

# RESEARCHNews

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VOLUME III ISSUE I

## AMCP Issues Template for Provision of Cost, Outcomes Data to Managed Care

The Academy of Managed Care Pharmacy (AMCP) in the U.S. recently issued the *Format for Submission of Clinical and Economic Data in Support of Formulary Consideration by Managed Health Care Systems in the United States*. These “guidelines”, which are posed as a ‘template’ for health plans to adapt to their respective needs, are intended to assist managed care organizations (MCOs) in the decision-making process for adding drugs to formulary. They set forth requirements for clinical and pharmacoeconomic information to be provided by manufacturers. Manufacturers are expected to provide, or at least help the MCO conduct, cost and outcomes impact analyses that are individualized to the respective health plan. To the extent that these guidelines are widely adopted, pharmaceutical manufacturers can expect to face fairly rigorous demands for both health and economic evidence of value. Importantly, the requirement for evidence of health impact transcends that of the efficacy evidence that typically stems from the pivotal trials required by the FDA for market approval.

The AMCP guidelines are patented after those adopted several years ago by Regence Blue Shield of Seattle, Washington. As is recommended by the AMCP document, Regence requires manufacturers to submit dossiers that conform to their requirements for formulary

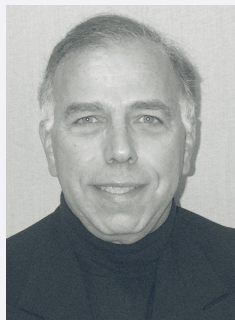
consideration. Otherwise the drug will not be considered for formulary approval. Reportedly, most companies are cooperating with Regence’ requests and submissions have improved over time. As well, we understand that neighboring MCOs to Regence have expressed interest in receiving copies of dossier submissions to Regence.

***The guidelines explicitly require manufacturers to estimate real world health effectiveness from efficacy data.***

The development and adoption of these guidelines is not necessarily bad news for pharmaceutical companies. In fact, a number of industry observers consider it good news. This is because innovative pharmaceutical products generally deliver value to the market. However, until now, there has not been much opportunity within the U.S. for manufacturers to communicate efficiently the value message. Since the FDA tightly regulates all promotional communication and its standards of acceptable evidence is based almost strictly on randomized controlled trial evidence, few cost-effectiveness analyses can meet these standards. Our understanding is that the FDA considers MCO submission requirements, such as the AMCP Format, to fall under the category of *unsolicited requests*,

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## SCIENCE AND POLICY OPINION



RICHARD SHIKIAR, Ph.D.

### PATIENT SATISFACTION: A Rapidly Growing Area of Inquiry

“Are our patients happy with our medication?” “How satisfied are our patients compared to those using our competitor’s top drug?” Just like automobile manufacturers, hotel chains,

and television networks, pharmaceutical manufacturers want and need feedback from the primary consumers of their products. Why does this seem so revolutionary for prescription medications? The

answer lies in the transition of the role of consumer in the health care process.

In the “old” role, once a physician prescribed the medication that was considered best for the patient, the patient quietly accepted the prescription and took the medication exactly as prescribed. However, in his/her “new” role, the *consumer/patient* has probably researched his/her condition on the Internet, has seen advertisements for treatments, and comes to the physician ready, willing, and able to be an active participant in treatment decision-making. If the consumer/patient is unhappy with the prescription, he or she is ready to suggest alternatives to the physician. So the pharmaceutical manufacturer must

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RUTH BROWN, M.S., M.H.S.A.

## Announcement

MEDTAP International is proud to announce that Ruth Brown, currently based in the firm's Bethesda office, will become the director of MEDTAP's London operations effective summer, 2001.

Ms. Brown, Vice President and Senior Research Scientist in MEDTAP's health economics group, will add to the already strong expertise in the London office and provide cross continent continuity for international projects. Her efforts will help MEDTAP accommodate and coordinate its growing client demands for global services throughout the U.K., Europe, and the U.S.

"MEDTAP scientists are increasingly called upon to develop health economics dossiers that document the intrinsic value of new pharmaceuticals and medical devices," commented Bryan R. Luce, Ph.D., and CEO of MEDTAP International. "With John Hutton concentrating on scientific leadership for all of Europe and Ruth Brown continuing the efficient, high-quality consulting services, MEDTAP is in a position to accommodate these increased demands effectively." ■

## AMCP Template

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thus not subject to FDA regulation. Therefore, manufacturers can legitimately communicate the complete value message that its health economics and outcomes

research departments routinely generate via the AMCP Format dossier submission.

