

Is Increased Health Care Spending Worth the Cost?

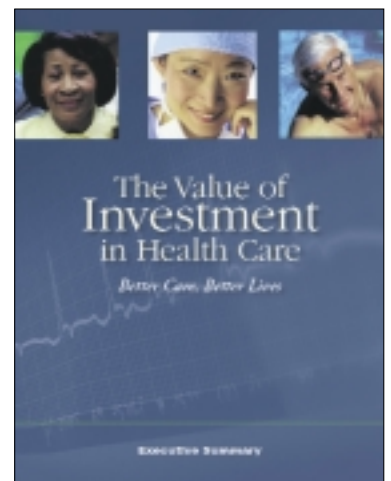
By Clark Paramore, M.S.P.H. and Manishi Prasad, M.P.H.

As reported in a recent edition of the *Washington Post*¹, health care spending in the U.S. has been steadily rising as a percent of GDP, from 8.8 percent in 1980 to 13.2 percent in 2000. In 2002, spending rose by 9.3 percent over the previous year. While much attention is paid to the rise in health care spending, the attributable health benefits are not often recognized. Over the past few decades, advances in medical technology and pharmaceutical products have led to significant reductions in mortality and morbidity for numerous conditions, such as heart disease, cancer and stroke. Furthermore, medical innovation has contributed to improved quality of life during the twentieth century.

In any society, money spent on health care must be balanced against money spent on other public or private commodities, such as education, defense and housing. The economic costs of researching and developing medical innovations, as well as the costs of preventing, diagnosing, and managing a population's health are shared among government, employers, and the general population. Determining the return on investment in health care is critical to each of these payers, as all face tradeoffs when allocating scarce funds. In order to determine optimal health care spending levels for both individuals and society, we first need to quantify the return on investment from health care expenditures in terms of health benefits (including increased life expectancy, reduced mortality and morbidity, and better productivity).

MEDTAP experience: determining the value of health care expenditures

Over the past year, MEDTAP International has conducted two major health policy projects that quantify the health benefits attributable to innovations in medical technology and pharmaceuticals. Both projects studied overall population health,



The *Value of Investment in Health Care* reports are available online at www.MEDTAP.com or request a copy at info@MEDTAP.com.

CONTINUED ON PAGE 4...

Science
& Policy
OPINION

Patient Satisfaction with Medication: A Key to Differentiating Between Medical Interventions



By Richard Shikiar, Ph.D. and Anne M. Rentz, M.S.P.H.

As knowledge has become more readily available via the Internet and other media, patients have increasingly become active consumers of information about health care and medical interventions. They are taking a more participatory role in their treatment decisions, making value judgments about medications and/or medical devices. Along with the rise of patient as consumer, pharmaceutical and medical device manufacturers are asking questions such as: "Are patients satisfied with our medication?" or "How satisfied are patients compared to patients on our competitor's

CONTINUED ON PAGE 6...



MEDTAP's Scientific Information Services: An Important Resource for Meeting Internal and External Information Needs

Literature search and review is one of the foundations of scientific research, including health economics and outcomes studies. With the extensive growth in global scientific research and publishing in recent years, this task has become increasingly challenging. Performing a thorough, accurate, and timely literature search can be as much of an art as a science.

Karen Mark, M.S.L.S., manager of MEDTAP's Scientific Information Services department recently discussed the challenges of meeting the needs of MEDTAP's scientific staff.

Q: What does MEDTAP's Scientific Information Services encompass?

A: We cover a rather broad spectrum of information, offering access to computerized information resources, such as MEDLINE, DIALOG databases and EBSCO host, as well as maintaining and cataloging our internal resources, such as journals, papers, reports and books.

Q: How important is the availability of this service to clients?

A: Our staff performs a substantial amount of literature review work. Many smaller biotech and pharma or device companies don't have dedicated staff to conduct detailed searches. Even larger companies with dedicated research staff can get overloaded. So MEDTAP is increasingly relied upon to provide literature search services as well as analysis.

Q: What kinds of support do you provide to MEDTAP researchers?

