, very appreciable. After getting basic knowledge about pharmacoeconomics and outcomes research, I feel more confident in supporting and promoting the objectives of the ISPOR Pakistan Regional Chapter.

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## Sharing Experiences Through The ISPOR Congress And Interacting With Global Intellectuals: Provision Of Guidance On The Appropriate Use Of Medical Technology In Diversified Ways And Means From The Bangladesh Perspective

*Haragobinda Baidya, MA, BED, Minority Self Empowerment Foundation, Dhaka, Bangladesh*



The ISPOR 15th Annual European Congress, held 3-7 November 2012, at the ICC Berlin, Germany, was a memorable, historical and globally useful event. This ISPOR Congress in Berlin marked my first time participating in such an event. The Conference was so exceptional, as it allowed for the gathering and sharing of knowledge. I received certificates from participating in four short courses, including, "Introduction to Retrospective Database Analysis," "Propensity Scores and Observational Studies of Treatment Effect," "Instrumental Variables," and "Risk-Sharing/Performance-Based Arrangements for Drugs and Other Medical Products." These courses were effective and useful for our organizational training for the ultra-stakeholders and the group's domestic members to learn about health issues. I will use the experience I gained from the ISPOR Congress to contribute to our NGO consortium and national health workshops, meetings, conferences and other periodicals of Bangladesh.

After the short courses, I attended the first plenary session, "Converging or Diverging Models of HTA in Europe" on 5 November. This session provided a multi-purpose developmental role in the use of medical and pharmacoeconomic knowledge and important issues regarding the output of research. In the

second plenary session on 6 November, there was a welcome by ISPOR President Deborah Marshall, PhD, MHSA, and the plenary session topic was, "An International Price Referencing –is There a 'Right' Way to Perform It?" This was successful and allowed for the participants to take part in an open 'question and answer' session. In the poster presentation session, the students played a vital role in outlining the global health issues. The various organizations and institutions focused on important, historic, dynamic, and innovative new ways of life. The exhibitors seemed to have a clear idea of aspects of international challenges for models in health and pharmacoeconomic use. The invited speakers' speeches provided volumes of information regarding new technology and outcomes research methodology of the European concepts of proposal.

At this very moment, most populations living in Asia have a much poorer health status, so we feel an international meeting is needed in Asia. The ISPOR Meeting Travel Scholarship was very helpful and useful for me in allowing me to participate at the ISPOR 15th Annual European Congress. I cordially thank ISPOR for the opportunity.

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## Pharmacoeconomics and Outcomes Research: Observations from Pakistan

*Anwar-ul-Hassan Gilani, PhD, Professor, Aga Khan University Medical College, Karachi, Pakistan*



With the financial support of an ISPOR Travel Scholarship Award, I attended the ISPOR 5th Asia-Pacific Conference, which was held in Taipei from 2-4 September 2012. This was the first official representation of the ISPOR Pakistan Regional Chapter in any ISPOR event. The 5th Asia-Pacific Conference provided an excellent opportunity for the Pakistan Chapter to display its existence to the international community. During the three-day conference, I represented the Pakistan Chapter at different important events of the Conference as well as had the opportunity to co-chair the workshop review committee

I attended meetings of the ISPOR Asia Consortium, its Program Committee Co-Chair Dinner, Executive Committee and the Education Committee. These meetings discussed key strategic issues in health economics and outcomes research (HEOR) in the Asia-Pacific region. I had a wonderful experience and learned where I could further contribute to health economics in Pakistan or similar. During the discussion on improving *Value in Health Regional Issues* (Asia edition), I raised the concern of a long waiting period (one year), which could affect the number of quality articles submitted to the journal as the authors, particularly in studies related to student participation, are not willing to wait for such a long period. I suggested there is a need to consider alternate options, such as, having a regular section of each region in each issue of the journal, instead of one full edition designated to one region once a year.

During the discussion, several members stated that the South-Asian countries are important to the Asia Consortium as they constitute around 40% of the population of Asia. The health care systems in these countries are weak and there are fewer financial protection mechanisms. In these situations there is little demand for HEOR research driven by the industry or the payer. It is a big challenge to the Asia Consortium to promote its activities in these regions. The local chapters in these countries should be involved to provide a better understanding of the situations in these countries and to formulate cohesive policies according to their specific needs.

I attended many other research and academic activities at the Conference and I met many people with whom I shared research ideas and methods. This meeting helped me to develop professional contacts' links, and I returned home with exciting ideas for HTA and other research-related ideas. I strongly believe that ISPOR's support has been very helpful for the promotion of evidence-based decision making in health care in developing countries such as Pakistan, and I would like to take this opportunity to thank the ISPOR authorities for granting this fellowship.

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## Improving Pharmacoeconomics and Health Outcomes Research in Brazil

*Marina Gonçalves de Freitas, Pharmacist, Coordenação Geral de Avaliação de Tecnologias em Saúde (General Coordination of Health Technology Assessment), Departamento de Ciência e Tecnologia- DECIT (Department of Science and Technology), Secretaria de Ciência, Tecnologia e Insumos Estratégicos- SCTIE (Secretariat for Science, Technology and Strategic Input), Ministério da Saúde - MS (Brazilian Ministry of Health), Belo Horizonte, Brazil*



The Department of Science and Technology (DECIT) is a department within the Brazilian Ministry of Health, responsible for fostering research priorities and training managers and technicians of the National Health System (SUS) in the development of HTA studies. These studies are developed according to the National Policy on Health Technology, following the principles of Evidence-Based Medicine, to be used to aid in the decision to incorporate new technologies within the SUS. Given the increasing judicialization in health, they will be crucial for assisting in responding to lawsuits. I submitted a study at the ISPOR 15th Annual European Congress to share my experience in this field and improve my knowledge in pharmacoeconomics.

