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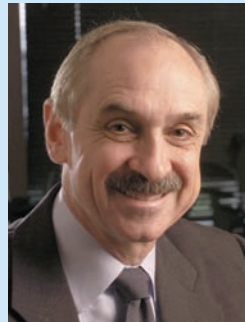
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SCIENCE & POLICY OPINION

UBC's Review of AHRQ's Draft Handbook: Registries for Evaluating Patient Outcomes



By Bryan R. Luce, PhD, MBA and Craig A. Hunter, MPP, PGDP

In October 2006, the Agency for Healthcare Research & Quality (AHRQ) released a draft handbook entitled, *Registries for Evaluating Patient Outcomes*. This draft document and supporting research were completed by Outcome Sciences, Inc. and reflect the knowledge and work of over 100 contributors drawn from a combination of academia, government, and the private sector. A summary of the document, as well as any information on the project, can be found at <http://effectivehealthcare.ahrq.gov/>.

Given United BioSource Corporation's (UBC) extensive experience in registry design and operations, health economics and outcomes, and science policy issues, UBC was engaged by multiple organizations to offer comments based on a thorough review of the draft handbook. This article relates how we conducted our review as well as a brief summary of our comments.



The review was conducted by a five-person team from UBC's research and scientific staff, including: Bryan R. Luce, PhD, MBA, Senior Vice President, Science Policy; Annette Stenhagen, DrPH, FISPE, Vice President, Epidemiology and Risk Management; Dennis Revicki, PhD, Senior Vice President and Scientific Director, Center for Health Outcomes Research;

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Identifying Good Practices for Budget Impact Analysis

By Peter Marangos, BS, BA and Clark Paramore, MSPH

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) is recognized as the leading organization with respect to scientific research in pharmacoeconomics, health outcomes assessment and related issues of public policy. Consistent with this leading role, ISPOR regularly publishes its recommendations with regards to good research practices across a wide range of topics in pharmacoeconomics and outcomes research. Their guidance documents, including those on modeling studies, patient-reported outcomes methods and cost-effectiveness analyses have become essential benchmarks for many researchers in the field. ISPOR has recently developed a guidance document covering the principles of good practice for budget impact analysis (BIA) (http://www.ispor.org/workpaper/budget_impact.asp).

A properly designed and executed BIA should provide an estimate of the financial consequences associated with the adoption and diffusion of a health care intervention within a specific population or health care setting. Taken alongside a cost-effectiveness analysis, a properly designed BIA is an essential part of a comprehensive economic evaluation of a new health technology. Decision makers such as the administrators of health care programs, health care delivery organizations and private insurance plans often rely on BIAs to assess the affordability and financial impact of alternative health care interventions. BIAs allow them to predict the level of adoption of a new technology and the resulting change in the approach to treating a health care condition, and how this change may

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Budget Impact Analysis

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then impact the trajectory of spending on that condition. These decision makers are responsible for differing populations with varying health care needs, and as a result, a flexible and effective BIA is a critical aspect of their technology assessment process. ISPOR recognizes the need for specific evidentiary requirements for the data, methods and reporting used in BIAs, and their guidance document was drafted with the intent of establishing a coherent set of guidelines for the development and presentation of BIAs so that they may be an effective tool for decision makers.

In meeting with these intended objectives, the ISPOR guidance document makes specific recommendations regarding the use of the appropriate analytic framework, inputs and

The document raises a number of key issues that merit the consideration of researchers and decision makers alike as they undertake constructing and interpreting BIAs.

data sources, and reporting format. The document raises a number of key issues that merit the consideration of researchers and decision makers alike as they

undertake constructing and interpreting BIAs. Each of the recommendations made by the document regarding analytic framework center around the idea that a BIA should provide a flexible computing platform, or model, that allows users to relate their current budgetary situation to the financial consequences associated with the adoption of a new technology. Therefore, the guidance document calls for the incorporation of scenarios (in the form of specific assumptions and data inputs) that are of interest to the decision maker, rather than a scientifically chosen “base case” based on generally applicable inputs and assumptions. They recommend that the BIA allow for alternative assumptions regarding the nature and size of the treated population over time. These assumptions may include usage restrictions, induced demand and the tendency for untreated patients to request treatment due to improved outcomes, greater convenience and fewer side effects attributed to the intervention of interest. The guidance document recommends that the BIA include a varying time horizon, costing that is relevant to the payer group of interest, and sensitivity analyses to account for both the most optimistic and pessimistic scenarios with regards to the assumptions being made.

Although the guidance document does not make any specific recommendations regarding the incorporation or

integration of BIAs into cost-effectiveness analyses (CEAs), it does mention that a BIA should be viewed as complementary to a CEA rather than as a variant or replacement. While a CEA highlights the efficiency of a technology, a BIA in turn highlights its affordability, and because these two aspects of technology assessment are of paramount importance to decision-makers and payers, it would seem then that their integration is a natural step in the evolution of health economic analysis as a whole.

Improving the quality of BIAs is of particular interest to the researchers here at UBC. Two issues that UBC hopes will be addressed in future iterations of the ISPOR BIA Guidance are: 1) how to link CEA results to the BIA when the cohorts analyzed in the CEA do not represent all of the potential patient types that could utilize a new therapy and thus impact a health plan budget; and 2) how to better frame the BIA structure and results for decision makers who represent interests other than standard health plan formularies (e.g., hospital formularies, nursing home administrators). UBC is excited about the ISPOR BIA guidance document as we believe it will succeed in enhancing not only the quality and credibility of BIA as a whole, but will also increase awareness surrounding the appropriate use and incorporation of BIA into decision making regarding the incorporation of health care interventions.

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Using Exploratory and Confirmatory Factor Analysis in PRO Development and Evaluation

By Donald E. Stull, PhD and Dennis A. Revicki, PhD

Patient-reported outcomes (PROs) are often complex and multidimensional. Researchers often need measures of multiple domains to adequately capture the range of content for health-related quality of life outcomes. Once a set of items is developed that we think captures the key content of our concepts of interest and we have obtained responses to those questions from the patients under study, we have several analyses to conduct and several decisions to make. First, how do we decide if all of the questions in our instruments are equally informative? Second, are there subsets of questions that cluster together, representing separate concepts, or are they dimensions of a larger concept? Finally, how do we generate empirical evidence to support the multidimensionality of the PRO measure and their relationships with other key variables in our studies? Exploratory and confirmatory factor analyses and structural equation modeling can help answer these research questions.

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UBC's Review of AHRQ's Draft Handbook

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Gregory de Lissovoy, PhD, Senior Research Scientist, Health Technology Assessment; and Craig A. Hunter, MPP, PGDP, Project Manager, Science Policy. All reviewers found the draft handbook to be a comprehensive, well-written, and well-thought out overview of registries and the key aspects that comprise them. What follows is our critique of the draft document.

Registry Design and Operation

Of particular use within the draft handbook is the outline of quality domains in Chapter 11. This section offers what is essentially a checklist of parameters that should be included in a good registry. Despite this accurate and helpful list, however, this section should not be used as the exclusive means to judge either a registry itself or those who are designing and carrying out the registry, since not all items deemed “necessary” may in fact be required under all circumstances. Related to this, the draft omits any discussions on global registries, despite the fact that many pharmaceutical and biotechnology companies increasingly utilize these types of registries.

Of major concern is the manner in which the handbook deals with privately held, funded, or managed registries. Any registries that are not publicly available and/or openly published are viewed by the draft handbook as “tainted” and “lacking in credibility.” While the reviewers agreed that the publication and open public utilization of registries can be a desirable approach, they disagreed with the handbook that it is the only way to maintain a credible and useful registry. In cases where registries are privately funded and include proprietary information, public utilization and reporting may be impossible, but that is not a barrier to ensuring the maintenance of high-quality registries.

Patient-Reported Outcomes

The patient-reported outcome (PRO)-specific sections of the draft document are consistent with the state-of-the-science for health outcomes measurement, with attention to identifying outcome instruments that are relevant to the research question, focus on ensuring the psychometric qualities (i.e., reliability, validity) of selected PRO measures, and/or attention to systematic development and psychometric evaluation of newly developed PRO measures for the registry. The focus on key research questions (i.e., “need to know” questions) and consideration of other questions (i.e., “nice to know” questions) was encouraging.

Health Economics

The handbook endorses the use of registries to explore cost of illness and cost-effectiveness of treatment interventions. Despite—or perhaps because of—the handbook’s relatively broad focus, the reviewers found that the handbook offers limited guidance on the use of registries to address research questions relating to economic or financial issues. The handbook includes a brief discussion of financial and economic data elements and sources, but no specific recommendations on registry design to measure resource utilization or costs of diseases or treatments. Thus, an opportunity exists to develop more detailed and specific guidance for use of registries to address economic issues.

POLICY ANALYSIS

Observational Evidence Relative to Traditional Evidence-Based Medicine, Including Systematic Reviews

This draft handbook would benefit from a discussion on the appropriate role of evidence derived from well-designed registries within the context of “traditional” evidence-based medicine (EBM)/systematic review processes (e.g., those which are conducted by the Oregon Health & Science University (OHSU)-based Drug Effectiveness Review Project (DERP), or the Cochrane Collaboration). The present draft document addresses the validity and usefulness of comparative effectiveness and cost-effectiveness evidence derived from well-designed comparative outcomes-focused registries, yet a number of traditional EBM processes (such as those noted above) characterize all data from

This draft handbook would benefit from a discussion on the appropriate role of evidence derived from well-designed registries within the context of “traditional” evidence-based medicine (EBM)/systematic review processes...

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so-called “observational” studies as rife with bias and not eligible to be considered legitimate evidence for inclusion within a systematic review.

Similarly, the document makes a strong and, we believe, valid case that randomized control trial (RCT)-derived evidence—which emphasizes internal validity—and high-quality observational, registry-derived evidence—which emphasizes external validity and thus generalizability—are complementary with one another for the purposes of informed health care decision-making. Despite this legitimate assertion, the analytical and increasingly policy-relevant question which has not been adequately addressed in the literature is how to combine these two bodies of evidence for informed decision-making. Thus, the larger issue of concern here, and an area in which further discussion could only serve to strengthen this document, is the role of high-quality, outcomes-focused registry evidence in health care decision making in light of existing RCT evidence.