This recent move in the U.S. builds upon the work of a number of authorities around the world which began in Australia earlier last decade and now includes Canada and a number of European countries. Clearly the initiative in the U.K., that of the National Institute of Clinical Excellence (NICE), is having an impact throughout the European Union and around the world. Acting in an advisory capacity to the National Health Service, NICE sponsors analyses and accepts clinical and economic evaluations from manufacturers of selected medical technologies, including drugs, as evidence of their societal value and impact on the nation's health budget. Japan as well as other countries are closely monitoring the NICE policies and actions.

To address the needs in the new guideline-driven environment, pharmaceutical manufacturers can use AMCP's Format for Formulary Submission as a template for developing a generalized dossier. The dossier is intended to provide a Pharmacy & Therapeutics (P&T) committee and other authorities around the world the clinical and pharmacoeconomic data from which to draw evidence-based decisions for the purpose of guiding adoption and treatment options available to the covered population.

**MEDTAP's Senior Research Leader and CEO, Dr. Bryan Luce, was a co-author of the AMCP Format. If you would like to learn more about these issues or related MEDTAP services please call 301.654.9729.** ■

## OUTCOMES IN THE NEWS

Coverage and reporting on health-related quality of life is increasing, and MEDTAP is closely monitoring ways in which studies can maximize their impact through their publicity in the press. We'll continue to share what we find as well as offer strategies to communicate your messages.

## MEDTAP-Authored Outcomes Research Attracts Media

MEDTAP's Center for Health Outcomes Research recently completed a project examining the prevalence of nocturnal GERD (gastroesophageal reflux disease) as well as its impact on health-related quality of life. Funded by the Janssen Research Foundation, the results of the project were published in Archives of Internal Medicine (Farup, Kleinman et al., 2001). Dr. Leah Kleinman of MEDTAP is the corresponding author for the paper. Results of the study demonstrated for the first time that nocturnal GERD was both common and associated with considerable impairment in health-related quality of life. The article attracted attention from both the Internet press and other professional journals. Dr. Kleinman was interviewed by Reuters and Health Scout (Internet press) — the interview appeared on the Web — and has been asked to prepare a summary version of the article that may be translated into Arabic and published in a journal designed specifically for Arabic-speaking physicians in the Middle East and the United States.

- Farup C, Kleinman L, Sloan S, Ganoczy D, Chee E, Lee, C, Revicki R. The impact of nocturnal symptoms associated with gastroesophageal reflux disease on health-related quality of life. *Arch Intern Med* 2001;161:45-52 ■



## NEWS BULLETINS

### MEDTAP International in Europe

- Led by John Hutton, MEDTAP International has completed a project to support the development of new guidance to manufacturers and sponsors of health technologies on the submission of clinical economic information to NICE (UK National Institute of Clinical Excellence). The new guidance has now been approved and is about to be implemented by NICE.
- In conjunction with staff at the London School of Hygiene and Tropical Medicine, MEDTAP International in London has recently started a project to scope the research requirements to underpin a new system of resource allocation for the UK's National Health Service.
- MEDTAP International's London office has moved to a new location in Bloomsbury. MEDTAP's clients will find the new office centrally and conveniently located, easily accessible by underground to Holborn station (Central and Piccadilly lines).

### MEDTAP International Welcomes Scientific Staff to Amsterdam and London Offices

MEDTAP International has added new research staff members to its offices in London and Amsterdam in response to increased client requirements in the UK and Europe.

**Andrew Davies, M.Sc.**, is a Senior Research Associate in the London office. Mr. Davies recently joined MEDTAP after three years of experience in economic evaluation and modeling studies in the Health Economics Research Group at Brunel University in West London. His master's degree is in Health Economics from the University of York.



ERWIN DE COCK

**Erwin de Cock, B.Sc.**, has joined the London office of MEDTAP International as a Research Assistant. He obtained his degree in applied economic sciences in June 1996 from the Katholieke Universiteit Leuven (Belgium), specializing in International Business. Prior to joining MEDTAP, he was a research assistant in the Small Business Research Institute from the Katholieke Universiteit Brussel (Belgium). He is

currently coordinating data collection activities from haemodialysis centres across Europe, as well as updating MEDTAP's Unit Cost Database and developing a user-friendly electronic version on CD-ROM.

**Jozsef Kosa, M.D., M.B.A.** is a Research Associate in the Amsterdam office. In addition to training as a physician, Dr. Kosa did postgraduate studies in health care economics and management. He prepared his thesis about the relationship between the health care sector and macroeconomics. Before joining MEDTAP, he earned an international MBA degree at the Case Western Reserve University (Cleveland, OH) with a concentration in marketing and finance. His work includes studies of pharmacological treatment for Parkinson's disease, STDs and hemostasis.