A: I do a lot of training with MEDTAP staff to help them develop more efficient ways of conducting literature

searches. Searching computerized databases of references can result in "information overload", so it's important to perform very targeted searches in order to avoid wasting time weeding through irrelevant material. Building this type of in-house expertise is an important asset to our client services operation — and a lot of fun for me.

Q: Once a staff member has a list of desired articles, what happens next?

A: I help them obtain either hard copy or electronic files of the articles for review and analysis. Doing this has become somewhat easier and faster in that many more publishers make material available in pdf format. Nonetheless, we still face challenges in accessing older or obscure items and coping with the high cost of obtaining scientific materials electronically.

Q: Does MEDTAP make available copies of articles to clients who request these?

A: At MEDTAP, we are very aware that any arrangements to supply article copies externally must be in full compliance with U.S. copyright law. In the past, we've been unable to distribute full text articles from literature reviews. We are now implementing a new system to allow us to provide copies of articles on request to our clients in the U.S. and developing similar arrangements for our European operations.

For more information, contact Karen Mark, Manager of Scientific Information Services at 301-664-7291, or by email at mark@MEDTAP.com.

Patient-Reported Outcomes Harmonization Group Publishes Meeting Results

Results of the February 16, 2001 meeting of the Patient Reported Outcomes (PRO) Harmonization Group at the Food and Drug Administration (FDA) have been published in *Value in Health*. The group, which consisted of representatives from ISPOR, ISOQOL, ERIQA, and PhRMA-HOC, met with representatives of the FDA to discuss standards for defining, measuring, and interpreting PROs and testing PRO effects of pharmacologic agents as part of the drug evaluation process in the United States. MEDTAP's Nancy Kline Leidy, Ph.D. and Dennis Revicki, Ph.D. participated in this meeting as representatives of ISPOR and ISOQOL, respectively.

For more information, contact the MEDTAP office at info@MEDTAP.com.

Recent Publications

- Acquadro C, Berzon R, Dubois D, Leidy NK, Marquis P, Revicki D, Rothman M. "PRO Harmonization Group. Incorporating the patient's perspective into drug development and communication: an ad hoc task force report of the Patient-Reported Outcomes (PRO) Harmonization Group meeting at the Food and Drug Administration, February 16, 2001". *Value in Health* 2003 Sep-Oct; 6(5):522-31.
- Coyne KS, Kelleher CJ. "Clinical versus patient outcomes: Whose outcome has greater value?" *British Medical Journal*. Nov 2003; rapid responses.
- Coyne KS, Wiklund I, Schmier J, Halling K, degl' Innocenti A, Revicki D. "Development and validation of a disease-specific treatment satisfaction questionnaire for gastroesophageal reflux disease (TSQ-G)." *Alimentary Pharmacology and Therapeutic* 2003; 18(9):907-15.
- Coyne KS, Zhou Z, Thompson C, Versi E. "Health-related quality of life impact of stress, urge and mixed incontinence." *British Journal of Urology International* 2003; 92(7):731-5.
- Coyne KS, Zhou Z, Bhattacharyya SK, Thompson CL, Dhawan R, Versi E. "The prevalence of nocturia and its impact on health-related quality of life and sleep in a US community sample." *British Journal of Urology International* 2003; 92(9):948-954.
- de Lissovoy G. "Weighing the evidence: trends in managed care formulary decision making." *Journal of Clinical Psychiatry* 2003 Dec;64 Suppl 17:29-32.
- Demicheli V, Hutton J. "Peer review of economic submissions." In Godlee F and Jefferson T (eds): *Peer Review in Health Sciences (2nd edition)*. BMJ Books, London, 2003.
- Gordon K, Lloyd A. "An exploration of the possible causes of occlusion problems in skin-tunnelled catheters used in paediatric oncology." *Nursing Times Research* 2003; 8(3):380-387.
- Mahadevia PJ, Sosa JA, Levine MA, Zeiger MA, Powe NR. "Clinical management of primary hyperparathyroidism and thresholds for surgical referral — a national study examining concordance between practice patterns and consensus panel recommendations." *Endocrine Practice* Nov/Dec 2003; 9(6):494-503.
- Murray BJ, Hutton J, Lloyd A. "Next generation electronic patient diary applications in life cycle management and economic outcomes studies." *European Pharmaceutical Contractor* Winter 2003; 74-76.
- Rasenack J, Zeuzem S, Feinman SV, Heathcote CJ, Manns M, Yoshida EM, Swain MG, Gane E, Diago M, Revicki DA, Lin A, Wintfeld N, Green J. "Peginterferon alpha-2a(40kd) [Pegasys] improves HR-QOL outcomes compared with unmodified interferon alpha-2a ([Roferon A] in patients with chronic hepatitis C." *Pharmacoeconomics* 2003; 21:341-349.
- Remák E, Hutton J, Price M, Peeters K, Adriaenssen I. "A Markov model of treatment of newly diagnosed epilepsy in the UK — an initial assessment of cost-effectiveness of topiramate." *The European Journal of Health Economics* 2003 Dec; 4(4):271-78.
- Szende A, Schramm W, Flood E, Larson P, Gorina E, Rentz AM, Snyder L. "Health-related quality of life assessment in adult haemophilia patients: a systematic review and evaluation of instruments." *Haemophilia* 2003 Nov; 9(6):678-688.
- van Zanten ARH, Engelfriet PM, van Diller K, van Veen M, Nuijten MJC, Polderman KH. "Importance of non-drug costs of intravenous antibiotic therapy." *Critical Care* 2003; 7:R184-R199. 🌐