I am very grateful and honored to have been awarded a 2012 ISPOR Meeting Travel Scholarship Award, which made my participation in this event possible. I attended two short courses: "Introduction to Patient Preference Methods Used for QALYs," and "Introduction to Retrospective Database Analysis." All of the topics included in the short courses were relevant to me, and the workshops, issue panels, plenary sessions and research presentations were all highly informative.

This ISPOR Congress gave me the opportunity to learn more about pharmacoeconomics and health outcomes research around the world, as well as the chance to present a poster, and meet some of the top researchers in areas such as bariatric surgery. Attending an event like ISPOR's Annual European Congress was very important to expand and acquire new knowledge about the topics covered. I believe that this opportunity will have great impact on future activities for DECIT and I hope to contribute to studies and pharmacoeconomic outcomes research within the Ministry of Health by facilitating and streamlining the practice of incorporating health technologies in the SUS.

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## The ISPOR 15th Annual European Congress Travel Scholarship Award Experience

*Syed Umer Jan, BPharm, MPhil, PhD. Assistant Professor, Department of Pharmacy, University of Balochistan, Quetta, Balochistan, Pakistan*



I really enjoyed the opportunity to participate at the ISPOR 15th Annual European Congress, and feel honored to have been awarded an ISPOR Meeting Travel Scholarship Award. This was made possible by ISPOR, and so I am grateful to the ISPOR Meeting Travel Scholarship Award Committee. It was a great opportunity for me to get in touch with the best experts and researchers from around the world in the areas of health economics and outcomes research. As this was my first ISPOR Congress, I wanted to utilize every opportunity on my part. I was privileged to be able to attend three short courses. The first course I attended was "Introduction to Health Economics/ Pharmacoeconomic Evaluations," a full day course. The second course was "Patient Registries," and the third course was "Network Meta-Analysis in Relative Effectiveness Research." All three courses were really valuable for me as I learned about this information from new perspectives and angles. I learned about indirect and mixed-treatment comparisons, and about the use of different types of outcomes and other methods in these courses, as well as other seminars and educational symposia that should prove essential for me and my students in the future.

The most impressive aspect of the Congress was its organization and the dedication of the ISPOR staff and committees. Several workshops and presentations were held simultaneously with the poster sessions, exhibitions, and interactive discussions, which converted the Congress into a mega scientific event.

I was also impressed by the intensive work of the ISPOR staff. They were quick in responding to all inquiries and questions during the organization of this Congress, and I was privileged to meet some key personalities from ISPOR.

As a new member of ISPOR, I was given the opportunity to be a reviewer/judge for one of the Congress workshops, which I found very exciting and proactive. The Congress also gave me, for the first time, an international platform to share my findings in my poster presentations, "Irrational Use of Antibiotics in Balochistan. A Warning for Health Care System" and "Irrational Use of Antibiotics in Children by Medical Prescribers."

As a pharmacist and member of ISPOR with an interest in drug use, clinical outcomes, health economics and outcomes research, I hope and wish to promote the mission of ISPOR and the development of clinical outcomes research and pharmacoeconomic guidelines which we lack in our country (Pakistan).

This Congress provided me with a platform to learn all about pharmacoeconomics and public health. I am most grateful to ISPOR for supporting researchers from developing countries to learn and share experiences on such platforms. I hope the experience and knowledge I gathered will help advance the objectives of ISPOR in my country.

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## Pharmacoeconomics and Outcomes Research – Blooming in India

*Uday Venkat Mateti, BPharm, PharmD, RPh, Department of Pharmacy Practice & PharmD, St. Peter's Institute of Pharmaceutical Sciences, Kakatiya University, Vidyanaagar, Hanamkonda, Andhra Pradesh, India*



At the outset, I would like to give my profound sense of gratitude to the ISPOR Awards Committee for conferring a 2012 ISPOR International Meeting Travel Scholarship Award in recognition of my contribution to the development of pharmacoeconomics and outcomes research in health care decisions in my own country, India.

The 2012 ISPOR Meeting Travel Scholarship Award, was sponsored by the noble mission of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) to promote the innovative idea of health care efficiency in the field of Pharmacoeconomic research; a very novel vision, and beneficial for the young scientists in India. ISPOR encouraged young scholars such as me, to participate in the esteemed ISPOR 15th Annual European Congress, held in Berlin, Germany, 3-7 Nov 2012. During Poster Session IV, I was able to present my paper entitled, "Evaluation of Healthcare Cost of Diabetes Before and After Counseling in South Indian Community Set-up."

I feel this award has been a great privilege for me, and it has enriched my understanding of the concept by virtue of my participation and interaction with eminent scholars, teachers and critics at the highly revered international conference. Hopefully, the opportunity has positively altered the lifecycle of my scholarly research and teaching by virtue of my visit.

During the first two days of the Congress I attended four short courses entitled: "Introduction to Patient-Reported Outcomes Assessment: Instrument Development & Evaluation," "Pharmacoeconomic Modeling – Applications," "Bayesian Methods in Economic Evaluations – Introduction," and "Cost Estimation and Assessing Financial (Budget) Impact of New Health Care Technologies."

These courses were very educative and thought provoking, and helped me to interact with the eminent international speakers regarding the case studies on Patient-Reported Outcomes, and Budget Impact Analysis. I received excellent training on the pharmacoeconomic modeling for HIV by using TreeAge Software. During the last three days of the Congress, I found the three Plenary Sessions, one workshop, an Educational Symposium, and many other poster sessions to have been very useful, as they enabled me to learn the new trends in pharmacoeconomics and outcomes research studies.