Role of Registry Evidence in Promotion for Manufacturers

An issue related to the discussion above as well as in the previous section is that the FDA considers any statements by manufacturers about the effectiveness, comparative effectiveness, or cost-effectiveness of their regulated medical products to be “false and misleading” when those statements are based on evidence that would meet the evidence standards described in the draft guidelines; that is to say, evidence derived from high-quality registry studies. This handbook should address this policy-relevant issue, especially considering the use of such evidence by the CMS for national coverage decision making (we refer specifically here to the Coverage with Evidence Development, or CED, policy). In addition to being good public policy, consistent with accepted health services research principles, permitting such evidence for promotional purposes should lower manufacturers’ funding barriers for voluntarily-sponsored comparative effectiveness-focused registries.

We recommend that the draft document include a discussion and analysis of all the above issues in a prominent chapter, possibly titled “Policy Issues Associated with the Use of Registry Evidence.”

Adaptive Designs

To our knowledge, there is virtually no literature that specifically addresses adaptive registries. However, adaptive clinical trial designs are garnering a great deal of attention at the FDA and among manufacturers and academic biostatisticians. Adaptive designs are more flexible, efficient, and are particularly well-suited for use in the late stage (post-marketing) arena, where evidence of comparative effectiveness, value, and safety is sought. Since there is little or no literature at present, combined with a paucity of experience specific to adaptive registry case studies, we recommend that AHRQ recruit an expert to prepare a chapter discussing this important emerging issue.

Conclusion and Next Steps

In summary, UBC found the draft handbook to be a well conceived, written, and supported document that will be useful as a reference point for designing and managing high-quality registries. There were a few deficiencies in the areas of global registries and the potential value of non-public registries. Further, we recommend that more attention be paid to both the health economic and health policy issues related to managing data registries.

On November 27, 2006, following a six-week public comment period, AHRQ stopped taking comments on the draft handbook. Neither AHRQ nor Outcomes, Inc. have made public the number or types of comments received, nor does it appear that they intend to do so. AHRQ intends to review all comments received and incorporate those ideas deemed most relevant into a final, web-based reference document. UBC is not aware of the expected date of completion and there is no timeframe included on the AHRQ website.

More information on the AHRQ project, including related documentation, is available via the website:

<http://effectivehealthcare.ahrq.gov/>.

For more information on UBC's review and analysis of the draft handbook, please contact Craig.Hunter@unitedbiosource.com or Bryan.Luce@unitedbiosource.com.

The Impact of the Deficit Reduction Act (DRA) on Medicaid Drug Reimbursement and Price Transparency

By Donald N. Muse, PhD and J. Cliff Johnson, III, MBA

With the shift in the legislative environment to a Democrat-controlled Congress, many are speculating about the impact of this change on the pharmaceutical industry. Pundits suspect that the first 100 hours of the new Congress will include an aggressive legislative agenda that promises to change everything from clinical trial requirements to marketing practices.

But while the industry is squarely focused on the Congress, bigger changes are taking place at the Centers for Medicare and Medicaid Services (CMS) and in the states. The Deficit Reduction Act of 2005 (DRA) is ushering in a new level of transparency around drug pricing and has the potential to significantly change the way pharmacists are reimbursed under Medicaid.

These changes are an attempt by Washington to recover value in health care. Many on Capitol Hill believe there is a value crisis in American health care—the nation spends ever-increasing amounts on care without seeing commensurate improvement in quality or outcomes. The DRA is a first step in closing this value gap and is consistent with the larger move toward an “ownership society,” the philosophy that empowering consumers with information and financial responsibility will lead to better decisions and outcomes.

Whether the DRA will successfully close this gap remains to be seen, but one thing is certain—it will reduce government spending on prescription drugs. The Congressional Budget Office estimates DRA reforms will reduce federal spending on prescription drugs by \$3.8 billion between now and 2010. Those savings are projected to grow to about \$12.6 billion between now and 2015. These savings will result from two key provisions—a change in the Medicaid reimbursement formula and the public release of pricing data.

If implemented as passed, the DRA will drastically change the way Medicaid pays for pharmaceuticals. As of January 1, 2007, Medicaid is scheduled to shift reimbursement from the current Average Wholesale Price (AWP) model to a mechanism based on Average Manufacturer Price or AMP. The DRA also revises the Federal Upper Limit (FUL) for multiple source drugs to 250% of the lowest AMP within a therapeutic class.

This is a significant change in reimbursement, especially for generic pharmaceuticals. In some cases, the new reimbursement levels will be below a pharmacy’s acquisition cost. Effectively, the “savings” from the DRA are coming straight out of pharmacists’ pockets. As expected, pharmacists are displeased with this provision of the DRA and have aggressively questioned the usefulness of the AMP for reimbursement calculations.

The pharmacists have a strong argument. According to the Omnibus Budget Reconciliation Act of 1990 (OBRA), AMP is the average price paid to manufacturers by wholesalers for drugs distributed to the retail class of trade.

In theory, the AMP represents the manufacturer’s net revenue per unit (i.e., capsule or tablet) for the sale of a drug to the manufacturer’s retail pharmacy customers. The AMP includes all of the rebates, discounts and price concessions provided to retail pharmacy customers, including the value of free goods.

The AMP therefore may not represent the price that the typical

pharmacy pays for a drug, and the pharmacists and others have mounted an extensive (and successful) lobbying campaign to oppose the new AMP-based reimbursement formula. As a result, CMS temporarily suspended use of the new formula while they drafted a new rule that addressed some of these concerns.

The newly drafted rule was issued on December 15, 2006 and expands the definition of “retail class of trade” to include not only independent and chain pharmacies, but also mail order pharmacies and pharmacy benefit managers (PBMs). This expanded definition is all but certain to have a negative impact on retail pharmacy economics, and the pharmacists’ lobbying efforts will surely intensify. CMS will be soliciting public comments on this issue and others in the rule until February 20, 2007. The final rule is expected on or before July 1, 2007.

In the meantime, the temporary suspension of the AMP-based reimbursement formula does more than delay changes in pharmacy reimbursement rates. It also pushes back what may be the most important provision of the DRA—the effort to improve price transparency and the public release of pricing data to the states, specifically the AMP.

Under the DRA, the states will now be receiving AMP pricing data on a regular basis, as will the public via the CMS website. From the industry perspective, this is problematic for a variety of reasons—the public will have access to pricing information without the proper context and competitors will have better market intelligence.

Interestingly, this public release of AMP data is also problematic for state Medicaid programs. The DRA requires the Secretary of Health and Human Services to issue an annual

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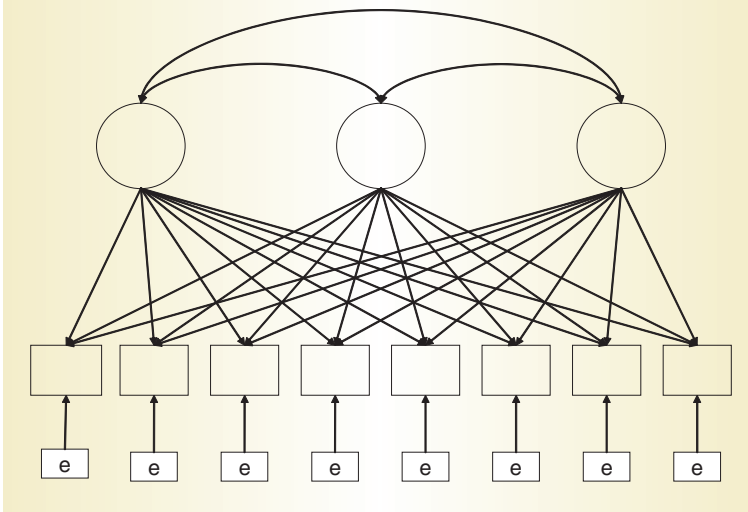
PRO Development and Evaluation

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The first step is to determine if we have collected data from enough cases to allow us to conduct our analyses and have confidence in the results. Typically, psychometric analyses such as exploratory factor analysis (EFA) need a minimum of 5-10 cases for each variable included in the analysis. Confirmatory factor analytic (CFA) techniques generally have larger sample size requirements, often 250 or more subjects.

The next step uses EFA to uncover latent (unobserved) variables by examining the patterns of correlations among our observed variables, that is, the questions completed by respondents. These latent variables, or factors, explain common variation in the items in the PRO instrument, giving us clues about which questions are most closely related to each other and what underlying content is being measured by our instruments. As a consequence, we may be able to reduce a larger number of questions to a smaller number of factors for subsequent data analysis and to describe the phenomena under investigation. As the name implies, EFA is typically carried out in the earlier stages of instrument development when

Figure 1. Hypothetical Exploratory Factor Analysis

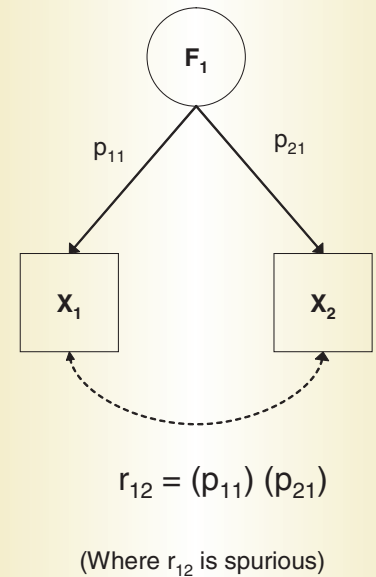


we are exploring whether items that we think have content validity also have some degree of construct validity. In EFA we are not testing *a priori* expectations about which items are measures of certain factors. Thus, each item can be related to each underlying factor, to a greater or lesser degree, depending on the strength and pattern of correlations with other items. An example of an EFA is presented in Figure 1.

In the simplest sense, EFA takes as a basic assumption that items in our PROs are not correlated spuriously and that the covariation among those items is due to another, latent variable. Referring to Figure 2, our goal at this point is to decide

(1) if the factor loadings (p_{11} and p_{21}) are large enough to claim that x_1 and x_2 are measures of F_1 (and thus reduce r_{12} close to zero), and (2) what common content do x_1 and x_2 measure? This latter issue is critical as the factor and its label will be used in subsequent analyses and may be the basis for a labeling claim. A factor label that does not correspond to the content being measured by the items can result in incorrect conclusions about the targeted construct.

Figure 2. Common Factor Accounting for a Spurious Correlation



EFA combines both art and science. The science of EFA is in the use of statistical methods to produce the mathematical solutions that are the hypothetical, common factors explaining the correlations between the items in the PRO instrument. The art of EFA lies in the decisions made to retain or drop items from a factor, determining the final factor solution, and in the interpretation of the factors. In other words, what does the factor seem to be measuring? We often have to make decisions about what to do with items that load on more than one factor. Retaining those items in our subsequent instruments will result in correlations between our factors/dimensions and thus our EFA will not yield “pure” factors. On the other hand, items with loadings on multiple factors may be giving us clues about underlying processes and relationships among the items and dimensions in the PRO measure. At this stage, we should acknowledge the exploratory nature of our analyses and consider investigating these unexpected results.