MEDTAP welcomes comments and inquires about our scientific work. Each issue we feature a list of current publications and industry presentations. For more information, please call 301-654-9729 or email info@MEDTAP.com.

Health Care Spending

CONTINUED FROM FRONT PAGE

as well as diseases common in the U.S. Both studies suggested that the benefits achieved with increased health care spending (such as longer lives, less disability, better quality of life) clearly outweigh the costs. Simply put, while health care spending has increased dramatically over the past few decades, individuals are living longer, more productive lives. Additional benefits include improvements in patients' quality of lives and the increased role they play in their care (leading to patient preference now being taken into account when treatment options are discussed). As described in the recent MEDTAP reports, health benefits have clear, quantifiable, economic value that cannot — and should not — be ignored in policy discussions.

One of the projects revisited an analysis MEDTAP performed 10 years earlier. This analysis evaluated the degree to which continued investment in health care innovations, including preventive innovations, would lead to a decrease in morbidity and mortality along with an increase in economic benefits (such as reduced health care costs and improved productivity). In the initial analysis, MEDTAP conducted extensive literature reviews and solicited guidance from expert panels to develop conservative, intermediate, and optimistic forecasts of disease burden (mortality and incidence rates), relative to the baseline disease burden. Variations in these forecasts depended on the degree of adaptation and penetration of technological advances and behavioral changes.

The objective of the recent follow-up analysis was to estimate and document the degree to which the levels of disease burden forecasted in 1990 for Year 2000 compared with actual Year 2000 disease burden for six diseases, including colorectal cancer, lung cancer, leukemia, coronary heart disease, cerebrovascular disease, and AIDS. Note that the Year 2000 forecast was based on trends observed prior to 1990 plus an expert-adjusted forecast. The results indicated that the actual incidence and mortality rates for three of the diseases (colorectal cancer, lung cancer, and AIDS) were lower than forecasted for 2000. These reductions are primarily due to significant public health campaigns that increase awareness about the diseases, associated risk factors, proven prevention strategies, and advances in drug therapy and medical technology. Incidence rates of cerebrovascular disease and coronary heart disease in 2000 were not significantly different from what was forecasted in 1990. However, morbidity and mortality gains were observed with both conditions throughout the 1990s; these gains are almost certainly indicative of patients surviving with a higher quality of life.

The second report, aimed to explain the value of investing in health care in the U.S. Produced with sponsorship from a consortium of trade associations representing the pharmaceutical, medical technology, and hospital industries, *The Value of Investment in Health Care* report was written for the general public, exploring whether or not the health benefits achieved over the past 20 years justified the financial investment made to achieve them. The report gathered and synthesized information from the public domain about:

- U.S. expenditures for overall health care and specific health care interventions for heart attack, type 2 diabetes, stroke, and breast cancer;
- Improvements in individual and public health resulting from these expenditures; and
- The extent to which these health care expenditures could be viewed as a sound investment.

