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LETTER FROM THE EDITOR

ISPOR CONNECTIONS continues to grow and expanding with the success of the organization. In today's issue you will see two of the changes thus far: a new cover design and headings for original articles. Articles will be classified into three categories: economic evaluations, outcomes assessments, and policy analysis.

The mission of this publication is to: “bridge the gap” between the conduct of pharmacoeconomics and outcomes research and the use of it in making health care decisions worldwide. In keeping with our mission to maintain an international perspective, the ISPOR CONNECTIONS technical news journal provides an array of articles covering economic evaluations, outcomes assessments, and policy analysis from around the world.

We are very interested in publishing summaries or insights on country-specific government guidelines or policies related to pharmacoeconomics/health economics and outcomes research. If your country has recently introduced or changed their position on the use of pharmacoeconomics/health economics and outcomes research for coverage, reimbursement decisions, or other health care decisions, we welcome an article from you about this change. Your insight is of great value and interest to all ISPOR members.

Finally, please remember that your constructive comments are always welcome. If you especially like something in past issues or this current issue, or have suggestions on how to improve this publication, be sure to send us an e-mail at: info@ispor.org.

Respectfully,

Steve E. Marx PharmD, MS, Editor-in-Chief

Steve E. Marx PharmD, MS, Editor-in-Chief
Pharmacoeconomics and Market Access in Europe: Case Studies in Scotland and The Netherlands

Keith Tolley MSc, Director, Market Access Unit Mapi Values, Macclesfield, UK, and Maarten Postma, University of Groningen, Groningen, The Netherlands

(This paper is based on the Workshop that the authors organised during the last European Conference of ISPOR in Florence (6-8 November 2005). Maarten Postma is a member of the Dutch “Commissie Farmaceutische Hulp” (CFH), Keith Tolley is an economic assessor for the New Drugs Committee of the Scottish Medicines Consortium (SMC). The CFH advises on the reimbursement of new drugs, whilst the SMC issues guidance on the use of new drugs and indications to the National Health Service in Scotland. The views expressed in this article are the responsibility of the authors and do not necessarily represent the opinions of the CFH or NDC/SMC.)

Introduction
Pharmacoeconomics has become established as a valuable aid to drug reimbursement, pricing and market access decisions for new drugs in many European countries. However, to be useful for such purposes, the methods used should be robust and the results of pharmacoeconomic evaluations timely. To aid robustness, guidelines for the conduct of pharmacoeconomic studies have been produced in numerous countries - many of these guidelines have been summarised and are available on the ISPOR website [1].

Timeliness for market access decisions means that pharmacoeconomic evidence is required at or around launch of a new product.

In this article we provide an overview of two established European agencies that use pharmacoeconomics as part of a system of rapid technology appraisal to aid reimbursement and market access decisions for new drugs at launch: the Scottish Medicines Consortium (SMC) and the Netherlands "Commissie Farmaceutische Hulp" (Committee for Pharmaceutical Help; CFH).

Scottish Medicines Consortium
The Scottish Medicines Consortium came into being in 2002. It provides guidance and recommendations to Health Boards in Scotland on the use of all new pharmaceuticals, covering new chemical entities and new indications for existing licensed drugs (launched since 2002). The SMC appraisal represents a two-stage process.

The first stage involves a company submission to the New Drugs Committee (NDC) of the SMC of the clinical and health economic data supporting the new product/indication. This submission is reviewed in detail by an NDC review team consisting of a clinical assessor, an economic assessor and a lead assessor (the latter is the only one of the three who is a full member of the NDC). Final draft guidance on the clinical and cost-effectiveness of the product, and a recommendation on use (which can be one of accepted for use, accepted for restricted use, or not accepted) is drawn up by the NDC. The NDC stage involves only consideration of the clinical and cost-effectiveness evidence supporting the drug.

The second stage of the process involves consideration of the draft guidance by the SMC Committee including a response by the manufacturer (who are sent the draft guidance after the NDC meeting), but also taking into account other factors such as budget impact, level of unmet need or innovativeness of the drug, precedence regarding earlier decisions for drugs in the same class/patient group, and patient advocacy submissions. The final guidance is issued by the SMC and posted on the SMC website about a month later.

It is not the intention here to go into detail about the process involved in an SMC submission - this is adequately covered on the SMC website at: www.scottishmedicines.org.uk. However, a number of observations can be made about the NDC and SMC process and the methods/approaches adopted for pharmacoeconomic analysis.

The SMC review at least provides a test bed for the health economic analyses, and the first indication of the strength of the economic case for the product.

Firstly, the whole process takes about 4 months to complete from receipt of manufacturer submission to final guidance being issued on the SMC website (assuming no appeal). This rapidity has the advantages of timeliness associated with delivery of guidance to the health boards in Scotland soon after the introduction of a new drug, and allows manufacturers with positive recommendations rapid access to the market (especially as manufacturers can submit prior to launch and plan to receive guidance straight after launch). The downsides are the limitations of clinical data at launch for pharmacoeconomic analysis producing high uncertainty in the cost-effectiveness results, a greater risk of false negatives or false positives due to speed of appraisal, and the possibility that cost-effectiveness of a product can change over time i.e. generally improve, for example due to dose reductions over time, or new clinical/economic evidence. Although not currently undertaken, this latter concern could be somewhat addressed via the use of a formal review period, whereby the original recommendation is reviewed by the SMC say 2-3 years later if there are reasons to do so (e.g. new evidence).

Secondly, whilst the process is rapid, it does not mean it lacks robustness in the technical requirements for the pharmacoeconomic submission. The guidelines for the pharmacoeconomic submission are available on the SMC website and are based on (but do not completely follow) NICE methodological guidance [2]. The preference is for net cost per QALY data for the new product >
(although other forms of economic evaluation are accepted if appropriate),
with choice of comparator(s) representing the drugs most likely to be
displaced in Scotland. If, as typically occurs, there is a lack of head to head
data against such comparators this has to be overcome through the use of
direct comparisons involving systematic review, meta analysis or other forms
of evidence synthesis. In addition, the time horizon has to be appropriately
specified and, if lifetime, adequately modelled from the shorter term data.
Resource utilisation and utility data should be robustly collected and suffi-
ciently relevant to the Scotland/UK context, and a full and transparent sensi-
tivity analysis should be conducted. Adherence to good decision analytic/
modelling practice (e.g. in the use of Markov models) is also very important.
There should be a clear link between the clinical evidence submitted and the
economic evidence. Currently, NDC requirements are (arguably) not as string-
ent as NICE, for example, probabilistic sensitivity analysis is not mandato-
ry and there is not a set reference case that needs to be followed. However,
unlike NICE, if no economic case is submitted the product will get an auto-
matic negative recommendation.

Thirdly, the onus is placed on the submitting manufacturer to be convincing
and transparent in the pharmacoeconomic case presented. Rejection of the
economic case is generally on one of two grounds:

a) The submission is transparent and pharmacoeconomic submission of
good quality, but the incremental cost per QALY is considered too high (i.e.
typically above £25-35,000 per QALY, although no formal threshold applies).
Not surprisingly, this reason for rejection is relatively uncommon, and

b) There are flaws or a lack of transparency in one or more key aspects of
the pharmacoeconomic submission, such that the assessor cannot deter-
mine the actual cost-effectiveness of the product. Most rejections are on this
ground (i.e. the economic case has not been demonstrated).

Hence, it is important for the manufacturer to make sure they are using suf-
ficiently robust pharmacoeconomic methods (but not over-complex) and fol-
lowing SMC guidelines. There is likely to be sympathy to limitations in data
faced by manufacturers, but this should not preclude efforts to produce a
sufficiently robust pharmacoeconomic model for the submission. Planning
early can help overcome some of these problems.

**Figure 1** New Drug Committee (NDC) and final SMC
recommendations Jan-Oct 2004 (n=46 full appraisals)

![Figure 1](image)

Figure 1 presents the recommendations issued by the SMC over the period
Jan-October 2004. The impact of the two stage process can be clearly seen
with just less than 70% of drugs reviewed over this period receiving a posi-
tive recommendation, but only 42% being accepted on the clinical and eco-

nomic evidence presented at the NDC stage. As mentioned other factors
come into play at SMC stage, but also some of the changed decisions may
have come about as a result of improved clarity in the pharmacoeconomic
case on the part of the manufacturer.

It is not currently clear what impact SMC guidance is having on clinical prac-
tice even in Scotland (although this is being investigated in a research proj-
due to report in 2007), let alone outside of Scotland. However, anecdo-
tally it appears to be having an impact. As the UK is often the first to launch
market, the SMC is likely to be the first HTA type body a manufacturer of a
new drug will have to submit to. Hence, the SMC review at least provides a
test bed for the health economic analyses, and the first indication of the
strength of the economic case for the product. This means it is important for
the manufacturer to be prepared with a robust economic model, especially
with the advent of the NICE single technology appraisal programme likely to
raise the stakes in the UK and beyond.

**Commissie Farmaceutische Hulp (CFH), The Netherlands**

From January 1st 2005 in the Netherlands, a favourable cost-effectiveness
result has become a further criterion for reimbursement, after quality (good
laboratory practices), safety, and effectiveness have been established. In
particular, manufacturers of new drugs who claim added “therapeutic value”
for their product must, in addition to a therapeutic file, submit an economic
to the Council for Health Insurance (“College voor Zorgverzekeringen”;
CvZ). These drugs aim for a listing on section 1B of the Dutch reference pric-
ing system (“Geneesmiddelen VergoedingsSytem; GVS). If newly registered
drugs are deemed comparable to existing drugs, they are clustered in sec-
tion 1A and a fixed maximum price applies. An economic submission is not
required for such drugs, which are typically “me-too’s” and generics.
However, to attain 1B listing an economic submission is required - which
should consist of a cost-effectiveness or cost-utility analysis with preferred
outcomes in net costs per life-year gained or QALY gained, but not a cost-
minimisation analysis. The “Commissie Farmaceutische Hulp” (CFH), advis-
es CvZ on reimbursement issues and pharmacoeconomists have participat-
ed on the CFH for several years now.