This Travel Scholarship enabled me to strengthen my hands as a guide to promote qualitative research and launch a new course in the area of pharmacoeconomics. I will also promote the development of the ISPOR Student Network and ISPOR Regional Chapters, which encourage the global flow of ideas and information related to health care decision making. Since I have derived the benefit of innovative, cost-saving ideas in health economics, patient health outcomes, networking and technical competency, I will disseminate them among the general public as well as the research community and health care professionals, to inform them of the usefulness of research in pharmacoeconomics. As a committed teacher and an active member of ISPOR, I will promote health care evaluation and work for patient safety in the pharmacy community. I will design a novel program to counsel the pharmacists to play a vital role in improving health care in the areas of community, clinical, and hospital pharmacy.

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## Expanding Knowledge and Initiating Health Economics Practices and Health Outcome Research in a Developing Country

*Victor L. Mendoza, MD, De La Salle Health Sciences Institute, Dasmariñas, Cavite, Philippines*



I would like to express my most sincere thanks and appreciation for being granted a Travel Meeting Scholarship Award, which allowed me to attend the ISPOR 15th Annual European Congress. This was my first time at an ISPOR meeting and it gave me the opportunity to expand my knowledge of pharmacoeconomics and health outcomes research. By attending the short courses, "Introduction to Modeling and Pharmacoeconomic Modeling – Applications and Transferability of Cost-Effectiveness Data between Countries" and "Network Meta-Analysis in Relative Effectiveness Research." I was able to learn more about economic modelling and its applications, and how to better use cost-effectiveness studies to date. The other sessions that I was able to attend were all informative and allowed me to gain more insight about how to improve health through research and other methodologies.

More than the formal sessions, however, I considered the Congress to be a success because of the people I met who more than willingly discussed and shared their knowledge with me. I was able to get in touch with people whose experiences more or less paralleled my own, as well as people who have totally different backgrounds. Though the people who attended the Congress have varied backgrounds, I felt that we all had something in common: the improvement of the health of our people through various processes, including economic evaluation, health technology assessment and outcomes research.

Although most of the topics during the Congress dealt with the European experience (which is understandable as it was the European Congress), I was still able to pick up a lot of information that I can adapt and hopefully make good use of in my own part of the world. As Dr. Carole Longson stated in her last slide during the First Plenary Session, we can actually "globalise the principles, [and] localise the practice."

The experiences and knowledge I gained during the Congress will be shared not only with my colleagues, but my medical students as well. Hopefully, I can convince the Curriculum Committee of our medical school to expand the topics of health economics and health outcomes research beyond mere introductory courses. Our future doctors as well as other health professionals will then become more aware of how these methods can be used to improve health care delivery, and ultimately, the health of our countrymen. I intend to maintain communication with the wonderful people I met during the Congress, especially those from my part of the world, and continue to exchange ideas, experiences, and hopefully collaborate on some projects of national or even regional impact.

Again, many thanks to ISPOR.

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## Ensuring Quality Health care Delivery in Ghana Through Pharmacoeconomics and Outcomes Research

*Archibald Nii Boye Okotah, BPharm, MPH, Ghana Health Service, Ho Municipal Hospital, Ghana*



As a new member of ISPOR, I was honored to receive an ISPOR Travel Scholarship Award. Indeed, I could not hold back my joy as this scholarship afforded me the opportunity to attend my first ISPOR meeting, the ISPOR 15th Annual European Congress in Berlin, Germany.

By attending the congress, I had the remarkable opportunity to interact with renowned experts in the various field of health economics and outcomes research.

Through the plenary sessions, workshops, and educational symposia I attended, I was privileged to obtain a great deal of information on innovative technologies in health care delivery, diverging and converging models of health technology assessment in Europe, different methodological approaches that are required for operational research, and reimbursement policy decisions for health insurance in different countries.

The most significant experience, for me, was the knowledge I gained from my participation in three short courses: "Introduction of Patient-Reported Outcome Assessment; Instrument Development and Evaluation," "Meta-analysis in Relative Effectiveness Research," and "Introduction of Health Technology Assessment," which gave me insight into how innovative health technology led to a transformation of health care delivery in Europe and other parts of the world.

In Ghana, for example, the introduction of the National Health Insurance Scheme (NHIS) had brought some relief to many Ghanaians regarding health care costs, and ultimately made health care more accessible to the general population. There are still some challenges confronting the NHIS, however, as to whether it

is truly universal and the intended quality of service delivery. The quality of care needs to be evaluated constantly to ensure that patients receive better service for optimum clinical output at a reasonable cost to the society and the nation at large.

It is estimated that 36% of health spending in Ghana is actually wasted due to inefficiencies and poor investment at the various health facilities [1]. Therefore, it is imperative that extensive pharmacoeconomic and outcomes research be encouraged to address a number of these issues bordering on health outcomes. Investing in health is critical for all citizens since it forms a foundation for achieving a healthy economy in the future.

With the knowledge and experience gained at the conference, I look forward to effectively participating in and contributing to the ISPOR Ghana Regional Chapter. I look forward to engaging in networking with other colleagues to conduct research in pharmacoeconomics, and also supporting policy decisions with evidence-based research at the district and national level to ensure quality of care.

I am particularly interested in taking up further courses to expand my horizons in the field of health economics. The conference was impressive and I am grateful for the exposure and the knowledge acquired. I also look forward to participating in future ISPOR events.

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## A Kosovo Point-of-View of the Berlin Congress

*Shkumbim Thaqi, PhD, MD, Family Health Center, Gjakova, Rep. of Kosovo, Albania*



I feel honored to have been selected by your committee as an ISPOR Meeting Travel Scholarship Award recipient and to participate at the ISPOR 15th Annual European Congress, held in Berlin, Germany, in November 2012. As a new ISPOR member as of 2011, on behalf of me and on my colleagues from the Center for Family Medicine, of Gjakova City, Republic of Kosovo, allow me to express my sincere thanks to you.