Timelines of innovations and their respective cost-effectiveness data (used to determine the return on investment for newer vs. older therapies) were gathered from the published literature and confirmed with clinical consultants. Case studies were also developed to highlight the evolution in treatment patterns over the past few decades. For example, a patient presenting with symptoms of stroke in the 1970s might have waited several hours before being seen, once arriving at the hospital. Additionally, no specific interventions (besides general care) were undertaken. In contrast, patients presenting with stroke symptoms today are immediately treated with thrombolytic therapy, which has resulted in reduced morbidity for these patients. In addition, long-term stroke-related disability can be minimized or even prevented.

“...each additional dollar spent on health care services produced health gains valued at \$2.40 to \$3.00.”

Findings from this report suggest that each additional dollar spent on health care services produced health gains valued at \$2.40 to \$3.00. Annual age-adjusted per person health care costs between 1980 and 2000 increased by \$2,254 (102%), but this was accompanied by significant health gains, including:

- Decline in annual death rates from 1,039 to 872 per 100,000 persons (16%).
- Increase in life expectancy from birth by 3.2 years (4%).

CONTINUED AT TOP

- Reduction in disability rates for people over 65 years from 26.2 to 19.7 per 100 persons (25%).
- Number of days Americans spent in the hospital fell from 129.7 to 56.6 per 100 persons (56%). *Note: While this may also be a response to the changing face of managed care, it's important to realize that this decrease is also due to a move towards more ambulatory care (i.e., outpatient and less invasive procedures, which allow for speedier recoveries, less disability, and better quality of life).*
- Death rates for heart attack, stroke, and breast cancer have fallen in the past 20 years.

While death rates for type 2 diabetes have risen throughout the 1990s (due to increased incidence of obesity), recent research suggests that effective management of the condition leads to improved clinical outcomes, including decrease in diabetes-related complication rates (such as diabetic retinopathy, nephropathy, and neuropathy).

Simply put, without the improvements in health and associated investment as described above, the U.S. would have spent \$634 billion less on health care in 2000, but would have experienced the following:

- 470,000 more deaths,
- 2.3 million more people with disabilities, and
- 206 million more days spent in the hospital.

Conclusion

On-going debates regarding the rise in health care spending consistently focus on “medical costs spiraling out of control” but rarely look at the other side of the debate: health benefits have grown significantly over the past few decades, thanks — in part — to this spending. Findings from both MEDTAP reports indicate that over the past 20 years, individuals have experienced longer, better lives, as well as reduced disability and less hospitalization than would have occurred without these investments.

Policy discussions must begin to consider not only the costs of health care, but also the added benefits. Both MEDTAP reports provide important findings from a growing body of evidence that suggest these benefits are, indeed, worth the costs.

¹ *Washington Post* — Friday, January 9, 2004; Page A03

For more information, contact Manishi Prasad (prasad@MEDTAP.com), Clark Paramore (paramore@MEDTAP.com) or call 301-654-9729. 🌐

NEWS Briefs

MEDTAP Welcomes Julia Fox-Rushby, Research Scientist



Julia Fox-Rushby, Ph.D., has joined MEDTAP's London office as a Research Scientist and will be responsible for performing health economics research as well as the development and testing of measures for disease status, quality of life and utility across countries.

Prior to joining MEDTAP, Dr. Fox-Rushby held, and continues to hold, a faculty position in the Department of Public Health and Policy at the London School of Hygiene and Tropical Medicine of the University of London. She has been a primary investigator on several multi-country evaluations of preventive health interventions including modeling the cost-effectiveness of new and underused vaccines, and determining, alongside a clinical trial, the cost-effectiveness of an evidence-based package of antenatal care.

In addition, Dr. Fox-Rushby has participated in research on the measurement and evaluation of quality of life. She led development of the first generic health-related quality of life instrument in an African country (Kenya), has been actively involved in the development and translation of the EQ-5D, and has been an advisor to the WHOQoL group. She has participated in several projects on the

willingness to pay for health benefits and products as well as non-monetary approaches to utility assessment.