The “cost-effectiveness” 4th hurdle that was erected in The Netherlands in
2005 was not a sudden event. For some years previously an arrangement
had been in place whereby manufacturers were free to add an economic file
to their reimbursement claim. However, this was not mandatory.
Nonetheless, in many cases manufacturers took the opportunity to submit a
pharmacoeconomic case. For example, economic files were submitted prior
to 2005 to underpin reimbursement claims for clopidogrel (Plavix®) and
pimecrolimus (Elidel®). These voluntary submissions enabled all parties
(the manufacturers, CvZ and CFH) to gather experience on how to handle the
pharmacoeconomic aspect of reimbursement submissions.

In dealing with the economic files, CFH and CvZ have made use of 19 guide-
lines for pharmacoeconomic research, derived from the Institute for Medical
Technology Assessment in Rotterdam that were developed in 1999 [3].
Important guidelines include the use of an appropriate perspective, the
choice of appropriate comparator, the discount rate to be used, and the need
for an adequate time horizon. CFH/CvZ determine an overall score based on
adherence to these guidelines, which contributes to the final assessment of
the quality of the pharmacoeconomic claim. For example, the company sub-
mission for the anti-platelet drug clopidogrel adhered to more than 60% of
the guidelines. Ultimately, it is the CvZ who advise the Ministry of Health -on
the basis of the CFH-advice - on the quality of the pharmacoeconomic file
submitted. In principle, this could mean an advice to the Minister to interpre-
t the economic file as adequate (for example, adhering to all important guide-
line items), even if the evidence for the drug is that it is not sufficiently cost-
effective. For the latter consideration, there are only informal thresholds used in the Netherlands, often around €20,000 per life-year or QALY gained.

The pharmacoeconomic guidance of the CFH/CvZ can be found on www.cvz.nl, but is only available in the Dutch language.

The main similarity between the CFH model and the NDC/SMC approach is in the timing of the assessment, with the pharmacoeconomic evaluation being based on the clinical data available at or soon after registration. Given this timing, in both countries only Phase III clinical studies are usually available to judge the clinical and cost-effectiveness of new drugs, which is opposite to the situation for full NICE appraisals which may be conducted several years post registration when observational data on drug utilization and outcomes is more likely to be available.

In addition, some of the key differences and similarities of the systems applied by CvZ/CFH- and NDC/SMC are:

- Both operate with a pharmacoeconomic checklist and use explicit “state of the art” guidelines for pharmacoeconomic research, although with some differences in content;
- For both the time from starting the assessment to actual advice being issued is 3-4 months;
- SMC-guidance is intended as a recommendation to local authorities in Scotland on the use (and indirectly the funding) of a new drug, whereas CvZ/CFH advice is specifically for determination of the reimbursement status of new drugs;
- SMC evaluates all new drugs and indications (whether hospital or non-hospital), whereas CvZ/CFH is primarily directed at the non-hospital market, and within this only those drugs that claim added value compared to the existing drugs for a specific indication;
- For CvZ/CFH a user-friendly electronic version of the pharmacoeconomic model is required, whereas NDC/SMC does not typically request the manufacturer’s electronic model;
- CvZ/CFH only advises on the quality of the economic file, whereas NDC attempts an assessment of whether the drug can be considered cost-effective or not;
- SMC may be overruled later by guidance from a full NICE appraisal, so in a sense it may be perceived as a preliminary recommendation; CvZ/CFH provide a final advice unless the manufacturer re-appeals; and
- SMC allows input from experts and patient advocacy groups, whilst this only occurs in exceptional circumstances for CvZ/CFH.

Of course, both the CvZ/CFH and the SMC can issue negative recommendations. This may not be due to the pharmacoeconomic submission alone. The clinical evidence may be limited to show therapeutic benefit, often due to weak study design, too small numbers or absence of evidence on “hard endpoints”, i.e. mortality and clinically relevant morbidity. Furthermore, the evidence in the clinical studies is not against the comparator drug or technology used in actual practice, leading to problems reconciling the clinical and pharmacoeconomic sections. Also, all assumptions (e.g. for resource use) in the economic model should be based on robust, ideally published data sources, which is not always the case. 

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Table 1 shows the outcomes of the evaluations for 3 selected drugs with economic files for CvZ/CFH, SMC and NICE. This illustrates how, due to a range of factors (both evidence based and other factors), outcomes can vary even across decision making bodies that have a similarly high technical standard for pharmacoeconomic submissions.

The status of the CvZ/CFH-advice is changing as a new health insurance system is being adopted in the Netherlands from January 1st 2006, with more independence in decision making being given to individual health insurance companies. Indeed, a number of individual insurance companies have already “overruled” CvZ/CFH advice and reimbursed methylphenidate OROS. Additionally, an extension of the reimbursement system to require pharmacoeconomic files for in-patient drugs to show added value is expected in The Netherlands.

Conclusions

Recent developments at NICE is a new programme of rapid single technology appraisals of new drugs/indications at launch [4]. This has started in 2006, initially for selected anti-cancer drugs. It is therefore interesting, and also to provide learnings for NICE, to assess experiences at SMC and CFH regarding the use of pharmacoeconomics as part of a process of rapid technology appraisal. Also, one of our aims in the original ISPOR workshop was to assess similarities and differences between the SMC and CFH, and so we have attempted to cover this objective in this article.

References


Table 1

<table>
<thead>
<tr>
<th>Drug</th>
<th>CvZ/CFH</th>
<th>NDC/SMC</th>
<th>NICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clopidogrel (Plavix®) for acute coronary syndromes</td>
<td>reimburse for 6 mths</td>
<td>maximum benefit from use identified as 3 mths</td>
<td>use for 12 months</td>
</tr>
<tr>
<td>Pimecrolimus (Elidel®) for atopic dermatitis</td>
<td>negative</td>
<td>negative</td>
<td>positive</td>
</tr>
<tr>
<td>Methylphenidate OROS (Concerta®) for ADHD</td>
<td>negative</td>
<td>positive</td>
<td>positive</td>
</tr>
</tbody>
</table>

Table 1 shows the outcomes of the evaluations for 3 selected drugs with economic files for CvZ/CFH, SMC and NICE. This illustrates how, due to a range of factors (both evidence based and other factors), outcomes can vary even across decision making bodies that have a similarly high technical standard for pharmacoeconomic submissions.
ISPOR has recently had an exchange of correspondence with the Journal of the American Medical Association (JAMA). We were concerned about JAMA’s policy, whereby submissions from pharmaceutical, devices, or biotech industry authors may have to be checked by an independent academic statistician prior to publication, a requirement that was not being placed on submissions from other sources [1]. From ISPOR’s viewpoint, it seemed to imply that some of our members were more dishonest, or more incompetent, than others.

JAMA’s reply was interesting. First, the journal claimed that the requirement was to compensate for the fact that in the case of submissions from other parties, such as academic institutions, the Journal could ask for extra scrutiny from the Dean of the faculty or other senior academics concerned with maintaining standards. Perhaps my experience is different from that of other academics, but the only monitoring my Dean or Head of Department ever did focus on how much grant income I was bringing in!

The other thing JAMA said was that if we didn’t believe that some parties were capable of making mistakes, or potentially misleading the public, we should read the newspapers!

The fact that the pharmaceutical industry occasionally makes mistakes, is caught withholding information, or puts an inappropriate spin on findings does not help its credibility. However, it is important not to jump to quick conclusions about the motives that produce these outcomes. Hill et al. [2], in reviewing 326 submissions to the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia found 249 methodological problems. However, they did not claim that the errors were necessarily intentional. Of course, on occasions governments have also been known to be economical with the truth and in some countries, such as the US, the payers or decision-makers face similar commercial motivations to those of the pharmaceutical, devices or biotech industries. Even academics may be under considerable pressure to produce exciting results, as some of the controversies over cloning have shown.

The fact that the pharmaceutical industry occasionally makes mistakes, is caught withholding information, or puts an inappropriate spin on findings does not help its credibility. However, it is important not to jump to quick conclusions about the motives that produce these outcomes.

I have always found credibility to be an elusive concept. In an average week, on Monday I might be working on a methodological piece of research, funded by a body such as the Medical Research Council in the UK, or the National Institutes of Health in the US. Here, according to the JAMA philosophy, my credibility is likely to be very high. It may still be high on Tuesday, when I could be working on a technology assessment review funded by the UK’s National Institute for Health and Clinical Excellence (NICE). However, on Wednesday my credibility may all but disappear if I am working on a product-related piece of research funded by a pharmaceutical company, and JAMA would probably want to have my work checked. Not being able to face the weekend with such low esteem, I am grateful that, on Friday, I may be Chairing one of NICE’s Guidelines Review Panels, where my credibility will again rise.

So what can we do to maintain credibility? My view is that the only way forward is to continue to strengthen the quality of methods, the transparency of studies and the rigour of the processes for evaluating health services research. Professional societies like ISPOR can, and do, make a contribution, through initiatives such as the Good Research Practices Task Forces. However, these voluntary measures probably need supplementing by rigorous review procedures. By strengthening its procedures, JAMA had it partially right. However, the new regime should have been applied to all submissions, without making assumptions about various organizations’ capabilities for self-regulation. All those involved in health services research face numerous pressures and constraints which may occasionally conspire to lead them away from the straight and narrow.