Once we are satisfied with the provisional factor structure and the items that correspond to each factor, the next step is to conduct a CFA. A CFA is typically conducted in the context of structural equation modeling (SEM). The goal of a CFA or SEM is to evaluate simultaneously (1) the measurement model (i.e., the relationships between the items and factors), derived in the EFA, and (2) the structural model (i.e., the relationships among the factors), while explicitly modeling measurement error. In a CFA the analyst explicitly hypothesizes, *a priori*, the relationships between items and factors and between factors. Moreover, each observed item has measurement error (“e”) that cannot be accounted for

by the underlying factor. An example of a CFA is presented in Figure 3.

Unlike the EFA model in Figure 1 in which all items can be related to all factors and all factors are expected to be correlated, in a CFA the analyst tests the likelihood, based on the observed data, that certain items are related to specific factors and unrelated to others and that the factors are related in particular ways. In addition, the researcher can evaluate the strength of the relationships of each factor with external criteria, such as assignment to treatment and control groups or results of clinical tests. It is also possible to conduct multi-group CFAs testing the invariance of factor structure, loadings and inter-factor correlations between groups, such as US versus Spanish samples or men versus women.

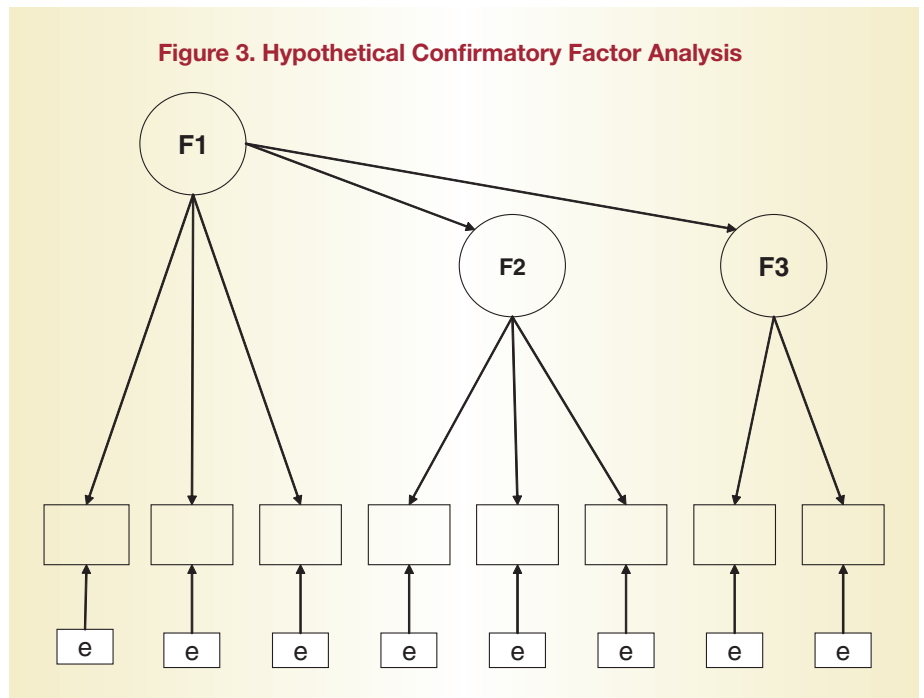
CFA tends to be a large-sample technique (~250 or more cases). Sample size requirements are not determined by the ratio of cases to variables (as in EFA), but on the basis of such things as the number of parameters to be estimated (e.g., factor loadings, path coefficients, and error variance) and the degree of non-normality in the data. More complex models or data that deviate substantially from normality will require larger sample sizes. Most Phase III and IV trials, and many Phase II trials, have sample sizes large enough to evaluate relatively complex models of the factor structures of key PROs and their relationships with clinical variables and other PROs.

Without CFA/SEM, researchers would have created multi-item composite variables for each factor based on the EFA. For evaluating construct validity, clinical variables and other PRO measures would then be regressed on these factors to examine the strength and direction of different relationships. CFA/SEM offers several advantages over regression for evaluating the validity of our measures. First, this technique allows assessment of the entire model of interest in one analysis, incorporating multiple factors and dependent variables simultaneously. This means that the model in Figure 3 could be evaluated in one analysis. Second, unlike regression analyses using composites, which assume perfect measurement of the underlying concept, CFA/SEM acknowledges imperfect measurement and explicitly models this measurement error. This results in more precise estimates of relationships. Third, we obtain an overall R^2 (variance explained by the model) and model fit information (i.e., does the model explain the patterns of relationships in the data?). Fourth, we can compare model fit by subgroups. This can yield insights about whether all factors are equally important in different samples. Finally, software for CFA/SEM incorporates sophisticated methods that handle missing data. The analyst is not restricted to less efficient and biased approaches such as listwise deletion.

Establishing the validity of PROs is a major focus for health outcomes researchers. EFA and CFA/SEM methods allow the researcher to examine the dimensionality of PRO data and to evaluate the fit of pre-specified measurement models to the observed data. The SEM methods enable researchers to specify and test models on the relationship among clinical and PRO measures, and among different PRO measures for examining construct validity.

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Figure 3. Hypothetical Confirmatory Factor Analysis



Suggested Readings

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SPOTLIGHT ON SCIENCE

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FOCUS ON:

Literature Reviews and Meta-Analysis

Choosing the Right Literature Review for Your Needs

By Manu Sondhi, MD, MPH and Susan Ross, MD, FRCPC

Pharmaceutical and device companies have varying needs for an evidence base throughout the developmental lifecycle of a product. These needs may include:

- Preparing for technology reviews by entities such as NICE (National Institute for Clinical Excellence) in the United Kingdom, DERP (Drug Effectiveness Review Project) at Oregon Health & Science University's Center for Evidence-based Policy, AHRQ (Agency for Healthcare Research & Quality), and other managed care organizations performing category reviews
- Understanding the safety and/or efficacy profile of market leaders within a class to support new product commercialization strategies
- Responding to safety threats or publications that bring their product's safety into question
- Supporting publication strategies
- Evaluating burden of illness or cost-effectiveness, or
- Informing clinical trial design.

The scientists at United BioSource Corporation (UBC) have a broad range of clinical, statistical, and epidemiologic expertise that is applied to determine the evidence base appropriate for each particular challenge. Besides the team of experts, UBC utilizes MetaHub®, a proprietary in-house relational database that is designed to capture, organize and distill vast amounts of compiled scientific data. Through the use of another tool, EvidenceHub®, clients can have online access to the data, and can sort, query, and export data efficiently for their evidentiary needs.

Depending on the type of evidence needed and the time frame available, there are six different types of reviews (Table 1- Page 10) as discussed below:

Systematic Review MetaWorks Method™

The systematic review (Figure 1) provides the most comprehensive and rigorous solution. The term "systematic review" denotes a review that addresses a focused question and incorporates established methodology to reduce bias and increase transparency. The evidence base obtained through systematic reviews can often be synthesized quantitatively through meta-analyses. A systematic review provides the

best evidence to inform product development, clinical trial planning, regulatory submission, formulary and reimbursement support, and marketing and communications. These reviews are typically published in peer-reviewed journals and are an important part of communication strategy. Data elements are entered into an updatable and expandable relational database (MetaHub®) and offered online to clients via EvidenceHub®. The time frame for completion of a systematic review is 4-12 months.

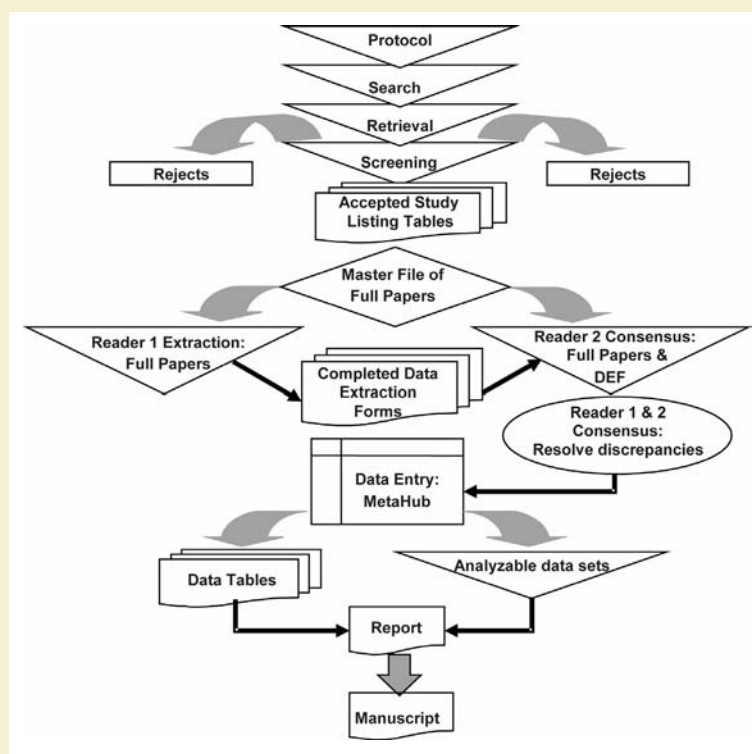
Structured Review

A structured review provides an in-depth review of all relevant studies answering a specific research question. The data are summarized qualitatively. A structured review is not as comprehensive as a systematic review, and these reviews are typically used to address specific research questions identified by the client and are generally for internal communication. Structured reviews are completed within 4-6 months. These are useful for preparation of "white papers" for internal use.

Expert Review

An expert review identifies a representative sample of studies answering a research question. A content expert selects and reviews the articles that are then summarized qualitatively.

Figure 1. Systematic Review MetaWorks Method™ Flow Diagram



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FOCUS ON:

Literature Reviews and Meta-Analysis

Literature Review

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This type of literature review typically informs pharmacoeconomic models. The time frame for completion of an expert review is typically 3-4 months.

Landmark Review

A landmark review helps to develop an understanding of the scientific evidence in an area by identifying and reviewing only the major studies available. Any study design in epidemiology, treatment, diagnostic, and prognostic literature regarding efficacy, safety and health economic outcomes may qualify. Focused extraction of study, patient, and treatment details, with outcomes and time points of interest, are delivered in a written report. These reviews are typically used for internal decision making on brand teams, and the time frame for completion is 3-4 months.