GERHART KNERER

**Gerhart Knerer M.A., M.S.C., PostCert (Econ)**, is a Research Associate in the London office. Mr. Knerer obtained his undergraduate training in social science statistics and research methodology, and postgraduate training in epidemiology and economics. His experience in health research has included work at Health

Canada, the Public Health Laboratory Service (PHLS), and the London School of Hygiene and Tropical Medicine.



EDIT REMÁK

**Edit Remák, B.A., M.Sc.**, joined the London office of MEDTAP International as a Research Associate in November 2000. Ms. Remak holds a bachelor of arts degree in economics and a master's degree in finance from the Budapest University of Economic Sciences, Hungary, where her thesis investigated the

current healthcare expenditure trends in developed countries and the possible theoretical explanations. She also obtained a master's in health economics (with distinction) from the University of York, U.K.

**Aldo Stein, M.Sc.**, is a Research Associate in the Amsterdam office. He studied medical biology at the University of Amsterdam, with an emphasis on molecular genetics and biochemistry. In addition, Mr. Stein served two internships, one at the Amsterdam Medical Centre (AMC) and the other at Unilever Research Vlaardingen. His area of special interest is the health economics of infectious disease. ■

## A STATUS REPORT FROM THE Bayesian Initiative

**OF NOTE:** Bryan R. Luce, Ph.D. and Ya-Chen Tina Shih, Ph.D. of MEDTAP International recently served with Karl Claxton, Ph.D. of the University of York as guest editors of the special section, "Bayesian Approaches to Technology Assessment and Decision Making" that appeared in *The International Journal of Technology Assessment in Healthcare*. The section was designed to provide an overview of selected aspects of the Bayesian approach that are most useful in healthcare technology assessment.

The Bayesian Initiative in Health Economics and Outcomes Research at MEDTAP International are pleased to announce that the following two proposals were awarded funding by the Initiative.

### 1) Building a Bayesian Cost-effectiveness Analysis Case Study: A Bayesian Analysis of the Canadian Implantable Defibrillator Study (CIDS).

Dennis G. Fryback, Ph.D.; Grace E. Flood, M.D., M.P.H. and Marjorie A. Rosenberg, Ph.D., University of Wisconsin-Madison; Ana Johnson-Masotti, Ph.D., Medical College of Wisconsin; Bernie O'Brien, Ph.D., McMaster University; David Spiegelhalter, Ph.D., (consultant) MRC Biostatistics Unit, Cambridge

These investigators will conduct a Bayesian cost-effectiveness analysis using primary data from the Canadian Implantable Defibrillator Study (CIDS), and prepare a case study comparing this analysis to a state-of-the-art frequentist analysis submitted for review by O'Brien et al. The case study findings comparing the analytic methods will be disseminated through a short course to be given at a future ISPOR meeting (2002).

### 2) Building a Reference Case for Bayesian Applications to Health Economics and Outcomes Research.

Karl Claxton, Ph.D., Stephen Palmer, MSc, Mark Sculpher Ph.D., and Elisabeth Fenwick, M.Sc., University of York; Keith Abrams, Ph.D. and Alex Sutton, Ph.D., University of Leicester; Martin Buxton, Professor, Brunel University

The specific objectives of the project are:

- a) To combine decision theoretic modeling with patient level data and simulate the results of a fully Bayesian trial design and to compare this to the value of frequentist design;
- b) To relax the restrictions of using conjugate prior distributions and a parametric approach to value of

- information analysis by using numerical methods to estimate predictive and posterior probabilities;
- c) To develop these methods in the context of two specific decision problems for which published evaluations exist;
- d) To provide a detailed description of analyses undertaken in such a way as to assist analysts undertaking Bayesian economic evaluation in other decision contexts.

These investigators will apply this decision theoretic approach to two clinical decision problems: the Assessment of Treatment with Lisinopril and Survival (ATLAS) study, and a trial of pre-operative optimization of oxygen delivery (using adrenaline or dexamethasone) to reduce the risk of major elective surgery.