Credibility is important to all those involved in health services research. However, we should be judged by how we behave not by who we are.

References
The German IQWiG - It’s Not NICE Benefit Assessment in Germany - New Sense or Nuisance?

Christian Conrad, Novartis Pharma GmbH, Nuremberg, Germany

In July 2004, the “Institute for Quality and Economic Efficiency in Health Care” (Institut fuer Qualitaet und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) was officially founded and established in Cologne in the form of a private foundation. Most of the current assessments were assigned in February 2005 (see below).

Some still refer to the IQWiG as the “German NICE”, although methods and objectives are fairly different from UK’s National Institute for Health and Clinical Excellence (NICE).

The German institute is comparable to HTA bodies in other countries but follows its own self-formulated “methods” (version 1.0 of March 2005, to be found on the institute’s website). First of all, cost-benefit assessment of pharmaceuticals is not one of the IQWiG’s tasks, although one might come to this conclusion reading the terms “Economic Efficiency” in the IQWiG title. Hence, IQWiG will not consider QALYs (Quality Adjusted Life Years) within its evaluation and there is currently no need for health economic modeling.

Assessment process

Assessments are commissioned by the “Joint Federal Committee” of physicians and health insurance funds (“Gemeinsamer Bundesausschuss”, G-BA) or the Ministry of Health. Unlike NICE, dialog, external exchange of information or hearing procedures of the IQWiG, e.g. with manufacturers or patients, are not directly subject to a formalized process.

Timelines are not as closely defined, as it is the case for the technology appraisal process in the UK. Approximately nine months had initially been planned to conduct an IQWiG-assessment, although this has not been achieved with current assessments.

It is worthwhile mentioning that study selection and inclusion criteria follow IQWiG internal standards and may vary substantially from assessment to assessment (e.g. duration of studies included, minimum patient number required). In many cases; these requirements can neither be derived from international recommendations (e.g. guidelines by the European marketing authorization institution EMEA or the international medical expert societies) nor do they meet standards that used to apply during the conceptualization and implementation of studies in these therapeutic indications. As a result, only selected partial quantities of the existing evidence are being viewed.

The evaluation criteria are defined in the corresponding “report schedules” (project descriptions) of the IQWiG, which are issued at the beginning of each assessment process; they are not discussed with concerned manufacturers. There is no such thing as a formal scoping workshop with manufacturers, although the IQWiG is free to consult any external expertise.

During the assessment process, the IQWiG will seek national as well as international scientific advice via external peer reviews to evaluate existing data. At this stage of the assessment, external experts are not made known to the public.

IQWiG will concentrate on head to head trials, it will focus on morbidity and mortality and it is unlikely that IQWiG will consider compliance or most of the commonly accepted surrogate endpoints as relevant factors.

After internal review and publication of an assessment pre-report, there is a timeline of four weeks for the manufacturers and other concerned parties to comment on the report. To structure this input, a form is provided by the IQWiG, restricting the comments to six pages. There are also substantial restrictions concerning the contents of the statement: study design etc. may not be discussed, comments have to address mainly formal issues of the previous assessment, e.g. comments on studies that have been missed by the institute.

The IQWiG may also invite patients or manufacturers and other experts for a hearing. The hearing is not mandatory. The (revised) report will finally be submitted to the G-BA for further processing and implementation.

It also has to be emphasized that none of the IQWiG’s assessments and recommendations of the final report will become effective before the G-BA converts the recommendations into binding guidelines (e.g. via so-called “Arzneimittelrichtlinien”, drug guidelines). After an IQWiG assessment, the G-BA may or may not evaluate any further aspects (e.g. related to drug costs), based on the IQWiG’s recommendations. Therefore, one may consider the IQWiG as the “assessment” body whereas the G-BA comprises the “appraisal” committee.

There is no explicit need for the G-BA to follow the IQWiG’s recommendations, although it might be difficult to completely ignore the previous findings. The G-BA may also consider the opinion of additional experts to challenge the results of an assessment and would then have to include additional evidence that had previously been ignored by the IQWiG due to restrictive data selection criteria.

However, even before any authorization and implementation by the G-BA, one may postulate an effect of the IQWiG’s publications (e.g. via the internet), as physicians (and their associations) or other organizations (as statutory health insurance companies) are certainly going to recognize, refer to and distribute the preliminary recommendations, e.g. to influence prescription behavior. The relevance and effects of such a premature use of preliminary recommendations are highly debatable.

Main tasks of the IQWiG are (as legally defined):
• Research, representation and assessment of current medical findings on diagnostic and therapeutic procedures for selected diseases;
• Generation of scientific papers, expert reports and statements on questions of quality and economic efficiency of the services rendered under statutory health insurance (SHI);
• Assessment of evidence-based guidelines for the most important diseases from an epidemiological standpoint;
• Issuance of recommendations on disease management programs (DMP);
• Assessment of the benefits of pharmaceuticals; and
• Provision of general information on the quality and efficiency of health care services that is understandable to all citizens.
As of February 2006, 53 employees have been hired, including 35 scientists, mainly physicians or life scientists. The Institute's staff will be raised to a head count of approximately 60-70 over the next years. The head of the Institute is Prof. Dr. med. Peter T. Sawicki, a diabetologist who had formerly been heading the department for internal medicine of a hospital in Cologne. Sawicki is also a critical expert for evidence based medicine and has been involved in the conception of guidelines for the DMP Diabetes mellitus.

The IQWiG has six scientifically oriented departments, responsible for data assessment and evaluation:
- Health Economics;
- Department of Biometrics;
- Department of Pharmaceutical Assessment;
- Department for the Assessment of Non-pharmaceutical Therapeutic Procedures, Diagnostic Procedures and Screening Measures;
- Department for Guidelines and Disease Management Programs; and
- Department for the Generation and Methodology of Patient Information.

Two additional departments (communication and quality management; administration) have supportive functions. Furthermore, a “Department for the Coordination of Studies” is planned, but will probably be formed only after the establishment phase of the Institute.

An internationally staffed scientific advisory board (9 members) and a board of trustees (30 members) have consulting functions to support the IQWiG in the process of decision-making. Until now, however, the boards held only one meeting.

In February 2005, the first assessments were assigned to the IQWiG. Concerning pharmaceuticals, a current focus of the IQWiG, the Institute is mainly about to assess the following indications and treatment options:
- Hypertension;
- Asthma and COPD;
- Alzheimer's Dementia (Cholinesterase-Inhibitors, Memantine, Ginkgo);
- Diabetes (mainly insulin analogues and oral antidiabetics); and
- Depression.

In addition, there also is a clear focus on compiling comprehensible information for patients and a new internet platform has recently been issued, addressing patients’ needs with respect to a wide variety of diseases and treatment options (http://www.gesundheitsinformation.de/index.htm). This also correlates with the Institute's frequently expressed claim to assess “patient relevant outcomes”.

Distribution of assignments between different IQWiG departments (Feb. 2006):
- Department of Pharmaceutical Assessment: 43 assignments;
- Department for the Assessment of Non-pharmaceutical Therapeutic Procedures, Diagnostic Procedures and Screening Measures: 18 assignments;
- Department for the Generation and Methodology of Patient Information: 7 assignments;
- Department of Biometrics: 2 assignments;
- Department for Guidelines and DMP: 2 assignments; and
- Department of Health Economics: 1 assignment.

Looking at the assignment distribution it becomes quite clear that approximately two-thirds of the assessments are related to evaluations of pharmaceuticals.

The IQWiG’s first important assessment result (in addition to a statin-assessment already published in September 2005, which did not have a substantial impact) is a final report for short acting insulin analogues. It was recently published and subsequently submitted to the G-BA. As expected, the criteria and results of this assessment have been very restrictive, considering only seven out of 1017 published studies as relevant. Finally, insulin analogues are not recommended as a therapeutic option owing to “lack of added value”.

Scientific acceptance and credibility of the IQWiG now strongly depend on contents, quality and implementation of the next assessment results, e.g. those for Cholinesterase-Inhibitors & Antihypertensives.

Only head to head trials of the short acting insulin analogues against the traditional insulins have been included. Indirect comparisons are not considered relevant. Furthermore only published studies and only comparisons against products, which are registered in Germany, have been included.

Currently, the G-BA is about to implement binding drug guidelines. This could lead to restricting the use of insulin analogues to a certain patient population.

In general, the G-BA’s implementation of IQWiG assessments is crucial and does not necessarily have to be congruent with all of the IQWiG recommendations. However, in the case of insulin analogues, the G-BA is going to follow the IQWiG’s recommendation to restrict SHI-reimbursement of this drug class.

Conclusions

In its evaluation of clinical effects, IQWiG focuses on complications and mortality based on data of RCTs. The first examples of IQWiG assessments lead to the following conclusions: IQWiG will concentrate on head to head trials, it will focus on morbidity and mortality and it is unlikely that IQWiG will consider compliance or most of the commonly accepted surrogate endpoints as relevant factors.

The core points one might criticize regarding IQWiG procedures are a lack of specification regarding assessment criteria; and that essential parts of the IQWiG paper on methods have not been put in more specific terms. Currently, the method paper is being re-evaluated by the IQWiG. The new version should therefore also include the development of a scientifically substantiated benefit concept, as this has not been defined in the method paper that is now being used for benefit assessment.