Rapid Review

When a highly focused review of current literature is needed immediately, UBC offers an innovative solution: Rapid

Review, a low-cost, practical and fast review of recently published literature. Expert scientific staff identifies the key issues that are most relevant to the specific need of the client, and then 20-40 studies are obtained that are the most relevant, of highest quality, the most current, and/or provide the most comprehensive coverage of the topic in question. A summary report is produced that includes literature review methods, findings, and concise data tables with clinical and epidemiological interpretations of the results. The rapid review has been used by clients to respond quickly to issues in the regulatory, safety and pharmaco-epidemiology arenas. This type of review also provides detailed information for internal evidence-based decision making. Data elements are entered into a relational database and can be updated and/or expanded later as needed. Rapid reviews are completed in 4-6 weeks.

Catalogues

Catalogues are used to systematically identify and categorize all relevant studies in a particular clinical setting. Catalogues give an insight to the landscape of studies in an area of interest and can help determine whether a systematic review or a meta-analysis is available, or advisable. Scientists extract

Table 1: Literature Review Offerings Available

	Systematic Review MetaWorks Method™	Structured Review	Expert Review	Landmark Review	Rapid Review	Catalogues
Purpose	To systematically review all relevant studies answering single or many research questions	In-depth review all relevant studies answering a specific research question.	To identify and review a representative sample of studies answering a research question.	To identify and review only the major studies in an area	To rapidly identify readily accessible studies addressing a safety question	To systematically identify & catalogue (not review) all relevant studies in a particular clinical setting
Client Need	The most rigorous & complete evidence to inform early product development, clinical trial planning, regulatory submission, formulary & reimbursement support, marketing & communications	Reliable answers re: specific research questions for outcomes research or pharmacoeconomics, typically.	Highlights of main issues surrounding research questions.	An understanding of the major studies in an area	Fast and reliable assessment of literature re: product safety	Searchable profiles of key features of all relevant studies in a particular clinical setting
Study types	Any study design in epidemiology, treatment, diagnostic, prognostic literature re: efficacy, safety, & HEOR outcomes	Any study design in epidemiology, treatment, diagnostic, prognostic literature re: efficacy, safety, & HEOR outcomes	Any study design in epidemiology, treatment, diagnostic, prognostic literature re: efficacy, safety, & HEOR outcomes	Any study design in epidemiology, treatment, diagnostic, prognostic literature re: efficacy, safety, & HEOR outcomes	Observational studies, case reports, and major clinical trials re: safety outcomes	Any study design in epidemiology, treatment, diagnostic, or prognostic literature
Deliverable	Stand alone comprehensive report or manuscript; Internet accessible database (EvidenceHub®)	Stand alone report or manuscript	Information is a component of the overall deliverable	Information is a component of the overall deliverable	Stand alone report	Internet accessible database (EvidenceHub®)
Use of MetaHub®	Yes: data elements are entered into a relational database and can be updated/expanded	No	Sometimes	Sometimes	Yes: data elements are entered into a relational database and can be updated/expanded	Yes: data elements are entered into a relational database and can be updated/expanded
Anticipated Delivery Timeline	4 months -1 year	4-6 months	3-4 months	3-4 months	4-6 weeks	4-9 months
Publishable	Yes	Yes	Yes	Yes	No	No

searchable profiles of key features of all relevant studies, including clinical setting and availability of particular outcomes at particular time points. Study level information is distilled and can be made Internet accessible via Evidence-Hub®. Catalogues are developed over 4-9 months and are particularly useful to plan product messaging in the peri- and post-approval period, especially for companies new to a therapeutic area.

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NICE is Requiring Mixed Treatment Comparisons for the Single Drug Technology Appraisals

By Rachael Fleurence, PhD

The National Institute of Health and Clinical Excellence (NICE) in the United Kingdom is requiring the use of mixed treatment comparisons methods in its guidelines for single drug technology appraisals.¹ These methods have recently been used to compare the efficacy and safety of agents for which head-to-head trials were lacking, and to inform their technology appraisals.² Specifically, the NICE guidelines state that:

“In circumstances where there are no RCTs that directly compare the technology with the comparator(s) of interest, consideration should be given to using indirect/mixed treatment comparisons. This analysis indirectly compares the proposed technology with the main comparator by comparing one set of RCTs in which participants were randomised to the intervention/common reference with another set of RCTs in which participants were randomised to the main comparator/common reference. The common reference is often placebo, but may be an alternative technology.”¹

Following the implementation of these guidelines, mixed treatment comparisons have been used in recent NICE technology appraisals of drugs. For example, they have been used in a comparison of topotecan, pegylated liposomal, doxorubicin hydrochloride and paclitaxel for second-line or subsequent treatment of advanced ovarian cancer³; methylphenidate, dexamfetamine and atomoxetine for the treatment of attention deficit hyperactivity disorder in children and adolescents⁴; and atypical antipsychotics for the treatment of bipolar mania.⁵

In a mixed treatment comparison, if we have studies providing direct comparisons between drug A and drug B and direct comparisons between drug A and drug C, using hierarchical modeling and either traditional or Bayesian meta-analysis methods, we are able to synthesize all of these sources of evidence and provide estimates of the difference of effects between drug A and drug C (mixed treatment

comparison) in addition to estimates for the difference of effects between drug A and drug B, and drug A and drug C.

UBC has extensive experience in conducting rigorous systematic reviews and can implement mixed treatment comparisons following the requirements set out by NICE.

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¹Single Technology Appraisal (STA): Specification for Manufacturer/Sponsor Submission of Evidence. National Institute for Health and Clinical Excellence (NICE). May 17, 2006. Available at: <http://www.nice.nhs.uk/download.aspx?o=316196>.

²Ades AE, Sculpher M, Sutton A, et al. Bayesian Methods for Evidence Synthesis in Cost-effectiveness Analysis. *Pharmacoeconomics*. 2006; 24(1):1-19.

³King S, Griffin S, Hodges Z, et al. A Systematic Review and Economic Model of the Effectiveness and Cost-effectiveness of Methylphenidate, Dexamfetamine and Atomoxetine for the Treatment of Attention Deficit Hyperactivity Disorder in Children and Adolescents. *Health Technol Assess* 2006 July; 10(23): 1-162.

⁴Main C, Bojke L, Griffin S, et al. Topotecan, Pegylated Liposomal Doxorubicin Hydrochloride and Paclitaxel for Second-line or Subsequent Treatment of Advanced Ovarian Cancer: A Systematic Review and Economic Evaluation. *Health Technol Assess* 2006 March; 10(9):1-148.

⁵Bridle C, Palmer S, Bagnall AM, et al. A Rapid and Systematic Review and Economic Evaluation of the Clinical and Cost-effectiveness of Newer Drugs for Treatment of Mania Associated with Bipolar Affective Disorder. *Health Technol Assess* 2004 May; 8(19):iii-iv, 1-187.

Improving the Use of Pharmaceutical Products in Children Using Evidence-Based Medicine

By Matthew W. Reynolds, PhD

Pediatric use of pharmaceuticals has always been, and continues to be, a challenging issue, and yet one of extreme importance. Before passage of the Food and Drug Administration Modernization Act (FDAMA), few drugs were labeled for children since neither Congress nor the Food and Drug Administration (FDA) required pediatric testing of drugs. A 1994 study found that six of the ten drugs most commonly prescribed to children had no pediatric labeling¹. In 2002, the Best Pharmaceuticals for Children's Act (BPCA) was signed into law in an effort to improve the labeling of pharmaceutical products for children. Additional primary objectives of the BPCA are the identification, synthesis and interpretation of available evidence of pharmaceutical use in children to improve the efficacy and effectiveness of those products, as well as to minimize their associated safety risks.

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FOCUS ON:

Literature Reviews and Meta-Analysis

Pharmaceutical Products in Children

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Since 2003, UBC has been working with the National Institute of Child Health and Human Development (NICHD) to provide evidence-based scientific approaches to help identify the most appropriate drugs for study in order to support BPCA's objectives. Over 55,000 published abstracts and almost 12,000 full text articles for over 100 pharmaceutical products have been reviewed to date. The research has resulted in a variety of literature reviews, including full systematic literature reviews to summarize the pharmacokinetics/pharmacodynamics, efficacy, effectiveness, and safety of pharmaceutical use in children 17 years and younger. All of the data from these reviews have been systematically extracted, condensed, and entered into our MetaHub relational database for easy summary and analysis. The NICHD and the FDA have used much of this evidence-based research to support and drive their design and conduct of pediatric clinical trials. Additional work with the NICHD has included focused examination of scientific and analytical methods (e.g., optimal designs and analytical methods to examine safety) to improve the research and labeling for pharmaceuticals in children.

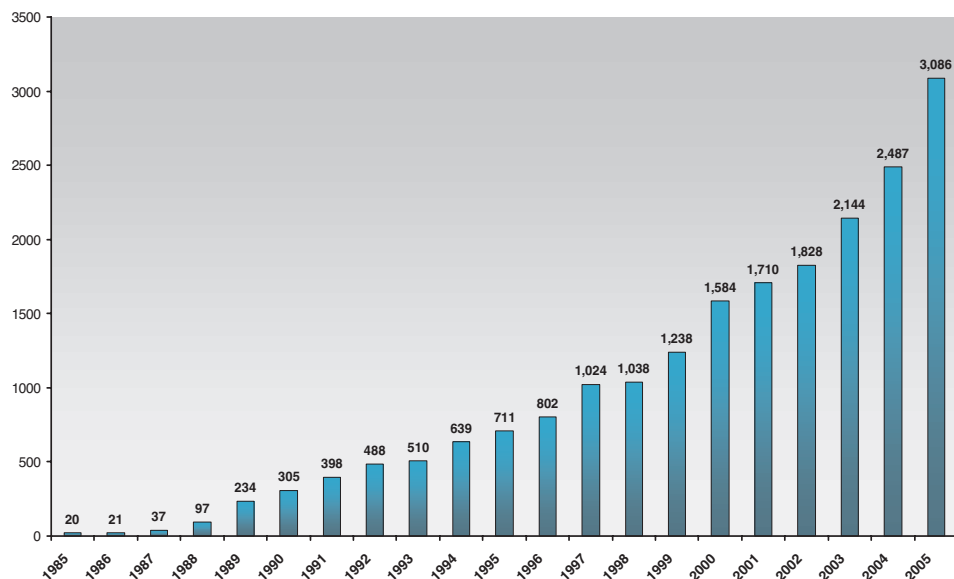
Through the BPCA, pharmaceutical companies also have an incentive to conduct pediatric randomized clinical trials to improve the use of pharmaceuticals in children. That incentive comes in the form of a valuable six month product patent extension. Given our experience in conducting this evidence-based pediatric pharmaceutical research, UBC

has also worked with pharmaceutical companies to identify and synthesize all the available evidence for their products' use in pediatrics. This evidence has been beneficial in identifying new drug indications and/or the information needed to most efficiently design a pediatric clinical trial. The published evidence has helped to determine 1) the characteristics of the most appropriate pediatric patient population for study, 2) the most likely effective and safe dosing, 3) appropriate comparators for trial inclusion, 4) the most appropriate study endpoints, and 5) reliable estimates for study sample size.