As a new participant from a developmentally growing country such as Kosovo, I am the first Albanian Citizen to be a member of ISPOR, and so it was a privilege for me to attend the Congress.

During the Congress, I attended one short course on Bayesian Analysis & Observational Data Methods, as well as many other sessions. I was interested in all of the Congress topics, especially: methods on high quality studies production and application, diabetes outcomes research, quality of life, lifetime database development and its value, and how to access real world data for better patient outcome research translation.

During the Congress, I discussed with ISPOR staff liaisons starting a Regional Chapter in Kosovo in the future, which is very important for us.

I met more colleagues from countries, which I have shared more experiences with, based on our scientific research. I have benefitted from their experiences, and will have more interesting professional memories to bring back to my country for the future.

So after this award experience with ISPOR, an organization that helps many countries, allow me once again to thank all the ISPOR staff who helped me to participate at the ISPOR Annual European Congress in Berlin 2012: Marilyn Dix Smith, David Goldstein, Malgorzata (Gosia) Juszczak-Punwaney, Stephen Priori, Eden McConnell, Nancy Sun, and Valerie Anderson.

I hope to see you all at next year's Annual ISPOR International Meeting in New Orleans in 2013.

# Bayesian Evidence Synthesis – Multi-Parameter Evidence Chains

Viktor V. Chirikov, BS, MS, Department of Pharmaceutical Health Services Research, University of Maryland School of Pharmacy, Baltimore, MD, USA



## INTRODUCTION

A need exists in the outcomes research arena to pool evidence from randomized clinical trials and observational studies and interpret it according to robust scientific criteria. An initiative by ISPOR and AMCP built upon the work of the ISPOR Task Force on the Use of Real-World Data to come up with a consolidated evidence quality assessment tool [1]. Furthermore, a checklist is being developed as a methodological instrument to evaluate the quality and application of observational studies for comparative effectiveness decision making [2]. Even when a reliable standardized instrument to assess the quality of evidence is made available, however, individual investigators and decision makers will still be faced with the sometimes daunting task of synthesizing the evidence. The next logical step in advancing our ways of educating decision- and recommendation-making would be to develop and employ better methods for synthesizing information. Gaining traction among the comparative effectiveness research (CER) community and health care agencies, Bayesian approaches have been implicated as a possible new-generation tool to inform decisions. Bayesian methods for synthesizing available evidence are still in methodological development but are seen as a powerful tool to guide decision making despite some of its limitations such as the requirement for similarity between trials and consistency of evidence [3]. The practicality of Bayesian methods for decision-making is reflected in using indirect evidence to, for example, compare several interventions for which no head-to-head trials but a common comparator is available (placebo or active comparator).

## MULTI-PARAMETER EVIDENCE CHAINS

A Bayesian approach for synthesizing evidence that has been gaining popularity is the Multi-Parameter Evidence Synthesis (MPES), which is sometimes referred to as evidence chains [4]. This approach is especially useful in decision models, which more often than not borrow parameter values from various sources. Incorporating borrowed parameter values could result in an inflexible methodology as those parameters are usually independent given that they come from different clinical trials having different inclusion/exclusion criteria, from different populations and different settings. The MPES is helpful in creating functional relationships between key parameters, including such parameters for which information could be missing, thus leading to jointly calculating probability distributions for all variables in the decision model and correctly addressing uncertainty of the available evidence. When data is available on more functional relationships than there are basic variables in the decision model, it could lead to a potential inconsistency or discrepancy between evidence sources. As the evidence is linked together, however, the chain of evidence allows for researchers to validate findings from all sources.

Welton, et al. provides an example for the use of MPES [4]. Imagine researchers have information on the incidence of a disease, the complications that develop from the disease, as well as the fact that the severity of the complications depends on time with the disease. These are three outcome variables that might have been evaluated in three different sets of clinical trials. Consider the following example:

Population → Disease Incidence → Complications → Degree of severity over time:

A	B	C, time
Trial set 1	Trial set 2	Trial set 3

Examples of functional relationships linking the findings from the three sets of trials could be the following:


$$\text{Degree of severity (C)} = (A) \cdot (B) \cdot (\text{time})$$

$$\text{Complications (B)} = (C) / [(A) \cdot (\text{time})]$$

Note we focus on sets of trials rather than findings from one randomized clinical trial. This builds the base for connecting sets of Bayesian network meta-analyses, synthesizing the evidence of trials on one particular outcome, in an MPES evidence chain. In the example above, we could have three separate network meta-analyses on trial sets 1, 2, and 3 and link them in a MPES model. Furthermore, when randomized clinical evidence is not available, evidence from observational studies or expert opinion could be incorporated, recognizing that they could be biased and needed to be properly down-weighted in the overall evidence chain estimation [5,6].

Bayesian approaches could be used when decision makers are concerned with the possibility of testing a scientific hypothesis in a simulation study before conducting a clinical trial. Comparing the effectiveness and cost of novel treatments, managed care professionals and health researchers could employ a MPES model to calculate their best estimate of the probability of which treatment could be the best given the constraints of all available information.

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## Recently Published Works: Innovatively Using Outcomes Research by ISPOR Members

Stephen Priori, Director, ISPOR Publications and Communications

*This column includes books, articles, and abstracts recently published by ISPOR members. To ensure that your published work in pharmacoeconomic or outcomes research is reported here, please keep your contact information up to date with the Society. Any questions, comments, or submissions concerning this review can be directed to Stephen Priori at: [spriori@isporg.org](mailto:spriori@isporg.org).*

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# International Society for Pharmacoeconomics and Outcomes Research

*Translating Outcomes Research to Health Care Decisions*



## ISPOR 18th Annual International Meeting

May 18-22, 2013

Sheraton New Orleans, New Orleans, LA, USA

Over  
2900  
attendees  
in 2012!