The transparency and participation principle needs to be further implemented. During the process of benefit assessment, the IQWiG must not shut itself off from structured professional dialog with the manufacturers concerned. The process that has been established with drug regulatory bodies and authorities (e.g. EMEA or the German BfArM) may very well serve as an example of such a structured and transparent dialog. To allow this valuable discussion and exchange of information, the IQWiG may not rely on separation but should intensify communication, also with corporate experts, e.g. for scoping issues. The IQWiG primarily evaluates the published results of controlled clinical endpoint studies (randomized controlled clinical trials, RCTs). As a result, benefit assessment is abbreviated to a secondary test of the efficacy of pharmaceuticals based on the clinical studies submitted during the marketing authorization process. An evaluation like that could also be achieved by a mere Cochrane review.

The effect of pharmaceuticals under everyday conditions is largely ignored, although the benefit of drugs shows itself in practical application compared to specifically available therapeutic alternatives. >
It is therefore also important to select an adequate point in time for the assessment and to apply a broad methodical assessment approach. Benefit assessments, especially those of innovative pharmaceuticals, should not be made directly after and certainly not before marketing authorization. Recently, there have been two assignments by the G-BA to conduct assessments for new drugs (for the treatment of diabetes) even before the official marketing authorization was granted for the German market. At this point, the practical benefit of a pharmaceutical under everyday conditions cannot be proven. Broad application experience will only be available a few years after marketing authorization. Depending on the therapeutic indication, a time window of at least three to five years between marketing authorization notification and assessment commission would seem appropriate.

Scientific acceptance and credibility of the IQWiG now strongly depend on content, quality and implementation of the next assessment results, e.g., those for Cholinesterase-Inhibitors and Antihypertensives. The restrictive evaluation of insulin analogues does confirm some of the initial criticism that has been associated with the IQWiG.

As mentioned before, G-BA and BMG (Bundesministerium fuer Gesundheit, MoH) also play a crucial role, as the G-BA is responsible for the final appraisal and implementation of the Institute’s recommendations and the BMG takes responsibility for the legal supervision. It remains to be seen to which extent certain political objectives or even public pressure will influence this final step of the appraisal process, especially in the light of the on-going process of the German health care reform and cost-containment measures.

In the end, similar to NICE changing its appraisal process and participation policy over the years, it will be exciting to see how long it takes until first relevant changes of the IQWiG’s assessment process will be implemented.

Further details and publications concerning the IQWiG may be found on the internet on the institute’s homepage: http://www.iqwig.de/.

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**OUTCOMES ASSESSMENT**

### Balancing Affordability and Value: The Universal Challenge in Health Care Delivery

Marc L. Berger MD, Vice President, Outcomes Research & Management, Merck & Company, Inc., West Point, PA, USA

The following is taken from the First Plenary Session, “Balancing Affordability and Value: The Universal Challenge in Health Care Delivery,” presented at ISPOR 11th Annual International Meeting, May 2006, Philadelphia, PA, USA.

One approach to framing the issue of balancing affordability and value with respect to health care is to define the dimensions of interest and place them in priority order. While the initial framing of the question appears to focus on optimizing health care allocations and investments, the real purpose is to maximize health. While implicitly acknowledged, we have not explicitly agreed that this is our national priority. Quality health care is a secondary priority - as it is a critical element in enhancing the health of the population. The third priority is value - getting the best “bang for the buck”; the fourth priority is affordability - not spending “too much” (however that is defined).

While we have not, as a society, normatively defined what our targets are for each of these four dimensions, we do know that our targets need to move. The United States is well below international norms (as determined by the WHO) with respect to measures of population health for countries with similar socio-economic standards of living. Indeed, recent data from Marmot and colleagues (JAMA 2006;295:2037-45) suggest that the richest third of Americans are not as healthy as the poorest third of the British, even though access to health care is arguably much better for rich Americans; thus health care is but one of many determinants of population health. We also know - based upon the work of McGlynn and colleagues (NEJM 2003;348:2635-45) - that half the time we fail to deliver evidence-based care. Moreover, as quality measurement has become widely adopted over the last 15 years, we can expect that our ability to assess health care quality will only improve in the future and therefore our expectations regarding health care quality will increase. Today we largely focus on process measures; in the future - with the availability of inter-operable electronic health information systems - we will be able to assess true outcomes.

But today, without the ability to measure outcomes and given our limited understanding of the “health care production function,” i.e., the incremental impact on population health of improved health care, it is difficult to know whether we are improving or enhancing value when we make additional investments in health care. Affordability is even more difficult to assess given U.S. cultural resistance to setting limits on access to care for insured individuals. And what about the uninsured? How can we achieve a goal of optimizing U.S. population health when more than 40 million Americans do not have coverage for essential preventive, diagnostic and therapeutic services? At the end of the day, what can we really afford? Is there a limit?

The next question to be asked is “What are health care payers and providers currently advocating and/or implementing and how does this match up with the four priorities?” A non-exhaustive list of current strategies that have been the focus of much attention would include: disease management, pay-for-performance, health care information technology, and new benefit designs (tiered co-pays, co-insurance, and consumer-directed plan designs). The first three strategies are designed to enhance health care quality. The last focuses on improving value and affordability. While some have argued that disease management and HIT may also improve affordability and value, data are limited and I suspect that the return on investment will be difficult to demonstrate across broad populations. Indeed, some have argued that disease management - originally promoted as a quality improvement strategy - was appropriated as a cost-containment tool. Current evidence suggests that disease management may decrease costs for certain populations (e.g., high risk patients) with specific conditions (e.g., congestive heart failure) but it is unlikely to be a panacea for rising health care costs.

Pay-for-performance can provide incentives for improving health care quality but issues remain - Where does the money come from? Who will pay more for higher quality? We do know that what you pay for gets done; therefore P4P should focus on important issues where there is a clear linkage to
health outcomes, though whether that can best be accomplished through P4P or suitable payment for those services is open for discussion.

Newer benefit designs were largely created to address the issue of “moral hazard” - i.e., overutilization occurs when services are free or too inexpensive relative to their value. Without addressing the merits of this point of view, we do know that financial incentives are blunt instruments. Thirty years ago the Rand Health Insurance Experiment taught us that elasticity of demand operates in health care as everywhere else - if you raise the price of health care services, the utilization of both essential and nonessential services will decrease. A number of recent studies show that lower adherence and higher medication discontinuation accompany patients’ increased out-of-pocket costs- who are also “consumers.” Such behavior can lead to worse health outcomes and can lead others to delay seeking necessary medical care. Thus the overall impact of increased cost-sharing with patients is unclear as short-term decreases in “drug spend” may be offset by increases in future medical costs.

What I have addressed thus far can be summarized as follows: Our ultimate priority is to improve population health. While improving healthcare can contribute to improvements in health, it is not the only determinant. Therefore we are in a difficult situation in trying to assess the value of investments in health care quality. The four major developments in recent years that have impacted health care delivery have yet to prove that they improve health care quality, value, or affordability.

What I want to turn to now is another dimension of value - increasing health care quality through scientific advances in therapeutic interventions. Advances in medical technology have contributed greatly to the longer lifespan we now enjoy and the enhanced quality of life enjoyed by aging Americans. While the Congressional Budget Office and others have calculated that the benefits of new treatments have more than outweighed their costs when considered from a societal viewpoint, increasing costs are the subject of much consternation by patients and payers. Should health care costs continue to increase, driven in no small part by innovative diagnostic and therapeutics, payers (including consumers) may exhibit a decreased “willingness to pay.” While the increased use of generic medications will provide some headroom for innovation - and there many “modern generics” that will be entering the marketplace in the next several years - payers are increasingly using formal health technology assessments to “raise the bar” for obtaining favorable coverage of new drugs. They are asking the following questions: “Does a new therapy really provide advantages over current therapy?” “Does it provide a good value?” These are reasonable questions and represent a shift from the latter 20th century when the questions were: “Does a new therapy provide significant benefit relative to any potential harms?” “Are there patients who would benefit from its availability?”

This provides a new challenge to pharmaceutical innovation. Investment in pharmaceutical R&D is sensitive to the prospects for commercialization which is in turn increasingly influenced by payer coverage decisions. Indeed given the long lead time between discovery and marketing, to make informed investment decisions manufacturers need to understand where the “goal posts” will be 10 years down the road. What is needed is for “rules of the road” to be developed that are acceptable to payers, providers, patients, and pharmaceutical companies. We at Merck & Co., Inc. embrace the transparent and appropriate use of evidence-based decision making as one of the “rules of the road.”

To understand what I mean by this, it is important to distinguish between and understand the dynamic relationship of evidence-based review/synthesis and evidence-based decision making (as discussed in the editorial I co-wrote with Steve Teutsch Med Decis Making 2005;Sept-Oct.: 487-9). [Figure 1]. An evidence-based review and synthesis is a critical review of the information regarding the benefits, harms if any, and costs associated with a therapy. This is an evolving and special discipline that answers the questions “What do we know?” and “How certain are we about what we know?” It integrates basic, clinical, and economic information in a structured and a priori fashioned guided by key questions and an underlying model of disease. It may aggregate data into evidence tables and/or include meta-analyses. Its focus is on the scientific evidence and may employ modeling to assess the economic impact of therapeutic choices with cost-effectiveness analysis. Evidence-based decision making takes these inputs on effectiveness, safety, and economic impact and interpolates it - in a transparent fashion - with other considerations including values/preferences, equity, acceptability, and budget constraints. When optimally performed, with adequate stakeholder involvement in a deliberative and transparent fashion, the basis for coverage recommendations are clearly understood and the fairness of decisions are more likely to be acceptable to key stakeholders, including those who may be disadvantaged by a particular decision. This is what Norman Daniels has called “accountability for reasonableness.”