In 2007, our pediatric research methods are expanding as we incorporate the study of a variety of medical claims and electronic medical record databases to further examine the real-life treatment patterns, effectiveness, and safety of pharmaceutical products in children. There is a significant amount of information that exists in the public domain that can help to improve the use of pharmaceuticals in children. The evidence is often difficult to identify and heterogeneous, ranging from case reports to randomized controlled trials across various patient populations who are treated by various dosing regimens. A systematic approach to conducting this evidence-based research can synthesize these published results and illustrate the effectiveness and safety of pharmaceuticals in pediatric populations.

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¹Food & Drug Admin., Dept. of Health and Human Services, The Pediatric Exclusivity Provision: January 2001 Status Report to Congress iii, 37 tbl. 7 (2001).



The number of meta-analyses published per year continues to increase, sustaining double digit growth rates in the past three years.

Graph produced by Laurie A. Smith, MLIS, Deirdre Banel, and Susan Ross, MD, FRCPC

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Deficit Reduction Act

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report ranking the comparative performance of all state Medicaid programs for the 50 most widely prescribed drugs. This report includes pricing data for each state.

The states are less than enthusiastic about this provision, and the state Medicaid Directors, in particular, are very unhappy. They know that as soon as the report becomes available, the first call received will be from the governor's office. The second call will be from the local newspaper. Both callers will be asking why the state pays two to three times more than their neighbor for the same drug.

Despite the short-term consequences of this public reporting, the end result will be what Washington intended—lower prices for pharmaceuticals. Once the Medicaid Directors finish defending their roles before the governor and the press, their next move will be to call the drug companies and demand lower prices—or at least the

price that the neighboring state is paying. Many industry observers are predicting a period of rapid price compression shortly after the pricing information is made public.

Of course, there is the possibility that CMS may decide to suspend the public release of either the AMP pricing data or the comparative reporting, or both—and some states are quietly lobbying CMS on this issue. It is too soon to tell whether they will be successful. In the meantime, it would be fair to say that many in the industry and the states are hoping the CMS team studying the AMP issue will conduct a thorough, rigorous (and lengthy) analysis.

So while many in the industry will be focused on the new legislative agenda in the coming year, it is safe to say that there will be perhaps even more to pay attention to at CMS and in the states. The use of AMP for reimbursement and the advent of price transparency are two major issues that could ultimately have greater impact on the industry than anything Congress proposes in 2007.

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Upcoming Presentations

2007 Annual Meeting of the American Academy of Allergy, Asthma, and Immunology

Feb 23–27, 2007, San Diego, CA, USA

“Perceived Onset of Effect of Budesonide and Formoterol Administered via One Pressurized Metered-dose Inhaler in Patients with Asthma Previously Receiving Inhaled Corticosteroids.”
Leidy NK¹, Patrick DL², Boggs R³, Parasuraman B³, O'Dowd L³;
¹United BioSource Corp.; ²Univ. of Washington; ³AstraZeneca

“Assessment of the Psychometric Properties of the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) in Moderate to Severe Pediatric Asthma Patients.” Lobo FS¹, **Revicki D²**, Grant W³, Turk F⁴, Massanari M¹; ¹Novartis Pharmaceuticals; ²United BioSource Corp.; ³James Madison Univ.; ⁴Novartis Pharmaceuticals.

“Prescribing of Fluticasone Propionate/Salmeterol Combinations as Initial Therapy for Patients With Asthma in a Commercially-Insured Population.” Friedman HS¹, **Wilcox TK²**, Reardon G³, Crespi S⁴, Yawn BP⁵; ¹Analytic Solutions, LLC; ²United Biosource Corp.; ³Informagenics, LLC; ⁴Schering-Plough Corp.; ⁵Olmsted Medical Center.

2007 Annual Meeting of the American Association for Geriatric Psychiatry

Mar 1–4 2007, New Orleans, LA, USA

“Primary Care Screening for Cognitive Impairment: The PROCOP Screener” (Presented at the symposium “New Developments in Dementia Screening for Older Adults”). **Frank L¹**, Bowman L², Flynn J², **Kleinman L³**; ¹United BioSource Corp.; ²Eli Lilly and Company; ³United BioSource Corp.

26th Annual Scientific Meeting of the American Pain Society

May 2–May 5 2007, Washington, DC, USA

“Development and Validation of the Modified Brief Pain Inventory Short Form (MBPI-SF) in CABG and General Surgery Patients.” **Chen W¹**, Chan KS², Chen C³, Lakshminarayanan M³, **Revicki D¹**; ¹United BioSource Corp.; ²Johns Hopkins School of Public Health; ³Pfizer Inc.

“Development and Validity of a Composite Clinically Meaningful Events (CMES) Score Based on the Opioid-Related Symptom Distress Scale (OR-SDS).” Chan KS¹, **Chen W²**; Chen C³; Lakshminarayanan M³, **Revicki D²**; ¹Johns Hopkins School of Public Health; ²United BioSource Corp.; ³Pfizer Inc.

2007 American Thoracic Society (ATS) International Conference

May 18–23 2007, San Francisco, CA, USA

“What Happens to Patients Who Have Their Asthma Medication Switched without Their Consent? A Qualitative Study.” **Lloyd A¹**, **Doyle S¹**, Williams A², Price D³, Thomas M³, Chrystyn H⁴; ¹United BioSource Corp.; ²GlaxoSmithKline; ³Univ. of Aberdeen; ⁴Univ. of Bradford.

International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 12th Annual International Meeting

May 19 - 23 2007, Arlington, VA, USA

Pre-Meeting Short Courses

Saturday, May 19, 2007, 8:00 AM-5:00 PM

“Bayesian Analysis: Overview & Applications”

FACULTY: **Bryan Luce PhD, MBA**, Sr. Vice President, Science Policy, United BioSource Corp.; **Christopher S. Hollenbeak PhD**, Surgery and Health Evaluation Sciences, Penn State

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UBC Scientific and Strategic Leaders

United BioSource Corporation has leading scientists and experts who contribute to the design of optimal programs and projects and provide valuable guidance and support to UBC and sponsor operations teams. The backgrounds and education of these senior-level experts are highlighted below.

David Daniel, MD, Senior Vice President, Training and Education

Dr. David Daniel is the Senior Vice President and Chief Medical Director of UBC's Training and Education Services, offering unique investigator education and data quality capabilities to help ensure the reliability of study results, particularly for trials with subjective outcome measures.

Prior to joining UBC, Dr. David Daniel served as President of Bioniche Global Learning. Dr. Daniel has an extensive background in the Neuroscience field with over 20 years of clinical experience and has held numerous medical director positions throughout his career. In addition to his responsibilities at UBC, he is Clinical Professor of Psychiatry and Behavioral Sciences at George Washington University in Washington, DC.

Dr. Daniel has authored numerous articles and manuscripts that have been published in scientific and psychiatric journals. He attended Emory University where he received his BA degree and graduated magna cum laude. Dr. Daniel attended Vanderbilt University Medical School where he received his MD and in addition, completed his residency in Psychiatry.

Gerald Faich, MD, MPH, Senior Vice President, Epidemiology and Risk Management

Dr. Gerald Faich heads UBC's Epidemiology and Risk Management Services and is a recognized leader in drug safety and pharmacoepidemiology. His research interests are risk assessment, pharmacoepidemiology and the design and conduct of registries and streamlined trials for phase IIIb and IV. Before joining UBC, Jerry served in senior management positions at FDA and Corning and provided high-level consulting on safety and risk issues. He is currently a visiting scholar at the University of Pennsylvania and Past-President of the International Society of Pharmacoepidemiology.

Dr. Faich received his undergraduate and medical degrees with honors from the University of Wisconsin. He followed this with an Internal Medicine residency and Masters Degree in Public Health from Harvard. He is a Fellow of the American Colleges of Physicians, Preventive Medicine and Pharmacoepidemiology and has authored over 90 scientific papers and received numerous awards, including

FDA's Outstanding Service Award for contributions to Postmarketing Surveillance and Public Health.

From 1983 to 1990, Dr. Faich was the Office Director in charge of statistics and postmarketing surveillance for drugs and biologics at the FDA. There he revitalized the adverse reaction reporting system, revised reporting regulations, expanded staffing and pharmacoepidemiologic research. He co-chaired the original Council for International Organizations of Medical Sciences (CIOMS) International Adverse Reaction Working Group and was a founding board member of the International Society for Pharmacoepidemiology.

After leaving FDA Dr. Faich served as President of PACT, a CRO which focused on postmarketing research and Corning Pharmaceutical Services (now Covance) where he had overall responsibility for toxicology, laboratory testing and phase I to IV clinical trial units. He formed a consulting company in 1996 and joined UBC in 2004.

Nancy Kline Leidy, PhD, Senior Vice President, Scientific Affairs

Dr. Nancy Kline Leidy is the Senior Vice President of Scientific Affairs for UBC. She has over 25 years of experience in clinical and health outcomes research, specializing in instrument development, psychometric testing, and the design and analysis of clinical trials involving clinical, quality of life, and functional outcomes assessment. Immediately prior to joining UBC, Dr. Leidy was an intramural scientist at the National Institutes of Health (NIH) where she studied performance variation and structure in people with chronic obstructive pulmonary disease. She currently serves as an Adjunct Faculty Member at Johns Hopkins University.

Dr. Leidy has presented her work at local, national, and international conferences and has over 80 papers published in refereed journals, books and monographs. Her publications have appeared in the American Journal of Respiratory and Critical Care Medicine, Chest, Journal of COPD, European Respiratory Review, PharmacoEconomics, and Quality of Life Research, among others. She has been the recipient of numerous awards, including the Michigan State University Teacher-Scholar Award and the Wolanin award for excellence in geriatric research, has served as a distinguished lecturer at a number of universities, and is an active member of several professional societies.