She has authored numerous articles in scholarly journals and her book *Disability Adjusted Life Years for Decision-Making?* was recently published by the Office of Health Economics. She has also worked with a range of international organizations, including the World Health Organization and World Bank.

To learn more, please contact Dr. Fox-Rushby directly at +44-20-7299-4550 or jfox_rushby@MEDTAP.com.

Erwin De Cock Participates in Award-Winning Poster

MEDTAP's Erwin De Cock, M.Sc., was one of five authors who garnered an award for Best New Investigator Poster Presentation at ISPOR's 6th Annual European Congress, in November. The poster, “Comparing the provider time and costs for red blood cell transfusions in the anaemia management of cancer patients using the activity-based costing (ABC) method in a French and Austrian setting,” was sponsored by Amgen Europe. He has Europe-wide experience in cost determination, time-and-motion studies and cost-of-illness studies. He is also coordinating the MEDTAP Unit Cost Database project.

For more information, contact Mr. De Cock at decock@MEDTAP.com. 🌐

Patient Satisfaction

CONTINUED FROM FRONT PAGE

Science & Policy OPINION

product?” Demonstrating greater satisfaction with one product compared to another provides a competitive marketing advantage. For this reason, pharmaceutical and device manufacturers stand to gain significantly from efforts to determine patients’ level of satisfaction with their products.

Patient satisfaction with medication is a very specific, narrowly defined aspect of patient-reported outcomes — one that should be measured using a theoretical and methodological framework to obtain credible results.

We define satisfaction with medication as the *patient’s evaluation of the process of taking the medication and the outcomes associated with the medication*. This definition focuses on the specific issue of medication, whereas the often-used term “treatment satisfaction” has come to represent the entire treatment experience — health care delivery, access to medical staff on a timely basis, perceived quality and responsiveness of medical staff, and quality of medical facilities, among others.

What are the potential benefits of studying patient satisfaction with medication?

First, it enables us to explore the specific relationship between patient satisfaction with medication and patient adherence to medication regimens. While there is little information on this link, most of the available information focuses on satisfaction with care, a much broader framework.

Next, it helps us to obtain detailed feedback for use in improving products. For example, if lack of convenience is specifically cited as a reason for decreased satisfaction, efforts can be made in the drug development cycle to improve the dosing frequency.

Finally, it helps us to understand patients’ preferences and requests for specific medications. This is most useful when a patient has tried several different medications. The medication of choice is most likely the one with which the patient is most satisfied.

When is it worthwhile to assess satisfaction with medication?

There are instances where trying to assess satisfaction with medication would result in ambiguous or distorted information. For example, when the medication is only a small part of a comprehensive treatment plan, patients

may have a difficult time discerning the impact of the medication from the rest of the treatment regimen. It is best to assess satisfaction with medication when:

- One medication offers offsetting advantages and disadvantages relative to another in terms of efficacy and side effects.
- Medications of approximate efficacy have competing modes of administration or other convenience factors such as dosing schedules.
- Medications of approximate equal efficacy have different side-effect profiles.
- The medication plays a central role in the treatment regimen.
- Situations in which being able to demonstrate satisfaction with medication relative to a comparator will offer a potential advantage in terms of marketing.

What are the domains of interest?

Exploring patient satisfaction with medication requires understanding important outcomes of medication from the patient’s perspective. The disease- and medication-specific outcomes under study fall into a number of domains:

Exploring patient satisfaction with medication requires understanding important outcomes of medication from the patient’s perspective.

Symptom relief/efficacy —

This domain can include the extent to which the medication is efficacious and provides symptom relief, the specifics about the type of relief, and time until symptom relief. This is especially important when there are tradeoffs between competing drugs (e.g. if one drug offers quicker action but a less favorable side-effect profile; or another drug offers faster relief but shorter duration of relief; or when one drug’s mode of administration or dosing schedule is more attractive than that of another drug).