The use of formal evidence-based reviews and decision making remains controversial across the pharmaceutical industry, in part because of the manner in which they have been conducted. Some view this as a method to justify cost-cutting decisions. Greater acceptance would follow from insulation of individuals conducting the evidence reviews/syntheses from those making decisions; this would minimize bias and conflicts of interest. Transparency is also critical to acceptance. Reviewers and decision makers must inform stakeholders about what drives their deliberations and considerations; scientific evidence must be distinguished from social science evidence (e.g., economic models and resource constraints) and colloquial evidence (e.g., values, precedent, professional opinion). Performed in this way, I believe that decision making will be improved and that a path forward can be found that balances the goals of affordability and value. Its in all of our best interests to make this work. ☺️


**WORLD BEAT**

News Briefs from Around the World
Prepared by Stephen L. Priori, Director, ISPOR Publications

**WESTERN EUROPE**

**AUSTRIA** Levels of prescription charges in Austria could in the future be based on earnings rather than on standardized fees dependent on the type of medicines prescribed, according to proposals outlined by the country’s health insurers’ association. (SCRIP 3193:9)

**FRANCE** France’s health Minister plans to raise €50 million with a higher tax on pharmaceutical wholesalers to keep the country’s health care budget within legal limits. (SCRIP 3191:2) Growth of just 1% in community and hospital spending on reimbursed medicines in France in July has dismayed the pharmaceutical industry. (SCRIP 3187/88:4)

**GERMANY** The German Krankenkassen association, the BKK, is considering removing the prescription charges from another 3,000 cheap medicines in November 2006. If agreed, the move will add to the 2,600 already available without a minimum prescription charge. (SCRIP 3192:4)

**UK** The UK has approved the reclassification of several medicines from either prescription-only medicine (POM) to pharmacy only (P) or P to general sales list (GSL), partly to reflect recent changes in national, European or international recommendations. (SCRIP 3192:6)

**EASTERN/CENTRAL EUROPE**

**ESTONIA** Pharmaceutical sales in Estonia grew by 15% to Eek1.1 billion ($88.9 million) at wholesale prices in the first half of this year. (SCRIP 3193:3)

**ROMANIA** Romania’s largest pharmaceutical trader, the A&D Pharma group, hopes to increase growth in its annual sales by 10 percentage points to 60%. (SCRIP 3192:7)

**RUSSIA** Pharmacy sales in Russia rose by 20% to $2.3 billion at wholesale prices in the first six months of this year, with 1.8 billion packs sold. The average price of pharmaceutical sold through pharmacies grew by the same 20% to $1.66 per pack, and the average pharmacy mark-up increased by 1.4 percentage points to 32%. (SCRIP 3187/88:4)

**UKRAINE** Pharmacy sales in Ukraine increased by 31% to Hr2.9 billion ($615.2 million) at wholesale prices or Hr3.7 billion at retail prices in the first six months of this year. The number of packs sold rose by 21% to 631 million, and their average retail price was Hr5.70 per pack. (SCRIP 3187/88:6)

**THE AMERICAS**

**US** The head of the US Medicare program, Dr. Mark McClellan, who was overseeing implementation of the massive Part D drug benefit, announced his resignation September 5, 2006. He will stay on as administrator of the Centers for Medicare and Medicaid Services (CMS) through a transition period expected to end early next month. No replacement has been named. (SCRIP 3190:13)

**AUSTRALASIA**

**CHINA** China’s National Reform and Development Commission has unveiled a new round of pharmaceutical price cuts in an ongoing effort to rein in profiteering amid rising public dissatisfaction with high medical and drug costs. (SCRIP 3190:13)

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**ISPOR CORNER**

**ISPOR Student Corner**
Prepared by Shilpa Kurpad, Chapter President, University of Michigan, Ann Arbor, MI USA

The ISPOR Student Council has exciting plans for the students who will attend the 9th Annual European Congress at the Radisson SAS Falconer Hotel and Conference Center in Copenhagen, Denmark from October 28-31, 2006. Presenters from over 45 countries will be attending this meeting and a variety of workshops and poster presentations will be featured for all members.

Student members can look forward to the Student Forum to be held on Monday, October 30, 2006 at 5pm. This year’s presenter at the Student Forum will be Veronica Sendersky, a Health Economist at the Ferring International PharmaScience Center in Copenhagen. Due to international nature of pharmaceutical companies and health economics as a discipline, many health economists and new graduates in Health Economics choose to work in a foreign country. This international move brings new challenges of working in a foreign country, with completely different language, culture, and work environment. This presentation will discuss the potential challenges of working in a foreign country and some of the tools to adapt and succeed in this new and challenging environment.

Dr. Sendersky’s anticipated presentation entitled “Working as A Health Economist in A Foreign Country - What You Need To Know About How To Adapt and Succeed,” will provide insight by addressing how to successfully adapt and work within different health environments.

Students are also invited to attend a general ISPOR networking event at the Copenhagen Town Hall on Monday, October 30 at 8pm. This reception features a welcome by the Lord Mayor of Copenhagen, as well as an historical atmosphere of architecture, sculptures, and paintings. The event is free to all European Congress attendees.

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**WEB CONNECTIONS**

Are you conducting a study focusing on the United States and are looking for state-specific information? Do you need to know the size of the population for a certain or the population size of those under 5 or 18? Do you need to know the gender or demographic distribution of a certain state? Do you need information regarding state specific crime rates, agricultural information or educational levels? If so, visit [http://www.fedstats.gov/](http://www.fedstats.gov/) for all your state specific needs.

This user friendly website is a collaboration of agencies within the United States Federal Government. The site is maintained by the Federal Interagency Council on Statistical Policy for public use.

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.
## INTERNATIONAL MEETINGS

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<td>Arlington, VA, USA</td>
<td>ISPOR 12th Annual International Meeting</td>
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<td>May 3-7, 2008</td>
<td>Toronto, ON, Canada</td>
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<td>May 16-20, 2009</td>
<td>Orlando, FL, USA</td>
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<td>May 15-19, 2010</td>
<td>Atlanta, GA, USA</td>
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**Abstract Submission Deadline:**
- January 8, 2007 (Arlington, VA, USA)
- January 7, 2008 (Toronto, ON, Canada)
- January 12, 2009 (Orlando, FL, USA)
- January 11, 2010 (Atlanta, GA, USA)

**Early Registration Deadline:**
- April 24, 2007 (Arlington, VA, USA)
- March 28, 2008 (Toronto, ON, Canada)
- April 14, 2009 (Orlando, FL, USA)
- April 13, 2010 (Atlanta, GA, USA)

## EUROPEAN CONGRESSES

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<td>20-23 October, 2007</td>
<td>Dublin, Ireland</td>
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<td>8-11 November, 2008</td>
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<td>October, 2009</td>
<td>Paris, France</td>
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<tr>
<td>October, 2010</td>
<td>Prague, Czech Republic</td>
<td>ISPOR 13th Annual European Congress</td>
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**Abstract Submission Deadline:**
- June 18, 2007 (Dublin, Ireland)
- June 23, 2008 (Athens, Greece)
- June 22, 2009 (Paris, France)
- June 21, 2010 (Prague, Czech Republic)

**Early Registration Deadline:**
- September 18, 2007 (Dublin, Ireland)
- September 16, 2008 (Athens, Greece)
- June 22, 2009 (Paris, France)
- September 16, 2010 (Prague, Czech Republic)

## ASIA-PACIFIC CONFERENCES

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<tr>
<td>7-9 September, 2008</td>
<td>Seoul, South Korea</td>
<td>ISPOR 3rd Asia-Pacific Conference</td>
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<td>2010</td>
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<td>2012</td>
<td>Singapore</td>
<td>ISPOR 5th Asia-Pacific Conference</td>
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**Abstract Submission Deadline:**
- March 17, 2008 (Seoul, South Korea)
- April 15, 2010 (Phuket, Thailand)
- July 15, 2012 (Singapore)
Recently Published Works: Using Pharmacoeconomics Innovatively
Prepared by Stephen Priori, Director, ISPOR Publications

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@ispor.org.

Disease Related Research

CARDIOVASCULAR DISEASE


DERMATOLOGY


ENDOCRINOLOGY, METABOLISM & DIABETES


GASTRO-INTESTINAL


GYNECOLOGY


INFECTIOUS DISEASE


Team. Three- vs four-drug antiretroviral regimens for the initial treatment of HIV-1 infection: a randomized controlled trial. JAMA 2006;296:769-81.


NEUROLOGY & MENTAL HEALTH


ONCOLOGY


PEDIATRICS


RESPIRATORY DISORDERS


SKELETAL/ARTHRITIS


SURGERY


General Interest

HEALTH SERVICES


**METHODOLOGY**


• Desimone BB. Curriculum design to promote the critical thinking of accelerated bachelor's degree nursing students. Nurse Educ 2006;31:213-7.


• Edwards SJ, Lind T, Lundell L. Systematic review: proton pump inhibitors (PPIs) for the healing of reflux oesophagitis - a comparison of esomeprazole with other PPIs. Aliment Pharmacol Ther 2006;24:743-50.


• Rothe CF. Last Word: Point:Counterpoint author responds to commentaries on “Active venoconstriction is/is not important in maintaining or raising end-diastolic volume and stroke volume during exercise and orthostasis”. J Appl Physiol 2006;101:1270.


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**Pharmacoecono-Comic Relief**

**Dr. Odds by Steve Marx**

Did your decision analysis include risk of adverse events?
Question for the practicising Bayesian ISPOR member . . .