**For complete abstracts of these two studies, visit [www.bayesian-initiative.com](http://www.bayesian-initiative.com). Results from both studies will be disseminated at national / international meetings and publications in scientific journals. For more information, contact Ya-Chen Tina Shih at 301.654.9729. ■**

## PATIENT-REPORTED OUTCOMES: A Meeting of the Minds

MEDTAP's Dr. Nancy Kline Leidy was team leader and presenter at a recent meeting on the use of PRO research in labeling and promotion titled "Issues in patient-reported outcomes (PRO) research." The meeting, which was organized by the harmonization coordination committee, a multi-organization effort that seeks to harmonize recommendations by the research and pharmaceutical communities to regulatory bodies in the U.S. and Europe, was organized around the following objectives:

1. To clarify aspects and components of PRO evaluation.
2. To discuss where PRO can add value to clinical endpoints.
3. To suggest use of this information within labeling and promotional claims.

Attending were representatives of the U.S. Food and Drug Administration (FDA), as well as representatives of European Regulatory Issues on Quality-of-Life Assessment, the International Society of Pharmacoeconomic and Outcomes Research, the Pharmaceutical Research and Manufacturers of America Health Outcomes Committee, and the International Society of Quality of Life.

The program consisted of four main presentations on areas of interest:

1. Conceptual and Definitional Issues — Team Leader, Margaret Rothman, Ph.D. *How health-related quality of*

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## RECENT PUBLICATIONS

**MEDTAP** International welcomes comments and inquiries about our scientific work. Each issue, we feature one or more abstracts and a list of current publications and recent industry presentations. If you wish to obtain reprints of papers or a complete publication list, please contact Rebecca Sergi at 301.654.9729.

BERRY E, KELLY S, **HUTTON J**, LINDSAY HSJ, BLAXHILL JM, EVANS JA, CONNELLY J, TISCH J, WALKER GC, SIVANANTHAN UM, SMITH MA. Intravascular ultrasound-guided interventions in coronary artery disease: a systematic literature review, with decision analytic modeling, of outcomes and cost-effectiveness. *Health Technology Assessment* 2000 4(35): 1-108.

BIDDLE AK, **SHIH YCT**, AND KWONG WJ. Cost benefit analysis of sumatriptan tablets versus usual therapy for the treatment of migraine. *Pharmacotherapy* 2000; 20(11): 1356-1364.

**DE LISSOVOY G**, YUSEN RD, SPIRO TE, KRUPSKI WC, CHAMPION AH, SORENSEN SV. Cost for inpatient care of venous thrombosis. A trial of enoxaparin vs. standard heparin. *Archives of Internal Medicine* 2000; 160: 3160-3165.

**FRANK L, REVICKI DA, SORENSEN SV, SHIH YT**. The economics of selective serotonin reuptake inhibitors in depression. A critical review. *CNS Drugs* 2001; 15(1): 59-83.

GRIEVE R, PORSDAL V, **HUTTON J**, WOLFE, C. A Comparison of the Cost-Effectiveness of Stroke Care Provided in London and Copenhagen. *International Journal of Technology Assessment in Health Care*, 16:2 (2000), 684-695.

HAMILTON SH, EDGEL ET, **REVICKI DA**, BREIER A. Functional outcomes in schizophrenia: a comparison of olanzapine and haloperidol in a European sample. *International Clinical Psychopharmacology* 2000; 15(5): 245-255.

HARRELL FE, **SHIH YCT**. Using Full Probability Models to Compute Probabilities of Actual Interest-to Decision Makers. *International Journal of Technology Assessment in Health Care* 2001;17:17-26.

**LEIDY NK, SCHMIER JK**, BONOMI AE, LEGRO M, ZYCZYNSKI T, KONG BW. Psychometric properties of the Vital Signs Quality of Life Questionnaire (VSQQLQ) in black patients with mild hypertension. *Journal of the National Medical Association* 2000;92, 550-557.

**LUCE BR, SHIH YCT**, CLAXTON K. Introduction: Bayesian Approaches to Technology Assessment and Decision Making. *International Journal of Technology Assessment in Health Care* 2001;17:1-9.

**PALMER CS, SCHMIER JK**, SNYDER E, SCOTT B. Patient preferences and utilities for 'off-time' outcomes in the treatment of Parkinson's disease. *Quality of Life Research* 2000;9:819-827.

**PARAMORE LC**, HALPERN MT, LAPUERTA P, HURLEY JS, FROST FJ, FAIRCHILD DG, BATES D. The impact of poorly controlled hypertension on healthcare resource utilization and cost. *American Journal of Managed Care* 2001;7(4):21-31.

**REVICKI DA**, OSOBA D, FAIRCLOUGH D, BAROFKY I, BERZON R, **LEIDY NK**, ROTHMAN M. Recommendations on health-related quality of life research to support labeling and promotional claims in the United States. *Quality of Life Research* 2000;9:887-900.