Side effects — Questions in this domain will be based on the specific side effects or adverse events of the medication, as well as the degree of satisfaction/dissatisfaction with these side effects. When obtaining data about side effects it is important to base the study questions not only on known side effects but also on patient input. The impact of side effects on patient satisfaction with medication tends to be most salient

CONTINUED ON BACK PAGE



Upcoming Presentations

American Thoracic Society

MAY 21-26, 2004 ■ ORLANDO, FL USA

“Making Hard Decisions: A Decision Analysis Approach to Controversies in Lung Cancer.”

Parthiv Mahadevia, M.D., MEDTAP International, Inc., Bethesda, MD, USA.

International Conference on Statistics in Health Sciences

JUNE 23-25, 2004 ■ NANTES, FRANCE

“Integrating Datasources to Optimize Cost-Utility Analyses — The Economic Sandwich.”

Parthiv Mahadevia, M.D., MEDTAP International, Inc., Bethesda, MD, USA.

Recent Presentations

SMi Conference: Pharmacoeconomics and Outcomes Research

FEBRUARY 18-19, 2004 ■ THE HATTON, LONDON

“Communicating and Reporting Economic Information: The Importance of Awareness of the Audience’s Needs.” **John Hutton, Ph.D.**, MEDTAP International, Inc., London, UK.

National Jewish Medical and Research Center Workshop on Minimal Clinically Important Differences in COPD

JANUARY 11-13, 2004 ■ MIAMI, FL, USA

“Bridging the Gap: Using Triangulation Methodology to Estimate MID.” **Nancy Kline Leidy, Ph.D.**, MEDTAP International, Inc., Bethesda, MD, USA.

American Society of Hematology 45th Annual Meeting

DECEMBER 6-9, 2003 ■ SAN DIEGO, CA, USA

“Development of a New Patient-Reported Symptom Questionnaire in Adult Hemophilia.” **Rentz A¹, Szende A¹, Flood E², Larson P³, Gorina E³, Leidy NK².**

¹MEDTAP International, Inc., London, UK; ²MEDTAP International, Inc., Bethesda, MD, USA; ³Bayer Corporation, Research Triangle Park, NC, USA.

CONTINUED AT TOP

2003 Annual Meeting of The International College of Geriatric Psychoneuropharmacology

DECEMBER 12-14, 2003 ■ SAN JUAN, PUERTO RICO

“Costs and Consequences of Nursing Home Falls in Dementia Patients Receiving Risperidone, Olanzapine, or Placebo.” **Sorensen S¹, de Lissovoy G¹, Kunaprayoon D¹,**

Resnick B², Rupnow M³, Studenski S⁴.

¹MEDTAP International, Inc., Bethesda, MD, USA;

²University of Maryland School of Nursing, Baltimore,

MD, USA; ³Janssen Pharmaceutica Products, L.P.,

Titusville, NJ, USA; ⁴VA Pittsburgh GRECC, Pittsburgh,

PA, USA.

FDA Drug Safety & Risk Management Advisory Committee Meeting

DECEMBER 4, 2003 ■ GAITHERSBURG, MD, USA

“Focus Group Methodology.” **Kimel M, Leidy NK,**

MEDTAP International, Inc., Bethesda, MD, USA.

Gerontological Society of America 56th Annual Scientific Meeting

NOVEMBER 21-25, 2003 ■ SAN DIEGO, CA, USA

“A Taxonomy of Falls and its Application to Evaluation of Risk Reduction Interventions in a Nursing Home Environment.” **Sorensen S¹, de**

Lissovoy G¹, Kunaprayoon D¹, Resnick B², Rupnow M³,

Studenski S⁴. ¹MEDTAP International, Inc., Bethesda,

MD, USA; ²University of Maryland School of Nursing,

Baltimore, MD, USA; ³Janssen Pharmaceutica Products,

L.P., Titusville, NJ, USA; ⁴VA Pittsburgh GRECC,

Pittsburgh, PA, USA. ☎

MEDTAP Staff Presents Use of Focus Group Methodology in Research to FDA Advisory Committee

The FDA Drug Safety and Risk Management Advisory Committee held a meeting December 4, 2003 to discuss current screening methods to assess sound alike and look alike proprietary drug names, in order to reduce the incidence of medication errors resulting from look alike and sound alike names. MEDTAP’s Miriam Kimel and Nancy Kline Leidy discussed the use of focus group methodology in multiple phases of research to identify relevant issues with regard to sound alike and look alike proprietary names.