Assuming two male health economists are also old friends with a common interest in motorbikes (motorcycles in the US)
They are both ISPOR members
One lives in Canada; the other in the UK.

What if they both independently make plans for a long-distance bike-based vacation?
What if they choose to take a younger drive partner on the ride (in both cases their son-in-law)?
What if one is riding North along the Blue Ridge Parkway and one is riding South along the same route?
What if their paths cross on the same day (June 6th 2006) at Winchester, Virginia?
What’s the probability of all this happening in the "real" world?

Well, they say a picture is worth 1,000 words and here’s that historic encounter between Paul Kind (l) and George Torrance (r) when all these things came together. It was not quite as random as it sounds, but how many other ISPOR health economists do you know who are also active "bikers”? George was en route from his Canadian home to Deals Gap, North Carolina to ride "Tail of the Dragon" - THE classic motorbike road through the Smoky Mountains. Paul was completing 4,000 miles from Los Angeles to New York, via Death Valley, Grand Canyon (North), Monument Valley etc., etc., . . .

Watch out for the film of the book!

PS: There is no truth in the rumour that Marilyn has plans for an ISPOR "biker" Chapter.

(ISPOR CONNECTIONS would like to thank Paul Kind MPhil, University of York, York, UK, for contributing this article)
HEALTH TECHNOLOGY ASSESSMENT

Centre for Evaluation of Medicines, Department of Clinical Epidemiology and Biostatistics, Faculty of Health Sciences, McMaster University and St. Joseph's Healthcare Hamilton

We are seeking exceptional candidates to fill a key position in Health Technology Assessment (HTA) at the Associate/Assistant Professor level. The appointment will be contractually limited to three years in the first instance but with high likelihood of renewal and extension in this rapidly growing area of research. You must have a Ph.D. or equivalent in Health Economics or a related quantitative discipline of evaluative health services research. We are looking for a strong track record in peer reviewed funding/publication and/or other evidence of research leadership in HTA. As well, we are particularly interested in candidates with quantitative skills and experience in decision analysis, cost-effectiveness analysis, and simulation modeling in the context of health technology assessment. A strong track record of collegiality and collaboration are prerequisites for this position. You will work as an investigator in our innovative Program for the Assessment of Technology in Health (PATH), funded in part by a $3 million grant from the Ontario Ministry of Health and Long-Term Care. Also, you will teach in the Health Research Methodology Graduate Program and/or other educational programs of the Department.

McMaster University is “research intensive” and perennially rated as the most innovative university in Canada. The successful candidate will join over 40 full-time/joint faculty and 150 research/administrative staff in the Department of Clinical Epidemiology and Biostatistics (CE&B). The Department enjoys an international reputation in the areas of clinical effectiveness research, evidence-based medicine, biostatistics, population health (community, occupational, and environmental), health economics, health services research, health policy analysis, and health informatics. For more information about CE&B, the Centre for Evaluation of Medicines, the Faculty of Health Sciences, St. Joseph’s Healthcare and PATH, visit www.fhs.mcmaster.ca/ceb, www.thecem.net, www.fhs.mcmaster.ca, www.stjosham.on.ca and www.path-hta.ca respectively.

Applicants will be accepted until a suitable candidate is appointed.

Applicants are invited to submit a cover letter of application, curriculum vitae, and contact details for three referees to:

R. Brian Haynes MD, PhD
Chair, Department of Clinical Epidemiology and Biostatistics
Faculty of Health Sciences
1200 Main Street West
Hamilton, Ontario, Canada L8N 3Z5
Tel. 905-525-9140 ext. 24931
E-mail: bhaynes@mcmaster.ca

All qualified candidates are encouraged to apply; however, Canadian citizens and permanent residents will be considered first for this position. McMaster University is strongly committed to employment equity within its community and to recruiting a diverse faculty and staff. The University encourages application from all qualified candidates, including women, members of visible minorities, Aboriginal persons, members of sexual minorities, and persons with disabilities.

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B: GRAY AREA

C: KNOWN QUANTITY

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Real-world market intelligence can be the difference between a successful product and one that fails short. As one of the world's largest health economics and outcomes companies, i3 Innovus provides a uniquely scientific view to help you market your product with greater precision to multiple stakeholders. Our incomparable data assets, expertise, and strategic methodology combine to deliver actionable answers — quickly and globally — through a single source. With i3 Innovus, you gain evidence-based research to help realize the full potential of your brands.

For this and other answers: Sign up for our next free web seminar at www.i3innovus.com/webinars or call 1.866.322.0959

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The company of specialists.
This course is designed to teach clinicians and new researchers how to incorporate pharmacoeconomics into study design and data analysis. Participants will learn how to collect and calculate the costs of different alternatives, 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 pharmacoeconomic models and techniques will be demonstrated and practiced in lectures and case studies. These include cost-minimization, cost-of-illness, cost-effectiveness, cost-benefit, and cost-utility analysis. Decision analysis, sensitivity analysis, and discounting, will all be demonstrated and practiced. Participants will also learn to compare and evaluate interventions such as drugs, devices and clinical services. This course is suitable for those with little or no experience with pharmacoeconomics.

Modeling: Design and Structure of a Model

Faculty: Marc Botteman MA, Managing Partner, PharMerit North America, Bethesda, MD, USA; Ben van Hout PhD, Scientific Director, PharMerit, Rotterdam, The Netherlands and Professor in Medical Technology Assessment, Julius Centre for Health Sciences and Primary Care, University Medical Centre Utrecht, Utrecht, The Netherlands; Joel Hay PhD, Associate Professor, USC School of Pharmacy, Los Angeles, CA, USA

Course Description: This course will assume participants have understanding of decision analysis. Enrollment for this course is limited; please register early.

Bayesian Analysis: Overview & Applications

Faculty: Bryan Luce MBA, PhD, Senior Vice President, Science Policy, United BioSource Corporation, Bethesda, MD, USA; Christopher S. Hollenbeak PhD, Surgery and Health Evaluation Sciences, Penn State College of Medicine, Hershey, PA, USA; David Vanness PhD, Assistant Professor of Population Health Sciences, University of Wisconsin Medical School, Madison, WI, USA

Course Description: The first portion of this course is designed to provide an overview of the Bayesian approach and its applications to health economics and outcomes research. The course will cover basic elements of Bayesian statistics, contrasting briefly with classical (frequentist) statistics and introduce available statistical packages. The second portion of this course will focus on the Bayesian “informative prior.” Several example vignettes of how a Bayesian analysis can be used within outcome modeling problems will be presented. Participants will learn how a Bayesian approach is different and why it is useful for their work and what tools are available to them. Participants of this course should be prepared to use their own laptops as the exercises presented use interactive software. This course is designed for those with a limited understanding of Bayesian statistical concepts.
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. This course is designed for those with some experience with pharmacoeconomic analysis.

USE OF PHARMACOECONOMICS / ECONOMIC / OUTCOMES RESEARCH INFORMATION

Elements of Pharmaceutical/Biotech Pricing I - Introduction
Faculty: TBD

Course Description: This course will give participants a basic understanding of the key terminology and issues involved in pharmaceutical pricing decisions. It will cover the tools to build and document product value including issues, information and processes employed (including pricing research); the role of pharmacoeconomics and the differences in payment systems that help to shape pricing decisions. These tools will be further explored through a series of interactive exercises. This course is designed for those with limited experience in the area of pharmaceutical pricing and will cover topics within a global context.

SATURDAY, MAY 19, 2007
1:00 PM - 5:00 PM (Afternoon Courses)

PHARMACOECONOMIC / ECONOMIC METHODS

Financial Impact / Cost of Illness
Faculty: Josephine Mauskopf PhD, Global Head, Health Economics and Outcomes Strategy, RTI Health Solutions, Research Triangle Park, NC, USA; C. Daniel Mullins PhD, Professor and Chair of Pharmaceutical Health Services Research, University of Maryland, School of Pharmacy, Baltimore, MD, USA

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. This course is designed for those with some experience with pharmacoeconomic analysis.

QUALITY OF LIFE/PATIENT-REPORTED OUTCOMES METHODS

Advanced Quantitative Methods for Quality of Life / Patient-Reported Outcomes
Faculty: Bruce Crawford MPH, MA, Director, Patient Reported Outcomes and Regulatory Consulting-Operations Director, Mapi Values, Boston, MA, USA; Kathleen Rosa, PhD, Director of Psychometrics and Statistics, Mapi Values, Boston, MA, USA

Course Description: This course will provide an in-depth discussion of operating characteristics, validity testing, analysis and interpretation with examples of each. It will provide a range of methods that may help to solve common problems encountered with quality of life / patient-reported outcomes. These include an overview of psychometric validation methods including: a brief overview of Rasch analysis, pragmatic issues in validating a PRO from clinical trial data, ePRO validation, methods of estimation of minimally clinically important differences and alternatives to provide information on interpretation Clinical trial analyses will include missing data analysis techniques and mixed modeling appropriate to PRO data and study design. There will be a focus on addressing these issues within the framework provided by the PRO guidance recently released by the SEALD group at the FDA. Specific examples will be used throughout the course and participants will be asked to complete a short exercise. This course is designed for those with intermediate experience in health-related quality-of-life assessment.

REAL WORLD DATA METHODS

Instrumental Variables in Addressing Selection Bias in Observational Studies
Faculty: TBD

Course Description: In any non-randomized study, selection bias is a potential threat to the validity of conclusions reached. Failure to account for sample selection bias can lead to conclusions about treatment effectiveness or treatment cost that are not really due to the treatment at all, but rather to the unobserved factors that are correlated with both treatment and outcomes. Sample selection models provide a test for the presence of selection bias. These models also provide a correction for selection bias, enabling an investigator to obtain unbiased estimates of treatment effects. This course will discuss the various models and their applications, and in particular will address instrument variables (two-stage least squares, intuition, RTCs), including an overview of examples from the current literature. This course is suitable for those with some knowledge of econometrics.