**REVICKI DA**. Cost effectiveness of the newer atypical antipsychotics: a review of the pharmacoeconomic research evidence. *Current Opinion in Investigational Drugs* 2001; 2(1): 110-117.

**REVICKI DA**, GOLD K, BUCKMAN D, CHAN K, KALLICH JD, WOOLLEY JM. Imputing physical health status scores missing owing to mortality. Results of a simulation comparing multiple techniques. *Medical Care* 2001; 39(1): 61-71.

**REVICKI DA**, NAMJOSHI A, EDGELL ET. Health-related quality of life measurement in schizophrenia: A review of previous research and clinical trial results with olanzapine treatment. In: Tran PV, Bymaster FP, Tye N, Herrera JM, Breier A, Tollefson GD, eds. *Olanzapine (Zyprexa): A Novel Antipsychotic*. Philadelphia: Lippincott Williams & Wilkins Healthcare, 2000:343-358.

**REVICKI DA, PALMER C**, MARCINIAK, MD. Burden of schizophrenia in Japan. Impact on patients, families and society. *Schizophrenia Frontier* 2001;2(1):41-49.

YABROFF KR, **BROWN R**, HALPERN M. Breast cancer epidemiology, prevention and costs of care. Implications for disease management programmes. *Disease Managed Health Outcomes* 2000;8(4):197-210.

ZYCZYNSKI TM, **COYNE KS**. "Hypertension and current issues in compliance and patient outcomes." *Current Hypertension Reports* 2000; 2: 510-514.

ZYCZYNSKI T, **LEIDY NK**, KONG BW, HELASZEK C, MICHELSON E for the Association of Black Cardiologists (ABC) Study Group. Effects of candesartan cilexetil on health-related quality of life in black patients with systemic hypertension: The ABC trial. *Heart Disease*. 2000; 2 (6): 400-406.

## RECENT PRESENTATIONS

### 11th International Congress on Anti-Cancer Treatment (ICACT)

PARIS, FRANCE, FEBRUARY 2001

PODIUM PRESENTATION:

- "A Cost-Effectiveness Analysis of Epoetin Alfa in the Management of Anemic Cancer Patients Receiving Chemotherapy" Shih YCT, Sasane M., Huang PW.

### 148th American Pharmaceutical Association (APhA) Annual Meeting

SAN FRANCISCO CA, MARCH 2001

POSTER PRESENTATION:

- "Patient Ethnicity and Antidepressant Prescribing" Ya-Chen Tina Shih

### The Eighth Annual Symposium of Contributed Papers "Quality of Life Evaluation"

HILTON HEAD ISLAND, SC, MARCH, 2001

PODIUM PRESENTATION:

- "On Health-Related Quality of Life, Symptoms, and the Complementary Nature of Two Patient-Reported Outcomes" Nancy Kline Leidy

POSTER PRESENTATION:

- "Patient and Physician Ratings of Treatment Satisfaction for GERD and Dyspepsia: Are They the Same?" Karin Coyne, Jordana Schmier, Dennis Revicki

## A Meeting of the Minds

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*life is defined relative to PRO, and what types of sources are used in patient outcome assessment.*

2. The Value of Patient-Reported Outcomes — Team Leader, Nancy Kline Leidy, Ph.D. *The importance of the patient's perspective and the uses of PROs in research and practice, including PROs as an indication of disease, evaluating treatment efficacy and interpreting clinical outcomes, and a key element in treatment decision making.*
3. Methodological Considerations in Obtaining PROs in Clinical Trials — Team Leader, Nancy Santanello, M.D., M.S. *The underpinnings of PRO as a scientific discipline, and its use in clinical trials.*

4. Interest and Demand for PRO Information — Team Leader, Rick Berzon, Ph.D. *Interest in and demand for PRO information on the part of patients, with recognition by clinicians of the value of patient evaluation and involvement.*

The presentations were followed by discussions with FDA representatives regarding the value, suitability, and practical applications of using PRO data in labeling and promotion. Because this was the opening round of discussion, all parties agreed that a good foundation had been laid to support expanded discussions in the near future.

***For more information, or for a copy of the discussion outlines, contact Nancy Kline Leidy, Ph.D. at 301.654.9729 or Leidy@MEDTAP.com. ■***



## BRIDGING THE GAP



CLARK PARAMORE, M.S.P.H.