For more information, contact Miriam Kimel at 301-986-6775 or by email: kimel@MEDTAP.com. ☎

Patient Satisfaction

CONTINUED FROM PAGE 6

Science & Policy OPINION

when comparing drugs of approximate clinical efficacy, but with different side-effect profiles.

Ease and convenience — This can include dosing schedule; mode of administration (e.g. pill, liquid, inhaler, etc.); restrictions associated with medications (take with food, water, on an empty stomach, etc.); and even product specific designs such as portability or operation of a device. Here again, the saliency of these factors is likely to be greatest when comparing medications of approximately equal clinical efficacy.

Impact on HRQL — From a patient's perspective, a key reason for following a medication in the treatment of illness is to either return to a normal (pre-disease) state of HRQL, or for chronic diseases, to attenuate the impact of the disease on HRQL. So part of assessing the impact of a treatment on a patient's HRQL is to assess the patient's satisfaction with that impact (e.g. determining overall satisfaction with a medication based on satisfaction with the time to return to normal activities).

Overall satisfaction — In addition to specific domain-related questions, including questions dealing with overall satisfaction helps researchers to understand the key drivers underlying satisfaction with a particular drug, e.g. how satisfied are you, would you recommend the drug to others, would you ask your doctor to prescribe this again in the future.

Additional domains — Other domains that are relevant to a specific disease, drug, or comparator should be considered and added in specific instances. Examples include patient confidence in using a new device, satisfaction with ease of storage of a drug or device, or even satisfaction with the information provided about a drug — whether by insert, physician, nurse, or pharmacist.

Requirements for measuring patient satisfaction with medication

In order to measure accurately, it is essential that psychometrically sound satisfaction instruments be developed and used. Developing an accurate instrument requires gathering information from different sources, with particular emphasis given to input by both patients and clinicians with experience of the disease in question. Once a draft instrument is formulated, it should then be tested with a group of patients who are interviewed at length to ascertain their interpretations of each item.

Care must be taken to avoid biases when framing questions. The psychometric properties of the instrument (reliability, validity, and sensitivity) should be established and evaluated according to existing standards and guidelines.

It is also important to recognize that the most rigorously designed and executed study of patient satisfaction with medication will not yield constant, long-lasting results. Beliefs and values underlying satisfaction can change over time, as a patient lives with a disease and becomes more focused on lifestyle effects or side effects. For that reason, it may be necessary to repeat the study over the long term.

Regulatory implications for patient satisfaction claims

As a patient-reported outcome, measuring patient satisfaction with medication should undergo all of the scrutiny and attention to process used in evaluating the validity of HRQL claims for labeling and promotion. This includes:

- Assurance that all relevant domains are included (content validity evidence for the instrument)
- A well-documented rationale for including specific domains
- Evidence of instrument reliability and validity
- Clear objective and hypotheses
- Adequate sample size
- Careful implementation of the studies with the same rigor that is used in clinical studies
- Complete disclosure of all results

In sum, measurement of patient satisfaction with medications is increasing, but for this patient-reported outcome to have an impact, these studies will have to be well designed and well executed.

For more information, contact Richard Shikiar (shikiar@MEDTAP.com) or Anne Rentz (rentz@MEDTAP.com). 

MEDTAP
International

ResearchNews is a publication of MEDTAP® International, providing health outcomes and economic analysis to the health care community.

MEDTAP IS A REGISTERED TRADEMARK OF
MEDTAP INTERNATIONAL, INC.

MEDTAP
INTERNATIONAL
7101 Wisconsin Avenue
Suite 600
Bethesda, MD 20814
Tel: 301-654-9729
www.MEDTAP.com

Contact:
Greg de Lissovoy, Ph.D.,
Scientific Editor
Denise Dixon,
dixon@MEDTAP.com

© 2004 MEDTAP
INTERNATIONAL, INC