Dr. Leidy has worked with the FDA on issues related to the use of patient reported outcomes (PROs), including symptom evaluation and health-related quality of life in pharmaceutical research. She was the lead author of the seminal paper, "Recommendations for Evaluating the Validity of Quality of Life Claims for Labeling and Promotion" (1999, *Value in Health*) and served as the ISPOR representative to the Harmonization Project, a multi-organizational effort designed to bring global harmony to regulatory requirements underlying the use of PRO information in labeling and promotion. Dr. Leidy served as one of four team leaders in one of the first Harmonization meetings at the FDA, presenting "The Value of Patient Reported Outcomes." The results of this meeting were published in *Value in Health*. She is currently the principal investigator of the EXACT-PRO initiative (EXAcerbations of Chronic pulmonary disease Tool), a multi-sponsor instrument development project with the FDA and clinical expertise in chronic bronchitis and chronic obstructive pulmonary disease (COPD).

Dr. Leidy holds a PhD in clinical research with specialties in social psychology and quantitative methods from the University of Michigan. She earned her Bachelor of Science degree from Michigan State University and her Master's degree from the University of Washington.

Bryan R. Luce, PhD, MBA, Senior Vice President, Science Policy

Dr. Bryan R. Luce is the Senior Vice President, Science Policy for United BioSource Corporation. Dr. Luce founded The MEDTAP® Institute in 1995 and served as its Chairman, President and CEO until 2002. Previously, he held positions as Director of Battelle's Centers for Public Health Research and Evaluation, Director of the Office of Research and Demonstrations, Health Care Financing Administration and as Senior Analyst, Office of Technology Assessment (OTA) of the United States Congress.

Dr. Luce has been a consultant to numerous government agencies as well as pharmaceutical and device firms worldwide. He is presently a member of The Medicare Coverage Advisory Committee (MCAC); a member or chair of socioeconomic and public health policy advisory boards for several leading pharmaceutical companies; a member of the Executive Advisory Board of the Tufts Center for Evaluation, Risk and Value; and on the editorial boards of *Value in Health*, the *American Journal of Managed Care*, and *Pharmacoeconomics*. He has authored more than 80 scientific publications, including three textbooks on technology assessment, health policy and cost-effectiveness analysis, and he founded and chairs the Bayesian Initiative in Health Economics and Outcomes Research. He is a Past President of the International Society for Pharmacoeconomics and Outcomes Research

(ISPOR), an Adjunct Senior Fellow of the Leonard Davis Institute, University of Pennsylvania, a Senior Scholar with the Department of Health Policy, Jefferson Medical College and is a Lieutenant Colonel (Retired), Medical Service Corps, US Army Reserves. Dr. Luce's undergraduate and masters training were at the Universities of Vermont and Massachusetts at Amherst. He received his Doctorate from the School of Public Health at the University of California at Los Angeles (UCLA).

Lukas Makris, PhD, Senior Vice President, Biostatistics

Dr. Lukas Makris is the Senior Vice President, Biostatistics for United BioSource Corporation, providing clinical data services such as protocol development, statistical regulatory representation, data entry and management, statistical programming and analysis and medical writing for Phase I-IV studies. He founded BioCor LLC in 1998, which was acquired by UBC in 2006. He has over 15 years of industry and CRO experience in the biostatistics and clinical development arenas. Dr. Makris has also provided statistical regulatory guidance and has had numerous interactions with the FDA, EMEA and local European regulatory authorities.

He has extensive regulatory experience, having served as the statistical representative in IND, end of Phase II and III and NDA review meetings, as well as in discussions and negotiations on the content and format of electronic submissions. He served as the statistical consultant to the Medical Imaging Contract Agent Association (MICAA) and drafted the statistical response to the FDA Draft Guidance Document to the Medical Imaging Industry. He has experience in a wide variety of therapeutic areas, including asthma, cardiology, depression, metabolic disorders, oncology, pain, and schizophrenia, as well as medical devices and diagnostics in several areas.

Dr. Makris' former experience includes Senior Director, Clinical Information, Management & Biostatistics for Bracco Diagnostics Inc. and Senior Biometrician Manager for Merck Research Laboratories. He has also been a Project Statistician for the School of Public Health and a Statistical Consultant and Instructor for the School of Statistics, both at the University of Minnesota. His expertise has been shown through various presentations at industry conferences internationally and through his co-authorship of publications.

Dr. Makris received his doctorate degree in Statistics and Bayesian Inference from the University of Minnesota School of Statistics and his bachelor's degree in Mathematics from the University of Patras School of Sciences in Patras, Greece.

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UBC Scientific and Strategic Leaders *continued from page 15*

Dennis A. Revicki, PhD, Senior Vice President, Health Outcomes Research

Dr. Dennis A. Revicki is the Senior Vice President and Scientific Director of UBC's Center for Health Outcomes Research, with over 25 years experience in designing and conducting studies involving health-related quality of life measurement, economic evaluation, health services research and psychometrics research assessments. Dr. Revicki's primary research interest is in studying health outcomes including applications of health-status assessment and health-utility measures in clinical trials and outcomes research, and mental health services research. He has designed and conducted health-related quality of life studies to evaluate outcomes of medical treatment for asthma, COPD, chronic hepatitis C, HIV disease, chronic renal disease, cardiovascular disease, chronic and acute pain, rheumatologic disorders, gastrointestinal disorders, bipolar disorder, schizophrenia, anxiety disorders and depression for private industry and government agencies. He is, or has been, the principal investigator on several cost-effectiveness studies for the pharmaceutical industry comparing treatments for schizophrenia, depression, bipolar disorder, and other chronic diseases.

Dr. Revicki completed his graduate work in quantitative psychology at the University of North Carolina at Chapel Hill in 1981. He has directed research and evaluation projects at UBC, Battelle, Veterans Administration Health Services Research and Development Service, East Carolina University School of Medicine and the University of North Carolina Department of Psychiatry and School of Education.

Dr. Revicki holds faculty appointments in the Department of Health Policy and Administration, University of North Carolina at Chapel Hill, and the Department of Psychiatry, Georgetown University Medical Center. Dr. Revicki has over 260 publications in journals such as *Journal of the American Medical Association*, *British Medical Journal*, *Archives of General Psychiatry*, *PharmacoEconomics*, *Quality of Life Research*, *Medical Care*, *Journal of Gerontology*, *Journal of Clinical Psychiatry*, *Archives of Internal Medicine*, *American Journal of Public Health*, *Journal of Family Practice*, and more than 25 book chapters on health status assessment and pharmacoeconomics. He recently edited a book with William Lenderking on advances in health outcomes research and methods. He is a member of the Academy Health and the International Society for Quality of Life Research. He was formerly the Treasurer and a Member of the Board for the International Society for Quality of Life Research.

Susan D. Ross, MD, FRCPC, Vice President, Medical Affairs

Dr. Susan D. Ross is the Vice President, Medical Affairs for United BioSource Corporation. In 1993, Dr. Ross co-founded MetaWorks® Inc., acquired by UBC in 2006, with Dr. Thomas Chalmers and established the company as an evidence-based medicine (EBM) consulting firm and the private sector's premier provider of meta-analysis. Today, Dr. Ross provides medical leadership on all UBC systematic review and meta-analysis projects. Prior to MetaWorks, she was an independent consultant to the pharmaceutical and biotechnology industries and a Vice President of Clinical Research at Cellcor. She is a recognized industry researcher with numerous publications and presentations regarding the methods and application of EBM in drug development and commercialization. Dr. Ross also is a peer-reviewer for several medical journals, including *Hypertension*, the *Archives of Internal Medicine*, and the *Canadian Medical Association Journal*.

Dr. Ross is a graduate of the advanced course in Biomedical Research Management at the Harvard School of Public Health. She graduated with honors in Medicine from the University of Toronto Faculty of Medicine and completed her Internal Medicine residency and a research fellowship at University of Toronto teaching hospitals. She is board certified in Internal Medicine in both Canada and the U.S., where she continues a limited clinical practice in a Boston area free care clinic.

Annette Stemhagen, DrPH, FISPE, Vice President, Epidemiology and Risk Management

Dr. Annette Stemhagen has more than 25 years of public health epidemiological research experience, including 15 years in safety surveillance of pharmaceutical, biotech and vaccine products. She is the Vice President of the UBC's Epidemiology and Risk Management Services, where she provides strategic consultative services and program oversight to pharmaceutical and biotech clients in epidemiology, safety surveillance, and risk management. Dr. Stemhagen has specific expertise in safety surveillance; design, implementation, and analysis of epidemiologic studies, registries, large streamlined safety studies; and actual use and observational studies for products in Phase IIIb and post approval. She has designed and evaluated risk assessment studies, including more than 10 regulatory-mandated long term safety studies. She has also developed risk intervention programs, risk management evaluation studies, and RiskMAPs for multiple products.

Dr. Stemhagen has also worked as an epidemiologist in several large pharmaceutical companies where she

supported multiple products with epidemiologic assessments and studies. She was also the Director of Research and Research Assistant Professor of Medicine in the Emergency Services Department of the Hospital of the University of Pennsylvania and served as Director of Cancer Epidemiology Services for the New Jersey State Department of Health. Dr. Stemhagen was a Principal Investigator for a National Cancer Institute SEER registry. For more than ten years, Dr. Stemhagen served as an industry representative to the PhRMA Clinical Safety Surveillance Committee, chairing both the Epidemiology subcommittee, and the Ethics subcommittee. Dr. Stemhagen has held leadership positions in both the International

Society for Pharmacoepidemiology and the Drug Information Association.

Dr. Stemhagen received her undergraduate degree from the University of Pennsylvania and her Masters and Doctoral Degrees from the University of Pittsburgh Graduate School of Public Health. She holds adjunct faculty appointments at the University of Pennsylvania School of Medicine Center for Epidemiology and Biostatistics and the Temple University School of Pharmacy. Dr. Stemhagen is a Fellow of the International Society for Pharmacoepidemiology. In 2004 Dr. Stemhagen was appointed as the Industry Representative to the FDA Drug Safety and Risk Management Advisory Committee.

NEWS BRIEFS

■ Lynn J. Okamoto, PharmD Appointed General Manager, Health Care Analytics Group

Dr. Lynn Okamoto has been appointed the General Manager of UBC's Health Care Analytics group, responsible for overseeing the scientific, strategic and operational performance of UBC's analytic services.



With the growing emphasis on evidence-based solutions in the health care industry, it is becoming increasingly vital to understand the importance and use of analytic services such as pharmacoconomics, health outcomes research, data management, systematic literature reviews and meta-analysis. Dr. Okamoto has

a deep understanding of these services and how they fit into the complete value story for pharmaceutical and device products. This knowledge is invaluable as she leads UBC's staff in providing these services and continues to envision the future needs of the industry to ensure UBC remains the premier provider of exceptional and comprehensive analytic offerings to meet changing demands.