### MEDTAP's Blueprint: Plan, Build, Communicate

*This new regular section of Research News will be devoted to exploring the challenges and solutions associated with the goal of linking the science of outcomes and health economics to the needs of pharmaceutical companies, and the decisions made in the health care system.*

The term “Bridging the Gap” within pharmaco-economic and outcomes circles has come to describe the need to improve the degree to which this science is utilized in health care decision making. Whether the audience is a managed care P&T committee or an individual physician, patient, or hospital pharmacist, more insights and practical applications are available from pharmaco-economic and outcomes research than are being made available and utilized.

MEDTAP's blueprint to help bridge the gap between pharmaco-economics and outcomes research and its marketplace application begins with the unwavering commitment to the quality and credibility of its scientific research, reports, and publications. This commitment is now being extended to include the “real world” application of its efforts and those of fellow health economists and outcomes researchers.

Therefore, you will increasingly encounter MEDTAP scientists referring to the “value message” that needs to be created — and how we'll work on planning, building, and communicating that message. By helping put these efforts into perspective and working to move from scientific hypothesis to message generation and application, delivering the value message will meet the evolving expectations of the market.

**Plan. Build. Communicate.** Simple but powerful. MEDTAP helps both internal and external audiences understand how outcomes and health economics creates and demonstrates the value message and what the building blocks are at each stage in communicating this message. Creating that context and showing how MEDTAP's “Bridging the Gap” strategy can support the development and application of a value message will be the focus of future discussions in this “Bridging” section. Here you will be introduced to approaches and services designed to address the gaps within pharmaceutical organizations as well as to new methods targeted at the all-too-familiar gaps in the marketplace. The goal is to foster a discussion — even debate — of the bridge building tools and techniques at our collective disposal.

***If you have specific examples of how your efforts in health economics and outcomes have helped your organization “bridge the gap” we encourage you to submit them to Bridging@MEDTAP.com. Or, if there are specific challenges you face that you'd like us to address, please contact Clark Paramore at 301.654.9729. ■***

**UPCOMING PRESENTATIONS & POSTERS**

**International Society for Pharmacoeconomics and Outcomes Research**

**SIXTH ANNUAL INTERNATIONAL MEETING, ARLINGTON, VA, MAY 20-23, 2001**

**BREAKFAST WITH THE EXPERTS:**

- Quality of Life Assessment and FDA Claims, **Dennis Revicki**

**PODIUM SESSIONS:**

- Can Unit Costs Be Compared Across Western European Countries? **Brown R<sup>1</sup>, Hutton J<sup>2</sup>, Nuijten M<sup>3</sup>**, <sup>1</sup>MEDTAP International Inc, Bethesda, MD, USA; <sup>2</sup>MEDTAP International Inc, London, UK; <sup>3</sup>MEDTAP International, Jisp, Netherlands
- Cost-Effectiveness Analysis of Irinotecan+5FU/FA Alone as First-Line Therapy In Advanced Colorectal Cancer In The UK, **Brown R<sup>1</sup>, Sorensen S<sup>1</sup>**, Burrell A<sup>2</sup>, Bearne A<sup>2</sup>, <sup>1</sup>MEDTAP International Inc, Bethesda, MD, USA; <sup>2</sup>Aventis Pharma, Kent, UK
- Cost-Effectiveness Analysis of an Intranasal Influenza Vaccine For Healthy Children, **Luce B<sup>1</sup>, Zangwill K<sup>2</sup>, Palmer C<sup>1</sup>**, Mendelman P<sup>3</sup>, Yan L<sup>4</sup>, Wolff M<sup>4</sup>, Cho I<sup>3</sup>, Iacuzio D<sup>5</sup>, Belshe B<sup>6</sup>, <sup>1</sup>MEDTAP International Inc, Bethesda, MD, USA; <sup>2</sup>Harbor-UCLA Medical Center, Torrance, CA, USA; <sup>3</sup>Aviron, Mountain View, CA, USA; <sup>4</sup>The EMMES Corporation, Potomac, MD, USA; <sup>5</sup>Roche Pharmaceuticals, Nutley, NJ, USA; <sup>6</sup>St. Louis University, St. Louis, MO, USA

**QUALITY OF LIFE FORUM:**

- Quality of Life Outcomes: Controversial Issues & Practical Solutions, **Nancy Kline Leidy** representing ISPOR Quality of Life Special Interest Group