SUNDAY, MAY 20, 2007
8:00 AM - 12:00 PM (Morning Courses)

PHARMACOECONOMIC / ECONOMIC METHODS

Cost-Effectiveness Analysis with Clinical Trials
Faculty: Scott Ramsey MD, PhD, Associate Member, Fred Hutchinson Cancer Research Center, Seattle, WA, USA; Richard Willke PhD, Senior Director, Group Leader, Global Outcome Research, Worldwide Outcomes Research, US Development Sites Pfizer, Inc., Bridgewater, NJ, USA

Course Description: The growing number of prospective clinical/economic trials reflects both widespread interest in economic information for new technologies and the regulatory and reimbursement requirements of many countries that now consider evidence of economic value along with clinical efficacy. This course will present the design, conduct, and reporting of cost-effectiveness analyses alongside clinical trials based on, in part, the Good Research Practices for Cost-Effectiveness Analysis alongside Clinical Trials: The ISPOR RCT-CEA Task Force Report. Trial design, selecting data elements, database design and management, analysis, and reporting of results will be presented. Trials designed to evaluate effectiveness (rather than efficacy), as well as clinical outcome measures will be discussed. How to obtain health resource use and health state utilities directly from study subjects and economic data collection fully integrated into the study will also be discussed. Analyses guided by an analysis plan and hypotheses, an incremental analysis using an intention to treat approach, and characterization of uncertainty, and standards for reporting results will be presented. This course is an introductory/intermediate level. Familiarity with economic evaluations will be helpful.
REAL WORLD DATA METHODS

Use of Real World Data in Outcomes Research
Faculty: Diana Brixner PhD, RPh, Associate Professor and Department Chair, College of Pharmacy, University of Utah, Salt Lake City, UT; Gregory de Lissovoy, MPH, Senior Research Scientist, Center for Health Economics and Policy, United BioSource Corporation, Bethesda, MD, USA; Daniel M. Huse MA, Practice Leader, Information Products, Thomson Medstat Inc., Cambridge, MA

Course Description: ‘Real world’ data is defined as information (data) collected beyond that which is normally collected in Phase III clinical trials that focus on efficacy. This course will address the issues and framework for analysis of ‘real world’ data in outcomes research. The types of ‘real world’ data (piggy-back information from Phase III clinical trials, large simple trials, registries, administrative claims databases, surveys) and benefits and challenges of these data, as well as evidence hierarchies and their usefulness will be discussed. Examples of the use of ‘real world’ data for different types of outcomes (clinical outcomes, economic outcomes, and quality of life / patient-reported outcomes) will be presented. Health care payer’s perspectives will also be addressed. This course is designed for those with little experience with ‘real world’ data assessment and use in health care decisions.

MODELING METHODS

Bayesian Analysis: Advanced
Faculty: Bryan Luce MBA, PhD, Senior Vice President, Science Policy, United BioSource Corporation, Bethesda, MD, USA; Keith R. Abrams PhD, Professor of Medical Statistics, Centre for Biostatistics & Genetic Epidemiology, Department of Health Sciences, University of Leicester, Leicester, UK; Christopher S. Hollenbeak PhD, Assistant Professor, Surgery and Health Evaluation Sciences, Penn State College of Medicine, Hershey, PA, USA; David Vanness PhD, Assistant Professor of Population Health Sciences, University of Wisconsin Medical School, Madison, WI, USA

Course Description: This course introduces the use of Bayesian methods in evidence synthesis (including meta-analysis) and allows participants to gain hands on experience using such modeling techniques within WinBUGS. Methodological issues considered in the course include; fixed & random effects models, choice of prior distributions, subgroups, meta-regression and adjusting for baseline risk, together with indirect and mixed treatment comparisons. Further meta-analysis topics for which a Bayesian approach can be of benefit will also be highlighted. Participants will be expected to be familiar with the use of WinBUGS and will be responsible for bringing a laptop with the latest, unrestricted version of WinBUGS pre-installed [Details at www.mrc-bsu.cam.ac.uk/bugs]. This course is a follow-up to the courses: Bayesian Analysis-Overview and Bayesian Analysis-Applications. Basic knowledge of Bayesian approach and use of WinBUGS (equivalent to attendance at Bayesian Analysis-Applications) will be assumed.

Discrete Event Simulation for Economic Analyses
Faculty: J. Jaime Caro MDCM, FCRCPC, FACP, Adjunct Professor of Medicine, Adjunct Professor of Epidemiology and Biostatistics, McGill University, Montreal PQ and Scientific Director, Caro Research Institute, Concord, MA, USA; Jörgen Möller MSc Mech Eng, Simulation Specialist, Caro Research Institute, Concord, MA, USA

Course Description: This course will provide a basic understanding of the key concepts of discrete event simulation. The focus will be on the use of these simulation models to address pharmacoeconomic (and device-related) problems. The course will be structured around practical exercises. Topics to be covered are: Why DES? Dynamic simulation as a tool; Components of a DES; How do you build a model? Modeling of processes and resource use; Modeling of variables and decisions. If time permits, simple animation will be demonstrated. We will use ARENA to build simple models. Participants who wish to have hands-on experience should bring their laptops. Instructors will distribute training versions of Arena. This course is designed for those with some experience with modeling.

QUALITY OF LIFE / PATIENT-REPORTED OUTCOMES / PREFERENCE-BASED METHODS

Patient-Reported Outcomes - Item Response Theory
Faculty: Bryce Reeve PhD, Psychometrician, National Cancer Institute, Bethesda, MD, USA

Course Description: Item Response Theory measures the mathematical relationship between an examine ability and item response, in order to attain more accurate readings of actual aptitude/conceptions of health related devices and issues. It was developed in response to a growing need for more advanced tools and models to measure such constructs. This course will highlight the background of Item Response Theory as well as discuss in-depth its applications in patient outcomes research. Instructors will also evaluate the usefulness of Item Response Theory in comparison with other patient outcomes measures. This course is designed for those with little experience with Item Response Theory.

USE OF PHARMACOECONOMICS / ECONOMIC / OUTCOMES RESEARCH INFORMATION

Case Studies in Pharmaceutical/Biotech Pricing II – Advanced
Faculty: TBD

Course Description: Case studies will be employed to lead participants through the key steps of new product pricing, with focus on the need to thoroughly analyze the business environment and its constraints and opportunities and the need to closely integrate the pricing, reimbursement and PE strategy for the new product with the clinical development and marketing strategies. Practical exercises will allow participants to consolidate the concepts delivered in the “Elements” introductory session and expanded here. Areas covered will include the post-launch issues of reimbursement and pricing maintenance as a part of life-cycle management in a global environment. This course is for individuals who have completed Elements of Pharmaceutical Pricing I – Introduction or are familiar with both the key determinants of pharmaceutical pricing and the main international health systems.

SUNDAY, MAY 20, 2007
1:00 PM - 5:00 PM (Afternoon Courses)

PHARMACOECONOMIC / ECONOMIC METHODS

Statistical Considerations in Economic Evaluations
Faculty: Henry Glick PhD, University of Pennsylvania, School of Medicine, Philadelphia, PA, USA; Jalpa Doshi PhD, University of Pennsylvania, School of Medicine, Philadelphia, PA, USA; Daniel Polsky PhD, University of Pennsylvania, School of Medicine, Philadelphia, PA, USA

Course Description: The adoption and diffusion of new medical treatments depend increasingly on evidence of costs and cost-effectiveness.
This evidence is increasingly being generated from patient level data in randomized study designs. This course will discuss design and analysis issues that arise when conducting such analyses. Specifically, we will address topics on strategic issues in the design of economic assessments, sample size and power calculations, analysis of costs and how it is affected by distributional assumptions, and assessing stochastic uncertainty. The course will be practical in orientation and will routinely provide examples to illustrate the "how-to’s". This course is an intermediate level. Familiarity with economics and statistics is helpful.

REAL WORLD DATA METHODS

Propensity Scores and Comorbidity Risk Adjustment

Faculty: Fadia Shaya MPH, PhD, Assistant Professor/Associate Director, University of Maryland School of Pharmacy, Center on Drugs and Public Policy, Baltimore, MD, USA

Course Description: A large part of the evidence about the effectiveness of different treatments is based on retrospective studies. Issues of bias and confounding relate to the non-random assignment of subjects and co-morbidity burden. This course will outline the concerns about bias and explain the methods for causal inference in observational studies, where researchers have no control over the treatment assignment. A lack of balance in the covariates between the treatment and control groups can produce biased estimates of the treatment effects. We will explain how propensity scores can be used to reduce bias, through stratification, matching or regression. Confounding and the pros and cons of standard adjustment, propensity scoring methodology (sub classification on one confounding variable, overlap in treatment groups, variable selection) will be discussed. In the second part, we will elaborate on risk adjustment models, focusing on morbidity indices, e.g the Charlson Comorbidity Index, and Chronic Disease Score. Examples using a step by step approach will be presented. This is an introductory course, designed for those with little experience with this methodology but some knowledge of observational databases.