Having directed UBC's Center for Health Economics & Policy and held key positions at Glaxo Wellcome and NDCHealth, a provider of value-added information services for the health care industry, Dr. Okamoto brings years of scientific, strategic, and management skills to this position. She has had numerous publications and presentations and received her Doctor of Pharmacy degree from the University of Michigan.

■ Tiepu Liu, MD, PhD Appointed Executive Director of Biostatistics and Data Management

Dr. Tiepu Liu has been appointed Executive Director of Statistics and Data Management for UBC's Health Care Analytics Group. In this position, Dr. Liu is responsible for the scientific and operational aspects of the data manage-

ment and statistical analysis services for the Health Care Analytics Group, providing guidance and consultation on program development, study design, analysis, and interpretation, as well as other scientific issues.



Most recently, Dr. Liu was the Director of Biostatistics for PPD, Inc. where he provided statistical and scientific guidance in conducting all phases of clinical trials; statistical consultation in clinical development program plans and submissions; and direction on study design and protocol development. His experience also

includes coordinating teams of data management, programming, biostatistics and pharmacovigilance in developing statistical analysis plans and preparing integrated clinical and statistical reports and summaries for safety, efficacy and regulatory submissions.

Dr. Liu has held faculty positions at the University of Cincinnati College of Medicine, University of Alabama at Birmingham, and Tongji Medical University. He has published more than 80 manuscripts and has given over 100 presentations at industry conferences. During his career, Dr. Liu has served in various review panels and scientific committees with numerous health organizations including the National Institutes of Health, the Society of Academic Emergency Medicine, and the Department of Defense Medical Research Programs. Dr. Liu received his Doctor of Public Health, with a focus in Biostatistics and Epidemiology, from the University of Alabama at Birmingham and his Doctor of Medicine and Master's in Public Health from Tongji University in Wuhan, China.

■ L. Clark Paramore, MSPH Appointed Managing Director, UBC Boston Office and Executive Director, Center for Health Economics, Epidemiology and Science Policy

Mr. Clark Paramore has been appointed Managing Director of UBC's Boston office. In this capacity, Mr. Paramore is

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NEWS BRIEFS



responsible for the scientific, strategic and operational performance of this office.

Mr. Paramore also holds the position of Executive Director of UBC's Center for Health Economics, Epidemiology and Science Policy. As the former Deputy Director of this Center, Mr. Paramore brings a strong background to both positions, allowing him to direct UBC's exceptional research staff in the areas of health economics, epidemiology and science policy issues, as well as systematic literature reviews and meta-analysis. With UBC being the leading provider of these services, Mr. Paramore is working to ensure that the importance of systematic literature reviews and meta-analyses, along with their use in combination with health economic and outcomes research offerings, is realized to support evidence-based health care decisions.

Mr. Paramore's extensive knowledge and use of nationally represented data sets makes him ideally suited to help lead our growing data, including electronic medical record data, and epidemiology specialty areas. His experience in health economic research serves him well in continuing to promote and expand our health economic and outcomes research capabilities.

Mr. Paramore holds a Master's degree in health policy from the School of Public Health at the University of North Carolina at Chapel Hill and an undergraduate degree in public policy from Duke University.

■ **Lori Frank, PhD Appointed Executive Director of UBC's Center for Health Outcomes Research**

Dr. Lori Frank has been appointed Executive Director of UBC's Center for Health Outcomes Research (CHOR). In this capacity, Dr. Frank uses her extensive experience in the



area of outcomes research to direct the scientific, strategic, and operational performance of this Center.

In addition to her role as Executive Director of CHOR, Dr. Frank is also a Senior Research Scientist whose current research activities include measurement of physical and mental health outcomes with an emphasis on development of patient-based assessment strategies. She also holds an adjunct appointment to the Georgetown University Department of Psychiatry with collaboration with the Center for Trauma and the Community.

Dr. Frank received her Doctorate in human development with a specialization in gerontology from the Pennsylvania State University, and received her Master's degree in biopsychology from the Johns Hopkins University. She completed her

postdoctoral training in mental health services research at the Veteran's Administration Health Services Research and Development program and the Department of Psychiatry of the University of Arkansas for Medical Sciences in Little Rock, AR. Her prior work experience includes psychophysiological research with the National Institute on Aging and program evaluation and hospital administration in a private psychiatric hospital.

She has presented at numerous scientific conferences internationally and has published widely in peer-reviewed journals, including *Journal of the American Geriatrics Society*, *Journal of Mental Health and Aging*, *PharmacoEconomics*, *Digestive Diseases and Sciences*, and *Gerontologist*.

Upcoming Presentations

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College of Medicine, & Visiting Scientist, United BioSource Corp.; David Vanness PhD, Asst. Professor of Population Health Sciences, Univ. of Wisconsin Medical School.

"Bayesian Analysis: Advanced"

Sunday, May 20, 2007, 8:00A M-12:00 PM

FACULTY: **Bryan Luce PhD, MBA**, Sr. Vice President, Science Policy, United BioSource Corp.; Keith R. Abrams PhD, Dept. of Health Sciences, Univ. of Leicester; **Christopher S. Hollenbeak PhD**, Surgery and Health Evaluation Sciences, Penn State College of Medicine, & Visiting Scientist, United BioSource Corp.; David Vanness PhD, Asst. Professor of Population Health Sciences, Univ. of Wisconsin Medical School.

"Real World Data Methods: Use of Real World Data in Outcomes Research"

Sunday, May 20, 2007, 8:00A M-12:00 PM

FACULTY: Diana Brixner PhD, RPh, Assoc. Professor and Dept. Chair, College of Pharmacy, Univ. of Utah; **Gregory de Lissovoy, PhD, MPH**, Sr. Research Scientist, Center for Health Economics and Policy, United BioSource Corp.; Daniel M. Huse, MA, Practice Leader, Information Products, Thomson Medstat Inc.

AcademyHealth 2007 Annual Research Meeting (ARM)

Jun 3–Jun 5 2007, Orlando, FL, USA

Methods Workshop

Sunday, June 3, 2007, 3:00 - 4:30 PM

"Bayesian Trial Designs." **Bryan R. Luce, PhD, MBA**, Sr. Vice President, Science Policy, United BioSource Corp.

43rd DIA Annual Meeting

Jun 17 - 21 2007 Atlanta, GA, USA

"Using Electronic Medical Records for Clinical Research." **Susan D. Ross, MD, FRCPC**, Vice President, Medical Affairs, United BioSource Corp.

"The Use of Patient & Disease Registries for Product Lifecycle Management." Co-Chair: **Annette Stemhagen, DrPH FISPE**, Vice President, Epidemiology & Risk Management, United BioSource Corp.

"Avoiding Pitfalls in the Conduct of Postmarketing Trials for Safety." Chair: **Gerald A. Faich, MD**, Sr. Vice President, Epidemiology & Risk Management, United BioSource Corp.

Recent Presentations

Emerging Technologies Spine Education Summit

Feb 7–10, 2007, Telluride, CO, USA

“The Future for Total Disk Arthroplasty: Lessons Learned from the Charite Experience.” **Isabella Sledge, MD, MPH**, Medical Director, Health Care Analytics Group, United BioSource Corp.

5th Annual LifeScience Alley Conference & Expo

Dec 6, 2006, St. Paul, MN, USA

“Planning Double-Duty Outcomes: Supporting FDA Approval & CMS Reimbursement.” **Diane Simison PhD**, Center for Pricing and Reimbursement, United BioSource Corp.

NICE 2006 Annual Conference and Exhibition: Tackling Health Priorities

Dec 6–7, 2006, ICC, Birmingham, UK

“Inhaled Corticosteroids for Asthma: Impact of Practice Level Device Switching on Asthma Control.” Thomas M¹, Price D¹, Chrystyn H², **Lloyd A³**, Williams AE⁴; ¹Department of General Practice, Univ. of Aberdeen; ²School of Pharmacy, Univ. of Bradford; ³United BioSource Corp.; ⁴GlaxoSmithKline R&D.

Modern Drug Discovery and Development Summit

Dec 4–6, 2006, Philadelphia, PA, USA

“Study Methods for Scientific Approaches to Understanding the Safety of Pharmaceuticals in Children.” **Matthew W. Reynolds, PhD**, Senior Director Safety Services, Health Care Analytics Group, United BioSource Corp.

DIA Conference on Electronic Patient Reported Outcomes (ePRO) Update: The Quest to Move From Paper to Plastic

Dec 4–5, 2006, Baltimore, MD, USA

“Validation of ePROs.” **Lori Frank, PhD**, Executive Director and Senior Research Scientist, Center for Health Outcomes Research, United BioSource Corp.

International Continence Society 36th Annual Meeting

Nov 27–Dec 1, 2006, Christchurch, New Zealand

“Men and Women with Overactive Bladder Symptoms Report Higher Prevalence of Depression and Lower Quality of Life: Results From the EPIC Study.” Irwin D¹, Milsom I², Reilly K³, Hunskar S⁴, **Coyne KS⁵**, Kopp Z³, Herschorn S⁶, Kelleher C⁷, Hampel C⁸, Artibani W⁹, Abrams P¹⁰; ¹Univ. of North Carolina; ²Sahlgrenska Academy at Goteborg Univ.; ³Pfizer, Inc.; ⁴Univ. of Bergen; ⁵United BioSource Corp.; ⁶Univ. of Toronto; ⁷St. Thomas' Hospital; ⁸Johannes-Gutenberg-Universität; ⁹Univ. of Padova; ¹⁰Southmead Hospital, Bristol Urological Institute.

“Overactive Bladder Symptoms Associated with a Negative Impact on Work Productivity: Results From the EPIC Study.” Irwin D¹, Milsom I², Reilly K³, Hunskar S⁴, **Coyne KS⁵**, Kopp Z³, Herschorn S⁶, Kelleher C⁷, Hampel C⁸, Artibani W⁹, Abrams P¹⁰; ¹Univ. of North Carolina; ²Sahlgrenska Academy at Goteborg Univ.; ³Pfizer, Inc.; ⁴Univ. of Bergen; ⁵United BioSource Corp.; ⁶Univ. of Toronto; ⁷St. Thomas' Hospital; ⁸Johannes-Gutenberg-Universität; ⁹Univ. of Padova; ¹⁰Southmead Hospital, Bristol Urological Institute.