*Patient-Centered Outcomes: Focusing on the Patient*

Abstract Submission  
Deadline:

**January 17, 2013**

Early Registration  
Deadline:

**April 9, 2013**

### MEETING HIGHLIGHTS:

#### *Plenary Sessions*

- >> Finding the Patient in Health Research & Policy
- >> Finding the Patient in the Drug Development Process
- >> Assessing the Evidence for Better Patient Care: A Health Care Decision-Maker Toolkit

• Short Courses • Issue Panels • Workshops • Research Podium & Poster Presentations • Educational Symposia • Exhibits

## Future ISPOR Meetings

### 2013



**ISPOR 18th Annual International Meeting**  
May 18-22, 2013  
New Orleans, LA, USA

Abstract Submission Deadline: January 17, 2013  
Early Registration Deadline: April 9, 2013



**ISPOR 4th Latin America Conference**  
12-14 September 2013  
Buenos Aires, Argentina

Abstract Submission Deadline: 21 March 2013  
Early Registration Deadline: 23 July 2013



**ISPOR 16th Annual European Congress**  
2-6 November 2013  
Dublin, Ireland

Abstract Submission Deadline: 25 June 2013  
Early Registration Deadline: 17 September 2013

### 2014



**ISPOR 19th Annual International Meeting**  
May 31-June 4, 2014  
Montreal, QC, Canada

Abstract Submission Deadline: January 16, 2014  
Early Registration Deadline: April 15, 2014



**ISPOR 6th Asia-Pacific Conference**  
6-9 September 2014  
Beijing, China

Abstract Submission Deadline: 20 March 2014  
Early Registration Deadline: 22 July 2014



**ISPOR 17th Annual European Congress**  
8-12 November 2014  
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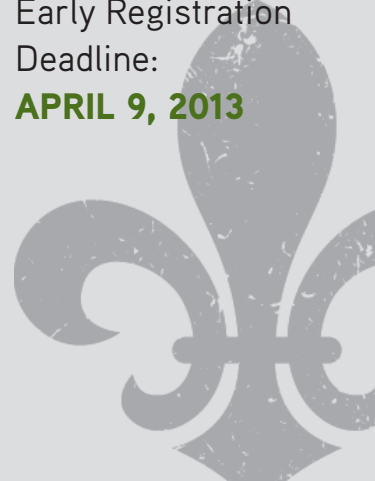
Patient-Centered Outcomes:  
Focusing on the Patient

Abstract Submission  
Deadline:

**JANUARY 17, 2013**

Early Registration  
Deadline:

**APRIL 9, 2013**



## CALL FOR ABSTRACTS

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# ISPOR 18th Annual International Meeting

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## ISPOR SHORT COURSES

### SATURDAY, MAY 18, 2013

#### ALL DAY COURSES 8:00AM-5:00PM

##### INTRODUCTION TO PHARMACOECONOMICS

This course demonstrates how to incorporate pharmacoeconomics into study design and data analysis. Participants learn to collect and calculate the costs of different alternatives, determine the economic impact of clinical outcomes, and to identify, track and assign costs to health care resources.

##### BAYESIAN ANALYSIS – OVERVIEW AND APPLICATIONS

This course provides an overview of the Bayesian approach and its applications to health economics and outcomes research. It covers basic elements of Bayesian statistics, contrasting briefly with classical statistics and introduces available statistical packages. Attendees then apply principles to data analysis problems using WinBUGS.

##### PHARMACEUTICAL/BIOTECH PRICING

Gain an understanding of the terminology and issues involved in pharmaceutical pricing decisions. Learn the tools to build and document product value. Use in-depth case studies to analyze the key steps of product pricing.

#### MORNING COURSES 8:00AM-12:00PM

##### INTRODUCTION TO RETROSPECTIVE DATABASE ANALYSIS

This course reviews analytic techniques and best practices to improve causal inference in studies using retrospective databases. Specific topics to be covered include: stratification analysis, multivariable regression, propensity scoring, instrumental variable and structural modeling techniques.

##### INTRODUCTION TO MODELING METHODS

This course introduces the principles and practice of decision analysis. Participants evaluate the appropriateness of decision analysis, construct simple decision trees, understand basic mechanics of tree evaluation and sensitivity analysis, and acquire skills in the interpretation of a published decision analysis.

##### INTRODUCTION TO PATIENT-REPORTED OUTCOMES

Conceptual, methodological, and practical methods for measuring quality of life, health status and other types of health outcomes are presented. Theoretical frameworks, reliability, validity, responsiveness, methods of administration, respondent and administrative burdens, and issues of analysis and interpretation are discussed.

##### INTRODUCTION TO CONJOINT ANALYSIS

This course introduces the conceptual basis for quantifying decision-maker preferences for medical interventions and the practical design and analytical issues that must be addressed to obtain valid empirical preference estimates.

##### COST-EFFECTIVENESS ANALYSIS ALONGSIDE CLINICAL TRIALS

This course presents design, conduct, and reporting of cost-effectiveness analyses alongside clinical trials based in part on the ISPOR RCT-CEA Task Force Report. Analyses guided by an analysis plan and hypotheses, an incremental analysis using an intention to treat approach, characterization of uncertainty and standards for reporting results are presented.

#### AFTERNOON COURSES 1:00PM-5:00PM

##### THE READER EXPECTATION APPROACH TO PROFESSIONAL WRITING

This short course will introduce participants to five essential components of professional writing, the first steps towards gaining new and better control of written communication.

##### META-ANALYSIS AND SYSTEMATIC REVIEWS IN COMPARATIVE EFFECTIVENESS RESEARCH

This course discusses six key areas: 1) comparative effectiveness research; 2) impetus for meta-analysis and systematic reviews; 3) basic steps to perform a quantitative systematic review; 4) statistical methods of combining data; 5) reporting of results; and 6) appraisal and use of meta-analytic reports.