**POSTER PRESENTATIONS:**

- The Long-Term Societal Economic and Humanistic Benefits of Treating Acute Exacerbations of Chronic Bronchitis (AECB) With Gemifloxacin Versus Larithromycin, Halpern M<sup>1</sup>, Kirsch JM<sup>2</sup>, **Palmer C<sup>3</sup>, Zodet M<sup>3</sup>**, Wilson R<sup>4</sup>, <sup>1</sup>Charles River Associates, Washington, DC, USA; <sup>2</sup>GlaxoSmithKline, Harlow, UK; <sup>3</sup>MEDTAP International, Bethesda, MD, USA; <sup>4</sup>Royal Brompton Hospital, London, UK
- Predictors of Chemotherapy-Related Neutropenia: A Review of the Clinical Literature, **Palmer C<sup>1</sup>, Brown R<sup>1</sup>**, Wilson-Royalty M<sup>2</sup>, Lawless G<sup>2</sup>, <sup>1</sup>MEDTAP International Inc, Bethesda, MD, USA; <sup>2</sup>Amgen, Inc, Thousand Oaks, CA, USA
- An Analysis of Resource Use in the Treatment of Advanced Colorectal Cancer in the UK, **Sorensen S<sup>1</sup>, Brown R<sup>1</sup>, De Cock E<sup>1</sup>**, Bearne A<sup>2</sup>, <sup>1</sup>MEDTAP International Inc, Bethesda, MD, USA; <sup>2</sup>Aventis Pharma, Kent, UK
- Utility Assessments of Opioid Treatment in the US, Canada and Australia for Patients with Chronic Non-Malignant Pain **Schmier J<sup>1</sup>, Palmer C<sup>1</sup>**, Ingham M<sup>2</sup>, Mathur S<sup>1</sup>, Dodd S<sup>3</sup>, Gourlay G<sup>4</sup>, <sup>1</sup>MEDTAP International Inc, Bethesda, MD, USA; <sup>2</sup>Janssen-Ortho Inc, Toronto, ON, Canada; <sup>3</sup>Janssen Pharmaceutica, Titusville, NJ, USA; <sup>4</sup>Flinders Medical Centre, Bedford Park, Australia
- The Reliability and Validity of a New OAB-Specific HRQL Questionnaire (OAB-Q), **Coyne K<sup>1</sup>**, Abrams P<sup>2</sup>, **Revicki D<sup>1</sup>**, Herzog R<sup>3</sup>, Hunt T<sup>4</sup>, <sup>1</sup>MEDTAP International Inc, Bethesda, MD, USA; <sup>2</sup>Bristol Urological Institute, Bristol, UK; <sup>3</sup>University of Michigan, Ann Arbor, MI, USA; <sup>4</sup>Pharmacia, Peapack, NJ, USA
- Single European-Level Cost-Effectiveness Analysis: Over the Fourth Hurdle and into the Ditch? **Hutton J<sup>1</sup>, Nuijten M<sup>2</sup>, Chambers M<sup>1</sup>**, <sup>1</sup>MEDTAP International Inc, London, UK; <sup>2</sup>MEDTAP International, Jisp, Netherlands
- Evaluating Bias Introduced by Annualizing Utilization and Cost Measures, **Zodet M, de Lissovoy G**, MEDTAP International Inc, Bethesda, MD, USA
- The Health and Work Questionnaire (HWQ): An Instrument for Assessing Workplace Productivity in Relation to Worker Health, **Shikier R<sup>1</sup>, Rentz AM<sup>2</sup>**, Halpern MT<sup>3</sup>, Khan ZM<sup>4</sup>, <sup>1</sup>MEDTAP International, Seattle, WA, USA; <sup>2</sup>MEDTAP International Inc, Bethesda, MD, USA; <sup>3</sup>Charles River Associates, Washington, DC, USA; <sup>4</sup>GlaxoSmithKline, Research Triangle Park, NC, USA

**First International Symposium about Quality of Life and Pharmacoeconomic Studies**

**BUENOS AIRES, ARGENTINA, APRIL 5-6, 2001**

**PODIUM PRESENTATIONS:**

- "Health-related quality of life: conceptualization, assessment and interpretation" Dennis Revicki
- "Health utility/preference assessment: methods and recent research" Dennis Revicki

**POSTER PRESENTATION:**

- "Cost-effectiveness of treatment with entacapone for patients with Parkinson's disease in the United States." Cynthia Palmer, Mark Nuijten, Jordana Schmier

**20th Annual Scientific Meeting of the American Pain Society**

**PHOENIX, AZ, APRIL 19-22, 2001**

**POSTER PRESENTATION:**

- "Utility Assessments of Opioid Treatment for Patients with Chronic Non-Malignant Pain" Cynthia Palmer, Jordana Schmier, Emuella Flood