Patient Registries: Overview & Application

Faculty: Jeff Trotter MBA, President, Ovation Research Group, Highland Park, IL, USA

Course Description: This course is designed to provide an overview of patient registries and their applications in identifying ‘real world’ clinical, safety, and patient-perspective issues. The advantages and disadvantages of patient registry versus other ‘real world’ data collection will be presented. The course will address safety and clinical objectives, as well as regulatory trends and requirements. Key operational components and challenges, and measures of program success will be discussed. Management issues, including creating effective partnerships with patient-oriented organizations and facilitating long-term program operations within a changing organizational structure will be addressed. This course is designed for those with some or no experience with patient registries.

QUALITY OF LIFE / PATIENT-REPORTED OUTCOMES / PREFERENCE-BASED METHODS

Utility Measures

Faculty: TBD

Course Description: Course participants will learn the conceptual and empirical features of various health-utility measures and their relative advantages for different health care decisions. This course evaluates new methods for bridging the gap between ordinal and cardinal utility measures. Newer methods allow analysts to estimate “super QALY” values using time or other non-monetary tradeoffs that do not require the restrictive assumptions of conventional cardinal-utility methods. The course focuses particularly on how to derive utility estimates from surveys, including developing valid and reliable tradeoff surveys and analyzing the resulting data. The uses of utility assessment involving individual decisions versus population resource allocations will be compared. This course is designed for those with some experience with psychometric measures.

OUTCOMES RESEARCH

Outcomes Research for Medical Devices & Diagnostics

Faculty: Seema Sonnad PhD, Associate Professor, Department of Surgery, University of Pennsylvania, Philadelphia, PA, USA; Stacey Ackerman, MSE, PhD, Vice President, Covance Market Access Services, San Diego, CA, USA

Course Description: This course will present outcomes research practices that are specifically tailored for the fast-paced medical device and diagnostics technology environment and address issues related to these health technology assessment methodologies. Outcomes research including clinical outcomes, economic outcomes, and patient-reported outcomes will be discussed. Outcomes research for medical devices & diagnostics will be differentiated from other health care interventions such as drugs. The evidence hierarchy for medical devices and diagnostic procedures including ‘real world’ outcomes research information in coverage and reimbursement decisions will be discussed. This course is designed for those with little experience with outcomes research for medical devices and diagnostic technologies.

USE OF PHARMAECOONOMICS / ECONOMIC / OUTCOMES RESEARCH INFORMATION

Risk Assessment: Analysis and Management

Faculty: Dennis W. Raisch, PhD, Associate Center Director, Scientific Affairs, VA Cooperative Studies Program, Clinical Research Pharmacy, Albuquerque, NM, USA; Anthony Lockett, MD, PhD, MBA, Medical Director, ICO, Leeds, UK; Suellen Curkendall, PhD, Principal Investigator, Cerner Health Insights, Vienna, VA, USA

Course Description: This course will provide an overview of risk management for pharmaceuticals and devices. The risk/benefit assessment process will be described in regards to stage of product development, from pre-marketing through post-marketing. Risk mitigation includes the various strategies employed by manufacturers, regulators, and health care providers, with an emphasis on international differences in risk mitigation and decision making. Risk/benefit communication processes will be described, focusing upon how decisions regarding risk of pharmaceuticals and devices are communicated to health care providers and the public. This includes direct mailing, direct-to-consumer marketing, and labeling. Real-world exercises will allow participants to discuss key topics and propose implementation strategies for risk management. This course is designed for those with a basic understanding of pharmacoepidemiology principles.
MEETING PRELIMINARY PROGRAM

MONDAY, MAY 21, 2007

8:00AM-8:30AM  WELCOME & INTRODUCTION
Scott D. Ramsey MD, PhD, Full Member, Fred Hutchinson Cancer Research Center & Professor, University of Washington, Seattle, WA, USA

PRESIDENTIAL ADDRESS
Michael Drummond PhD, Professor of Health Economics, University of York, Heslington, York, UK

8:30AM-9:45AM  FIRST PLENARY SESSION: HOW SHOULD THE MEDIA CONVEY INFORMATION ABOUT NEW MEDICAL TECHNOLOGIES?
Speakers: Drummond Rennie, MD, FRCP, MACP, Adj. Prof Medicine, Institute for Health Policy Studies, University of California San Francisco, Jacksonville, OR, USA; Snigdha Prakash, Reporter, National Public Radio, Washington, DC, USA

The media is now a prevalent and effective means for creating knowledge of and demand for new medical technologies. What patients demand after seeing advertisements and news stories on new products may conflict with what outcomes researchers feel is effective or cost-effective use of those technologies. This session will explore the media's role in the adoption and use of medical technologies, and what might constitute the ideal media message template for reports on new drugs and devices.

9:45AM-10:15AM  BREAK, EXHIBITS & CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION I

10:15AM-11:15AM  CONTRIBUTED PODIUM PRESENTATIONS - SESSION I
Research studies on the following topics may be presented:
• Cardiovascular Diseases
• Respiratory Disorders
• Cancer
• Infections

11:30AM-12:30PM  ISSUE PANEL - SESSION I

12:30PM-2:00PM  LUNCH, EXHIBITS & CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION I

2:00PM-3:00PM  CONTRIBUTED PODIUM PRESENTATIONS - SESSION II
Research studies on the following topics may be presented:
• Health Care Reimbursement
• Health Care Costs
• Health Care Modeling
• Screening

3:15PM-4:15PM  ISPOR FORUMS:
• ISPOR Student Forum
• ISPOR Special Interest Group Forums
• ISPOR Task Force Forums
• ISPOR Council Forums

4:15PM-5:00PM  BREAK, EXHIBITS & CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION I

4:30PM-5:00PM  ISPOR ANNUAL BUSINESS MEETING

5:00PM-6:00PM  CONTRIBUTED PODIUM PRESENTATIONS - SESSION III
Research studies on the following topics may be presented:
• Prescribing Studies
• Adherence/Compliance
• Pharmacoepidemiology
• Outcomes & Preferences

6:00PM-8:00PM  EXHIBITORS' OPEN HOUSE RECEPTION & CONTRIBUTED POSTER PRESENTATION - SESSION I
MEETING PRELIMINARY PROGRAM

TUESDAY, MAY 22, 2007

8:00AM-9:00AM CONTRIBUTED PODIUM PRESENTATIONS - SESSION IV
Research studies on the following topics may be presented:
• Diabetes
• Mental Health
• Neurological Disorders
• Health Policy Evaluation

9:15AM-9:45AM ISPOR AWARDS PRESENTATION

9:45AM-10:00AM INCOMING PRESIDENTIAL ADDRESS
Diana Brixner PhD, Associate Professor, University of Utah, College of Pharmacy, Salt Lake City, UT, USA

10:00AM-11:00AM SECOND PLENARY SESSION: DO PHYSICIANS USE COST EFFECTIVENESS RESEARCH? SHOULD THEY?
Speakers: Hal Sox MD, MACP, Editor, Annals of Internal Medicine, American College of Physicians, Philadelphia, PA, USA; Allan Detsky MD, PhD, Physician-in-Chief, Mt. Sinai, Toronto, Ontario, Canada
Cost-effectiveness analysis is designed for population-level decision making, yet health resource allocation decisions are primarily made at the level of the physician and the patient. This session will explore whether cost-effectiveness analysis should be incorporated into physician decision-making “at the bedside.” Speakers will discuss barriers to implementing population level studies at the level of the patient, and potential approaches to encourage physicians to practice more cost-effectively.

11:00AM-11:30AM BREAK, EXHIBITS, CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION II

11:30AM-12:30PM ISPOR FORUMS
• ISPOR Council Forums
• ISPOR Special Interest Groups Forum
• ISPOR Task Force Forums

12:30PM-2:00PM LUNCH, EXHIBITS, CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION II

2:00PM-3:00PM ISSUE PANEL - SESSION II

3:00PM-3:30PM BREAK, EXHIBITS & CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION II

3:30PM-5:00PM THIRD PLENARY SESSION: WHAT IS UNCERTAINTY IN COST-EFFECTIVENESS ANALYSIS? HOW SHOULD WE CHARACTERIZE IT?
Speakers: Milton Weinstein PhD, Professor Health Policy & Management, Harvard School of Public Health, Center for Risk Analysis, Boston, MA, USA; Andrew Briggs DPhil, Professor, University of Glasgow, Glasgow, UK
Recent advances in methods for handling uncertainty in cost-effectiveness analyses have created dilemmas for researchers. Some feel that multi-way uncertainty methods better characterize uncertainty, others feel that one-way analysis provides more useful information to decision-makers. Others note that all approaches are artificial constructs that may under-represent true uncertainty in cost-effectiveness analyses. This session will explore methods for analyzing uncertainty, the strengths and weaknesses of those approaches, and future research directions.

5:00PM-7:00PM EXHIBITORS’ WINE & CHEESE RECEPTION & CONTRIBUTED POSTER PRESENTATIONS VIEWING - SESSION II

7:00PM-11:00PM ISPOR ROCKS WASHINGTON - SOCIAL EVENT!!!

WEDNESDAY, MAY 23, 2007

8:00AM-9:00AM CONTRIBUTED WORKSHOPS - SESSION I

9:15AM-10:15AM CONTRIBUTED WORKSHOPS - SESSION II

10:15AM-10:45AM BRUNCH & ISPOR CONTRIBUTED RESEARCH AWARD PRESENTATIONS

11:00AM-12:00PM CONTRIBUTED WORKSHOPS - SESSION III
**hotel information**

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<td>Bayesian Analysis: Overview and Applications</td>
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**SHORT COURSE FEE:**

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\text{SHORT COURSE FEE} = \left( \text{# of full day courses} \times \text{fee} \right) + \left( \text{# of half day courses} \times \text{fee} \right)
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