##### FINANCIAL IMPACT / COST OF ILLNESS

This course will describe the methods used to estimate the budget impact of a new health care technology. Both static and dynamic methods for estimating the budget and health impact of adding a new drug to a health plan formulary will be presented.

##### UTILITY MEASURES

This course explores: concepts of health-related quality of life in terms of their differences and similarities; methods used to capture utilities (standard gamble, time trade off and rating scales); and instruments to measure quality of life (EQ-5D, Health Utilities Index and SF-36).

##### MODELING: DESIGN AND STRUCTURE OF A MODEL

This course reviews Markov models and other techniques, referencing the *ISPOR Principles of Good Practice for Decision Analytic Modeling in Health Care Evaluations*. Using a series of examples, the course reviews practical steps in developing and using these models.

### SUNDAY, MAY 19, 2013

#### ALL DAY COURSES 8:00AM-5:00PM

##### DISCRETE EVENT SIMULATION FOR ECONOMIC ANALYSES

This course provides a basic understanding of the key concepts of discrete event simulation. It focuses on the use of these models to address pharmacoeconomic (and device-related) problems. Students will use ARENA software to build simple models.

##### STATISTICAL CONSIDERATIONS IN HEALTH ECONOMIC EVALUATIONS

This course discusses the effect of distributional assumptions, analyzing univariate and multivariable analysis data, sample size and power calculations, sampling uncertainty, point estimates for variables, net monetary benefit, and confidence intervals for cost-effectiveness ratios.

#### MORNING COURSES 8:00AM-12:00PM

##### RISK-SHARING/PERFORMANCE-BASED ARRANGEMENTS FOR DRUGS AND OTHER MEDICAL PRODUCTS

There is significant and growing interest among payers and producers of medical products for arrangements that involve a "pay-for-performance" or "risk-sharing" element. Theory and practice, including incentives and barriers, of these arrangements will be analyzed along with several examples of performance-based schemes from Europe, the United States, and Australia.

##### ADVANCED DECISION MODELING FOR HEALTH ECONOMIC EVALUATIONS

Key aspects in the development of decision modeling, how models can be made probabilistic to capture parameter uncertainty, and how to analyze and present results are discussed. How results should be interpreted and decisions should be made (including decisions with uncertainty, expected value of perfect information [EVPI], and expected value of sample information [EVSII]) are presented.

##### BAYESIAN ANALYSIS – ADVANCED

This course focuses on the use of Markov Chain Monte Carlo methods in conducting policy-relevant outcomes research.

Participants engage in hands-on exercises and address certain methodological issues, concluding with a discussion on the role of Bayesian methods in policy-making.

##### APPLICATIONS IN USING LARGE DATABASES

This course reviews 3 databases – CPRD (UK database), GE Centricity electronic medical record (EMR) and Medicare (USA databases). Each database is discussed in-depth including directions on accessing information and how researchers utilize this information.

##### PATIENT-REPORTED OUTCOMES – ITEM RESPONSE THEORY

Applications of IRT have increased considerably because of its utility for instrument development and evaluation, assessment of measurement equivalence, instrument linking, and computerized adaptive testing. This short course discusses the basics of IRT models and applications to improve health outcomes measurement.

##### INSTRUMENTAL VARIABLES IN ADDRESSING SELECTION BIAS IN OBSERVATIONAL STUDIES

Sample selection models provide a test and correction for the presence of selection bias, enabling an investigator to obtain unbiased estimates of treatment effects. This course discusses various models and their applications, in particular instrument variables.

#### AFTERNOON COURSES 1:00PM-5:00PM

##### OUTCOMES RESEARCH FOR MEDICAL DEVICES AND DIAGNOSTICS

This course presents outcomes research practices specifically tailored for the medical device and diagnostics technology environment. Outcomes research for medical devices and diagnostics is differentiated from other health care interventions. The evidence hierarchy for medical devices and diagnostic procedures is discussed.

##### NETWORK META-ANALYSIS FOR INDIRECT TREATMENT COMPARISON

Based in part on two ISPOR Task Force Reports on Indirect Treatment Comparisons, the fundamentals and concepts of network meta-analysis are presented. The material in this course is motivated by instructive and real examples implemented with the WinBUGS package.

##### PROPENSITY SCORES AND OBSERVATIONAL STUDIES OF TREATMENT EFFECT

Discuss how propensity scores can be used to mitigate confounding, the advantages and disadvantages of standard adjustment relative to propensity score-based methods, details of propensity score methodology and risk adjustment models.

##### ESTABLISHING THE CONTENT VALIDITY OF PATIENT-REPORTED OUTCOMES (PRO) INSTRUMENTS

Review definitions of evidence requirements, issues necessitating clarity, and logistical needs for gathering acceptable evidence. Participants take part in practical exercises to determine and establish evidence of content validity for PRO, ClinRO & ObsRO instruments.

##### NEW! AGENT-BASED MODELING (ABM) FOR ECONOMIC EVALUATIONS

This course covers basics of ABMs (drugs, vaccines, medical devices, etc.), areas of applications and hands-on tutorials using NetLogo.

##### NEW! VALUE OF INFORMATION AND PROBABILISTIC ANALYSIS

This course will present how to conduct probabilistic sensitivity analysis and then assess the cost of uncertainty using value of information analysis.

GO TO [WWW.ISPOR.ORG](http://WWW.ISPOR.ORG) FOR COMPLETE SHORT COURSE DESCRIPTIONS





# ISPOR 18th Annual International Meeting

May 18-22, 2013 • Sheraton New Orleans Hotel, New Orleans, LA, USA

## CALL FOR ABSTRACTS

Abstract Submission Begins: October 17, 2012 / Abstract Submission Deadline: January 17, 2013

### SUBMISSION INSTRUCTIONS

All abstracts and proposals MUST be submitted through ISPOR's online abstract submission system by January 17, 2013.