**DIA's Third Annual Workshop on Pharmaceutical Outcomes Research**

**SAVANNAH, GA, APRIL 22-24 2001**

**PRE-CONFERENCE WORKSHOP:**

- "Health Outcomes Measurement and Psychometrics" Dennis Revicki

**School of Pharmacy, University of Maryland Course: "Pharmaceutical Economics"**

**COLLEGE PARK, MD, MAY 10, 2001**

**LECTURE:**

- "Introduction to Decision Analysis" Ya-Chen Tina Shih

**2001 American Thoracic Society Annual Meeting**

**SAN FRANCISCO, CA, MAY 18-23, 2001**

**INVITED LECTURE:**

- "Health-related quality of life outcomes in COPD" Nancy Kline Leidy

**PODIUM PRESENTATION:**

- "Economic Impact of Uncontrolled Asthma" Clark Paramore

**Digestive Disease Week, ATLANTA, GA, MAY 21, 2001**

**POSTER OF DISTINCTION:**

- "Willingness to Pay for Relief of Gastroesophageal Reflux Disease" Leah Kleinman, Jordana Schmier, Greg de Lissovoy

## Science and Policy Opinion...

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now obtain feedback about its product from both the physician **and** the patient. This brings up several questions about the concept of patient satisfaction.

**Why Measure Satisfaction?** First, patient satisfaction can influence the patient's and/or physician's choice of medications. Especially when confronted with equally efficacious drugs, it is reasonable to expect the patient to request the one with which he or she is — or expects to be — most satisfied. Second, satisfaction is logically related to patient adherence to the prescription regimen. Finally, in-depth understanding of the reasons for satisfaction or dissatisfaction with a medication can help inform a pharmaceutical company's marketing and product improvement programs.

**What Do We Mean by Patient Satisfaction?** Simply put, we define satisfaction with medication as the patient's evaluation of *the process* of taking the medication and *the outcomes* associated with the medication. That makes satisfaction a multi-dimensional question — one for which we need to understand:

- a) The salient aspects of taking the drug — including the dosing schedule as well as ease and convenience of administering the drug; and
- b) The salient outcomes that the patient perceives to be associated with the medication, such as rapidity, duration, and extent of symptom relief; ability to resume normal activities; and side effects.

Since it is the *patient's* satisfaction that we are attempting to assess, we need to understand those aspects of the process that are salient to the patient as the ultimate consumer. This is done by directly querying the patient, using carefully constructed instruments for assessing satisfaction.

Salient aspects of a medication may differ across patient populations (e.g., some patients will care more about rapidity of symptom relief, while others will focus more on side effects). Moreover, efficacy alone does not always guarantee satisfaction. For example, often the pharmaceutical manufacturer is interested in patients' satisfaction of their drug relative to others that may have equal efficacy, but a more convenient mode of administration, a better side effect profile, or some other advantage.

**Isn't Patient Satisfaction the Same as Health-Related Quality of Life?** Although health-related

quality of life (HRQL) and patient satisfaction increasingly are being included as outcome measures in clinical trials, the two types of assessment are measuring conceptually different things. HRQL outcomes focus on the impact of treatment on selected, relevant domains of life, such as physical, psychological, and social functioning and well being. Satisfaction with medication focuses on the *patient's evaluation of the medication*. One aspect of this evaluation may be on the impact of the drug on HRQL. However, the focus, in this case, is still on *satisfaction* with the impact of the drug on HRQL, and not assessment of HRQL itself. Hence, researchers often will want to include both HRQL and patient satisfaction measures when planning research involving a medication.

**How Do We Measure Patient Satisfaction?** First, we start with a review of the dimensions of patient satisfaction we expect to be relevant in assessing the particular drug. Candidate dimensions include ease and convenience of administering the drug, symptom relief, information about the drug, side effects, impact on HRQL, etc. In developing the instrument, we use knowledge of the specific disease for which the medication is intended, as well as the medication's known side effects and those of its competitors. In addition, we typically include items that assess overall or general satisfaction. It is then useful to enlist patients to help identify major areas of omission or commission with respect to the dimensions being covered by the instrument. The instrument can contain as few as 4 or 5 and as many as 40 questions, with multiple items measuring each of the important dimensions of patient satisfaction.

It is also important to ensure that the highest scientific standards are being maintained in developing and validating the instrument. If claims are to be made about patient satisfaction, the FDA will likely apply standards for evidence that are consistent with the standards to which other clinical claims are held. Well-designed and conceived studies with validated instruments are crucial for such evidence. ■

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