Podium Presentations

“Impact of Overactive Bladder on Frequency of Sexual Activity and Erectile Dysfunction in Men: Results From the EPIC Study.” Irwin D¹, Milsom I², Reilly K³, **Coyne KS⁴**, Hunskar S⁵, Kopp Z³, Herschorn S⁶, Kelleher C⁷, Hampel C⁸, Artibani W⁹, Abrams P¹⁰; ¹Univ. of North Carolina; ²Sahlgrenska Academy at Goteborg Univ.; ³Pfizer, Inc.; ⁴United BioSource Corp.; ⁵Univ. of Bergen; ⁶Univ. of Toronto; ⁷St. Thomas' Hospital; ⁸Johannes-Gutenberg-

Universität; ⁹Univ. of Padova; ¹⁰Southmead Hospital, Bristol Urological Institute.

“Prevalence, Symptom Bother, and Healthcare Seeking Among Individuals with Overactive Bladder: Results From the EPIC Study.” Milsom I¹, Irwin D², Reilly K³, **Coyne KS⁴**, Hunskar S⁵, Kopp Z³, Herschorn S⁶, Kelleher C⁷, Hampel C⁸, Artibani W⁹, Abrams P¹⁰; ¹Sahlgrenska Academy at Goteborg Univ.; ²Univ. of North Carolina; ³Pfizer, Inc.; ⁴United BioSource Corp.; ⁵Univ. of Bergen; ⁶Univ. of Toronto; ⁷St. Thomas' Hospital; ⁸Johannes-Gutenberg-Universität; ⁹Univ. of Padova; ¹⁰Southmead Hospital, Bristol Urological Institute.

59th Annual Meeting of the Gerontological Society of America

Nov 16–20, 2006, Dallas, TX, USA

“Evaluating the Relationship between Self-Rated Health and Depression Using an Accelerated Growth Curve Model.” Kercher K¹, Kosloski K¹, **Stull D²**, van Dussen D³; ¹Univ. of Nebraska at Omaha; ²Center for Health Outcomes Research, United BioSource Corp.; ³Univ. of Maryland.

2006 Annual Meeting of American College of Allergy, Asthma & Immunology

Nov 9–15, 2006, Philadelphia, PA, USA

“Impact of Congestion Associated with Allergic Rhinitis on Sleep, Daytime Somnolence and Fatigue, and Work and School Productivity.” **Stull DE¹**, **Roberts L¹**, **Frank L¹**, Heithoff K²; ¹Center for Health Outcomes Research, United BioSource Corp.; ²Schering-Plough.

“Development and Validation of the Congestion Quantifier 5-Item (CQ5): A Screening Tool for Nasal Congestion.” **Stull DE¹**, Krouse J², Naclerio R³, Meltzer EO⁴, Long A⁵, Lund V⁶, Kim S⁷; ¹Center for Health Outcomes Research, United BioSource Corp.; ²Dept. of Otolaryngology/Head and Neck Surgery, Wayne State Univ.; ³Dept. of Surgery, Section of Otolaryngology, Head and Neck Surgery, Univ. of Chicago; ⁴Univ. of California at San Diego and Asthma Medical Group and Research Center; ⁵Allergy Associates, Massachusetts General Hospital; ⁶Institute of Laryngology and Otolaryngology, Univ. College London; ⁷Schering-Plough.

Alzheimer's Association Research Roundtable

Nov 8, 2006, Washington, DC, USA

“Patient Reported Outcomes (PROs): FDA Draft Guidance”. **Lori Frank, PhD**, Executive Director and Senior Research Scientist, Center for Health Outcomes Research, United BioSource Corp.

SMS 2006 Fall Meeting

Nov 2–5, 2006, Las Vegas, NV, USA

“Overactive Bladder Is Associated With Erectile Dysfunction and Reduced Sexual Quality of Life in Men: Results From the EPIC Study.” Irwin DE¹, Milsom I², Reilly K³, **Coyne KS⁴**, Kopp Z³, Herschorn S⁵, Kelleher CJ⁶, Hampel C⁷, Artibani W⁸, Abrams P⁹; ¹Univ. of North Carolina; ²Goteborg Univ.; ³Pfizer Inc.; ⁴Center for Health Outcomes Research, United BioSource Corp.; ⁵Univ. of Toronto; ⁶St. Thomas' Hospital; ⁷Johannes-Gutenberg-Universität; ⁸Univ. of Padova; ⁹Southmead Hospital, Bristol.

“The Impact of Overactive Bladder on the Sexual Health of Women: A Qualitative Study.” Rogers R¹, **Coyne KS²**, **Stoeckl M²**, Jumadilova Z³, Bavendam T³; ¹Univ. of New Mexico School of Medicine; ²Center for Health Outcomes Research, United BioSource Corp.; ³Pfizer Inc.

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Recent Publications continued from page 8

- Measuring?" *Heart & Lung* July/August 2006; 35(4):217.
- **Nafees B, Lloyd A**, Kennedy-Martin T, Hynd S. "How Diabetes and Insulin Therapy Affects the Lives of People with Type 1 Diabetes." *European Diabetes Nursing* 2006; 3(2).
 - **Niebauer K, Dewilde S**, Fox-Rushby J, **Revicki DA**. "Impact of Omalizumab on Quality-of-Life Outcomes in Patients with Moderate to Severe Allergic Asthma." *Annals of Allergy, Asthma & Immunology* 2006; 96(2):316-326.
 - Powers A, Marden S, McConnell R, **Leidy NK**, Campbell C, Soeken K, Barker C, Davey R, Dybul M. "Effect of Long-Cycle Structured Intermittent Versus Continuous HAART on Quality of Life in Patients with Chronic HIV Infection." *AIDS* 2006; 20(6):837-845.
 - Reeve BB, Hays RD, Bjorner JB, Cook KF, Crane PK, Teresi JA, Thissen D, **Revicki DA**, Weiss DJ, Hambleton RK, Honghu L, Gershon R, Reise SP, Lai J, Cella D. "Psychometric Evaluation and Calibration of Health-related Quality of Life Items Banks: Plans for the Patient-Reported Outcome Measurement Information System (PROMIS)." *Medical Care*; In Press.
 - **Revicki D**, Weiss KB. "Clinical Assessment of Asthma Symptom Control: Review of Current Assessment Instruments." *J Asthma* 2006; 43(7):481-7.
 - **Revicki DA**, Cella D, Hays RD, Sloan JA, Lenderking WR, Aaronson NK. "Responsiveness and Minimal Important Differences for Patient Reported Outcomes." *Health and Quality of Life Outcomes* 2006; 4(70):1-5.
 - **Revicki DA**, Feeny D, Hunt TL, Cole BF. "Analyzing Oncology Clinical Trial Data Using the Q-TWiST Method: Clinical Importance and Sources for Health State Preference Data." *Qual of Life Res* 2006 Apr; 15(3):411-23.
 - **Revicki DA**, Feeny D, Hunt TL, Cole BF. "Clinically Important Differences in Q-TWiST—One TWiST too Many, or TWiST and Shout?" *Qual of Life Res* 2006 Apr; 15(3):427-8.
 - **Revicki DA**, Gnanasakthy A, Weinfurt K. "Documenting the Rationale and Psychometric Characteristics of Patient Reported Outcomes for Labeling and Promotional Claims: The PRO Evidence Dossier." *Quality of Life Res* 2007; In Press.
 - **Revicki DA, Kimel M**, Beusterien K, Kwong JW, Varner JA, Ames MH, Mahajan S, Cady RK. "Validation of the Revised Patient Perception of Migraine Questionnaire: Measuring Satisfaction with Acute Migraine Treatment." *Headache* 2006; 46: 1-13.
 - Scranton RE, Bozeman SR, Burton TM, Hoaglin DC, Sirko S, **Hollenbeak CS**, Wilson PWF. "Simple Demographic Model to Predict Multiple Cardiometabolic Risk Factors in Two Well-Known Observational Cohorts." *Value in Health* 2007; 10(s1): S37-S44.
 - Shikar R, Heffernan M, Langley RG, Willian MK, Okun MM, **Revicki RA**. "Adalimumab Treatment is Associated with Improvement in Health Related Quality of Life in Psoriasis: Patient-Reported Outcomes from a Phase II Randomized Controlled Trial." *Journal of Dermatological Treatment*; In Press.
 - Shikar R, Willian MK, Okun MM, **Thompson CS, Revicki DA**. "The Validity and Responsiveness of Three Quality of Life Measures in the Assessment of Psoriasis Patients: Results of a Phase II Study." *Health and Quality of Life Outcomes* 2006; 4(71):1-17.
 - Shikar, R, Heffernan M, Langley RG, Willian MK, Frevert LM, **Revicki DA**. "Impact of Adalimumab Treatment on Health Related Quality of Life: Results from a Phase II, Double-blind, Randomized Controlled Trial." *Journal of Dermatological Treatment*; In Press.
 - **Sondhi M**, Jagannath A, Wong JB. "A Meta-Analysis of Randomized Controlled Trials With Coronary Drug-Eluting Stents Compared With Bare-Metal Stents." *The Internet Journal of Cardiology* 2006; 3(2).

Recent Presentations

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14th United European Gastroenterology Week

Oct 21–25, 2006, Berlin, Germany

"The Gastroesophageal Reflux Disease Impact Scale—A Patient Management Tool for Primary Care." Jones R¹, **Coyne K**², Wiklund I³; ¹Dept. of General Practice and Primary Care, King's College; ²Center for Health Outcomes Research, United BioSource Corp.; ³AstraZeneca R&D Mölndal.

27th Annual AUGS Scientific Meeting

Oct 19–21, 2006, Palm Springs, CA, USA

"Validation of the Overactive Bladder Family Impact Measure (OAB-FIM)." **Coyne KS**¹, **Matza L**¹, Brewster-Jordan J¹, Goldfischer E²; ¹United BioSource Corp.; ²Hudson Valley Urology, P.C.

"The Impact of Overactive Bladder on the Sexual Health of Women: A Qualitative Study." **Coyne KS**¹, **Stoeckl M**¹, Rogers R², Jumadilova Z³, Bavedam T³; ¹United BioSource Corp.; ²Univ. of New Mexico School of Medicine; ³Pfizer, Inc.

28th Annual Meeting of the Society for Medical Decision Making

Oct 15–18, 2006, Boston, MA, USA

"Effect of Time Horizon on Incremental Cost-Effectiveness Ratios: How Long Do We Count?" **Sondhi M**¹, Wong JB², Pauker SG²; ¹United BioSource Corp.; ²Tufts-New England Medical Center.

"Effect of Work Up Intensity Bias on the Sensitivity of CT Colonography." Tamara DJ¹, Shah BB¹, **Sondhi M**², Wong JB¹; ¹Tufts-New England Medical Center; ²United BioSource Corp.

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