Abstracts accepted for other ISPOR meetings can NOT be submitted and research published or presented at other national or international meetings is discouraged.

**SUBMISSION INSTRUCTIONS, EXAMPLES & SPECIFIC EVALUATION CRITERIA AVAILABLE AT [www.ispor.org](http://www.ispor.org)**

#### RESEARCH ABSTRACTS

Outcomes research on all health care interventions (including drugs, devices, behavioral modification programs, surgery, disease prevention, gene therapy, screening, diagnostic procedures and health education) and on all diseases or health disorders are considered. Research abstracts (except for conceptual papers) must be organized by OBJECTIVES, METHODS, RESULTS, CONCLUSIONS. All accepted research abstracts are published in *Value in Health* as submitted. Accepted research is presented as a 15 minute podium presentation or poster presentation (with a poster author discussion hour). Abstracts are evaluated on the quality of the study (or concept) and quality of the abstract presentation.

Research topics include: **Clinical Outcomes Studies, Cost Outcomes Studies, Patient-Reported Outcomes & Patient Preference Studies, Health Care Use & Policy Studies, Research on Methods, Conceptual Papers.** See the ISPOR website for research subtopics, diseases and health care treatments.

#### ISSUE PANEL PROPOSALS

Issue panel proposals should show real debate on new or controversial issues in health economics and outcomes research or real debate on the use of outcomes research in health care decision-making. Issue panel proposals must be organized MODERATOR, PANELISTS, ISSUE, OVERVIEW. An accepted issue panel is one hour in duration with a moderator and 2-3 panelists representing different organizations. Panelists should present distinct views about the topic.

Issue Panel topics are: **Clinical Outcomes Research Issues, Economic Outcomes Research Issues, Patient-Reported Outcomes & Patient Preference Research Issues, Health Policy Development Using Outcomes Research Issues.** See the ISPOR website for issue panel subtopics.

Issue Panel proposals on the theme of the meeting "Patient-Centered Outcomes: Focusing on the Patient" will be given priority consideration.

#### WORKSHOP PROPOSALS

Workshop proposals should show novel and innovative experiences in the conduct of outcomes research (including, but not limited to, experiences with conjoint analysis, large database analysis, modeling, observational studies, record review, surveys, sensitivity analysis and patient registries) or novel and innovative experiences in the use of outcomes research (clinical, economic, or patient-reported/patient preference outcomes) in health care policy development. Workshop proposals must be organized by DISCUSSION LEADERS, PURPOSE, DESCRIPTION. Accepted workshops are one hour in duration with a minimum of 2 and maximum of 4 discussion leaders (more than one organization must be represented). An audience interactive element must be included in the proposal and during the workshop.

Workshop topics include: **Clinical Outcomes Research, Economic Outcomes Research, Patient-Reported Outcomes & Patient Preference Research, Use of Real World Data, Health Policy Development Using Outcomes Research.** See the ISPOR website for workshop subtopics.

Workshop proposals on the theme of the meeting "Patient-Centered Outcomes: Focusing on the Patient" will be given priority consideration.

## PRELIMINARY PROGRAM

MONDAY, MAY 20: 7:15AM-7:15PM

### FIRST PLENARY SESSION: FINDING THE PATIENT IN HEALTH RESEARCH & POLICY

The new buzz words are 'patient-centered' and 'patient-focused'. Why is the focus on the patient? Why wasn't the focus on the patient before now? What is being done differently to truly focus on the patient in health care delivery and health technology (drug) development? During this session, steps for assuring the patient is the focus of health care delivery and drug development will be presented from the perspective of the FDA, PCORI (Patient-Centered Outcomes Research Institute) and a patient advocate. The new FDA patient-focused drug development program, as well as the PCORI research agenda, will be discussed. In addition, the definition of patient-centered outcomes, and its use by these organizations will be explored. The patient advocate will provide a realistic point-of-view of 'focusing on the patient'.

\*20 Research Podium Presentations \* 5 Issue Panels \* 7 Workshops \* 7 ISPOR Group Forums \* Exhibits \* 600 Research Poster Presentations – Session I & II

TUESDAY, MAY 21: 7:15AM-7:15PM

### SECOND PLENARY SESSION: FINDING THE PATIENT IN THE DRUG DEVELOPMENT PROCESS

During the first phases of the drug development process, researchers are focusing on a technology (drug) for treating a disease or disorder at a molecular or mechanism of action level. However, during the technology development process, when is the patient's well-being actually taken into consideration - Phase II or Phase III or ever? During this session, whether the patient's well-being 'is' or 'is not' being considered during the drug development process will be debated from the perspective of a pharmaceutical company, the FDA, and most importantly – the patient. This session will include a pharmaceutical company CEO, a patient advocate, and the FDA.

\* 40 Research Podium Presentations \* 5 Issue Panels \* 14 Workshops \* 7 ISPOR Group Forums \* Exhibits \* 600 Research Poster Presentations – Session III & IV \* Evening Social Event

WEDNESDAY, MAY 22: 7:15AM-4:00PM

### THIRD PLENARY SESSION: ASSESSING THE EVIDENCE FOR BETTER PATIENT CARE: A HEALTH CARE DECISION-MAKER TOOLKIT

ISPOR, in cooperation with the Academy of Managed Care Pharmacy (AMCP) and the National Pharmaceutical Council (NPC), have developed a health care decision-maker toolkit to help decision-makers assess and effectively use available data, with the goal of improving evidence-based health care decision making and ultimately improving patient health. The toolkit contains web-based questionnaires focusing on 'relevance' and 'credibility' when assessing the evidence from prospective and retrospective observational studies, as well as modeling and indirect treatment comparison evidence synthesis studies. These educational tools help users in reviewing evidence and provide information and assistance in the review and effective use of the information. During this session, the elements of this toolkit for these four types of studies, as well as the use of these tools by health care decision-makers for better patient care will be presented.

\* 5 Issue Panels \* 10 Workshops \* Exhibits \* 300 Research Poster Presentations – Session V

**OVER 2900 ATTENDEES IN 2012!**

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## REGISTRATION FORM



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### PRE-MEETING SHORT COURSES THROUGH APRIL 9, 2013 AFTER APRIL 9, 2013 FEE

#### SATURDAY, MAY 18, 2013

<b>ALL DAY COURSES 8:00AM-5:00PM</b>	Regular fee: \$300 Student fee: \$150	Regular fee: \$400 Student fee: \$200	
<input type="checkbox"/> Introduction to Pharmacoeconomics			\$ _____
<input type="checkbox"/> Bayesian Analysis – Overview and Applications			\$ _____
<input type="checkbox"/> Pharmaceutical/Biotech Pricing			\$ _____
<b>MORNING COURSES 8:00AM-12:00PM</b>	Regular fee: \$150 Student fee: \$75	Regular fee: \$200 Student fee: \$100	
<input type="checkbox"/> Introduction to Retrospective Database Analysis			\$ _____
<input type="checkbox"/> Introduction to Modeling Methods			\$ _____
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<b>AFTERNOON COURSES 1:00PM-5:00PM</b>	Regular fee: \$150 Student fee: \$75	Regular fee: \$200 Student fee: \$100	
<input type="checkbox"/> The Reader Expectation Approach to Professional Writing			\$ _____
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<input type="checkbox"/> Modeling: Design and Structure of a Model			\$ _____

#### SUNDAY, MAY 19, 2013

<b>ALL DAY COURSES 8:00AM-5:00PM</b>	Regular fee: \$300 Student fee: \$150	Regular fee: \$400 Student fee: \$200	
<input type="checkbox"/> Discrete Event Simulation for Economic Analyses			\$ _____
<input type="checkbox"/> Statistical Considerations in Health Economic Evaluations			\$ _____
<b>MORNING COURSES 8:00AM-12:00PM</b>	Regular fee: \$150 Student fee: \$75	Regular fee: \$200 Student fee: \$100	
<input type="checkbox"/> Risk-Sharing/Performance-Based Arrangements for Drugs and Other Medical Products			\$ _____
<input type="checkbox"/> Advanced Decision Modeling for Health Economic Evaluations			\$ _____
<input type="checkbox"/> Bayesian Analysis – Advanced			\$ _____
<input type="checkbox"/> Applications in Using Large Databases			\$ _____
<input type="checkbox"/> Patient-Reported Outcomes – Item Response Theory			\$ _____
<input type="checkbox"/> Instrumental Variables in Addressing Selection Bias in Observational Studies			\$ _____
<b>AFTERNOON COURSES 1:00PM-5:00PM</b>	Regular fee: \$150 Student fee: \$75	Regular fee: \$200 Student fee: \$100	
<input type="checkbox"/> Outcomes Research for Medical Devices and Diagnostics			\$ _____
<input type="checkbox"/> Network Meta-analysis for Indirect Treatment Comparison			\$ _____
<input type="checkbox"/> Propensity Scores and Observational Studies of Treatment Effect			\$ _____
<input type="checkbox"/> Establishing the Content Validity of Patient-Reported Systems (PRO) Instruments			\$ _____
<input type="checkbox"/> <b>NEW!</b> Agent-Based Modeling (ABM) for Economic Evaluations			\$ _____
<input type="checkbox"/> <b>NEW!</b> Value of Information and Probabilistic Analysis			\$ _____

### MEETING REGISTRATION May 20-22, 2013 THROUGH APRIL 9, 2013 AFTER APRIL 9, 2013 FEE

<b>STANDARD</b>	Member \$650 Non-Member* \$790	Member \$750 Non-Member* \$890	\$ _____
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<b>FULL-TIME GOVERNMENT AND ACADEMIA</b>	Member \$350 Non-Member* \$490	Member \$450 Non-Member* \$590	\$ _____
<b>FULL-TIME STUDENTS</b> (must provide current enrollment docs)	Member \$150 Non-Member* \$185	Member \$200 Non-Member* \$235	\$ _____
<b>ONE DAY REGISTRATION (PER DAY)**</b>	Member \$350 Non-Member* \$490	DAY: __ May 20 __ May 21 __ May 22	\$ _____

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<b>CONTINUING EDUCATION ACCREDITATION (CPE &amp; CME)</b>	Member \$100 Non-Member* \$100	\$ _____
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\*\* **ONE DAY REGISTRATION DETAILS:** One day registration cannot be combined.

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## Quintiles acquires Outcome to offer full spectrum of interventional and observational research

Regulators, payers, prescribers and patients demand to know about your product in the real world. That's why Quintiles, a leader in interventional IIIB/IV studies, recently acquired Outcome Sciences, the unparalleled experts in observational research. Together, we offer the expertise and experience in real-world and late phase research that you need to determine the right approach for the right question. Whatever your research objectives — from monitoring safety and evaluating benefit-risk, to demonstrating effectiveness and gaining market access, to proving efficacy in new indications — our experts provide you with the most comprehensive approach to evidence development.

More at [www.quintiles.com/outcome](http://www.quintiles.com/outcome)



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- Demonstrate economic value
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US +1 866 458 1096  
EU +44 (0) 20 8834 0100  
[unitedbiosource.com](http://unitedbiosource.com)



International Society for Pharmacoeconomics and Outcomes Research  
505 Lawrence Square Blvd South  
Lawrenceville, NJ 08648 USA

