

**Will Wider Use of Evidence-Based Medicine  
Significantly Enhance Health Care Quality  
and Affordability?  
Implications for Consumer-Driven  
Health Benefits**



**Evidence-based  
Medicine**



EDUCATION &  
RESEARCH FUND

Edited by Paul Fronstin

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Education and Research Fund  
2121 K Street, NW, Suite 600  
Washington, DC 20037-1897  
(202) 659-0670

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## for employee benefits research



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Established in 1978, the Employee Benefit Research Institute (EBRI™) is the only nonprofit, nonpartisan organization in the United States totally committed to original public policy research and education on economic security and employee benefits.

EBRI's overall mission is to encourage, to contribute to, and to enhance the development of sound employee benefit programs and sound public policy through objective research and education.

EBRI does not lobby or endorse specific approaches. Rather, it provides balanced and unbiased analysis of alternatives based on the facts. Through its activities, EBRI advances knowledge and understanding among the public, the news media, and government policymakers of how employee benefits function and why they are critically important to our nation's economy.

Since its inception two decades ago, EBRI has grown to include a cross section of the public and private sectors with an interest in economic security programs. EBRI is funded by membership dues, grants, and contributions from foundations; businesses; labor unions; trade associations; health care providers and insurers; government organizations; and service firms, including actuarial firms, employee benefit consulting firms, law firms, accounting firms, and investment management firms. International members look to EBRI's work to gain understanding of the U.S. economic and employee benefit systems.

Today, EBRI is recognized as one of the nation's most authoritative, objective, and reliable resources on the rapidly changing employee benefits sector—health, savings, investment, retirement, work/family issues, demographics, and economic security.

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## ***About EBRI-ERF Policy Forums***

The Employee Benefit Research Institute-Education and Research Fund (EBRI-ERF) holds two policy forums per year. The goal of the policy forums is to bring together a cross section of EBRI sponsors, congressional and executive branch staff, benefit experts, and representatives from academia, interest groups, and labor to examine public policy issues. It is a roundtable discussion featuring verbal and written exchange among speakers and participants. The roundtable format is designed to encourage discussion.

Past EBRI-ERF policy forums include:

- 5/4/03 “Will Wider Use of Evidence-Based Medicine Significantly Enhance Health Care Quality and Affordability? Implications for Consumer-Driven Health Benefits”
- 12/05/02 “Will Today’s Workers Retire With Adequate Income? And, How Are Today’s Retirees Surviving From A Financial Perspective?”
- 5/2/02 “Consumer-Driven Health Benefits: A Continuing Evolution?”
- 12/6/01 “The Ongoing Growth of Defined Contribution and Individual Account Plans: Issues and Implications”
- 5/3/01 “Defined Contribution Health Benefits: The Next Evolution?”
- 5/3/00 “The Economic Costs of the Uninsured: Implications for Business and Government”
- 12/1/99 “The Next 25 Years of ERISA: The Future of Private Retirement Plans”
- 5/5/99 “Severing the Link Between Health Insurance and Employment: What Happens if Employers Stop Offering Health Benefits?”
- 12/2/98 “Beyond Ideology: Are Individual Social Security Accounts Feasible?”
- 5/6/98 “The Future of Medical Benefits”
- 12/03/97 “Do Employers/Employees Still Need Employee Benefits?”
- 04/30/97 “Retirement Prospects in a Defined Contribution World”
- 12/04/96 “Assessing Social Security Reform Alternatives”
- 04/30/96 “Comprehensive Tax Reform: Implications for Economic Security and Employee Benefits”
- 12/07/95 “The Changing World of Work and Employee Benefits”
- 05/11/95 “When Workers Call the Shots: Can They Achieve Retirement Security?”
- 10/26/94 “The Future of Employment-Based Health Benefits”
- 05/04/94 “Retirement in the 21st Century: Ready or Not?”
- 10/06/93 “The Changing Health Care Delivery System”
- 05/05/93 “Pension Funding and Taxation: Achieving Benefit Security”



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## Foreword

America is currently spending more than 14 percent of its gross domestic product (GDP) on health care. Every modern-day president has declared that he would lead action to reduce the continuous trend of growth. Each has declared that the nation cannot afford more. Yet, advances in research, technology, marketing, population age, and more continue to come together to push national health spending higher each year. Real health care inflation is high relative to overall inflation, health insurance premium growth is at historically high levels, individuals are being asked to pay more when they seek health care services, and the Internet—more than any other advance of the modern age—has made it possible for the inspired individual to become an “informed” health consumer by placing the contents of thousands of libraries a simple mouse click away. We know, however, that not everything is on the Internet, and some of what is there may not be of actual value or may simply be wrong. How can individuals find what is right, or best, or proven? How can the health system be moved to do a better job of testing, documentation, communication, and performance? How can individuals find what is right (or best) or proven, and can they determine what’s best for them personally? Will increased evidence-based care stabilize or accelerate cost inflation?

For 25 years, the Employee Benefit Research Institute has been bringing together experts, reporters, analysts, legislative aids, employers, and unions in policy forums to explore issues of the day. Of late, topics like “Consumer-Driven Health Care” and “Making Evidenced-Based Medicine Work” have been high on our agenda, as well as the nation’s agenda. Annual double-digit increases in the cost of providing health benefits have proven to be an engine for experimentation, testing, and adoption of new approaches. Yet, the health

system and decision making are still highly fractured. Where evidence-based medicine has been developed, it cannot always be effectively communicated, and even if communicated, it cannot always be effectively used for decision making.

This policy forum on “Evidence-Based Medicine, Health Care Quality, and Affordability: Implications for Consumer-Driven Health Benefits,” was held in Washington, DC, on May 8, 2003. The forum was eye-opening with respect to how much has been done, but also with respect to the mountain of challenges that lie ahead if “evidenced-based” medicine is to become the rule rather than the exception, and if consumer-driven health care is to allow the consumer to have full information on all possible treatments and procedures and the evidenced-based efficacy of all of them.

Each of us has had personal experiences that underline the mountain—the uncertainty—of the challenges. During 2003, a friend with cancer was told at one of the nation’s best-rated health facilities that the only option was major surgery, that there was no radiation technique that could be used. The friend had been at a dinner some weeks earlier and by chance had been seated next to an oncologist from the same health center who described advances in targeted radiation. Upon being told to head for major surgery, the friend pulled out the card from the dinner and visited her dinner partner. Only feet away from the office in which she had been told the technique being described to her now did not exist, a course of treatment was decided upon. The targeted radiation worked, the tumor is gone, and the cancer is in remission. None of this is said to be critical; rather, it is said to underline the challenges faced by a nation this large, with so many facilities and practitioners, and so

much new—and often conflicting—health care information. The papers in this book outline many of the steps that will have to be taken in the years ahead if we are to overcome the challenges to improving evidence-based medicine, communication, delivery, and quality.

I want to thank Ray Werntz for his unstinting dedication to building the policy forum program. Paul Fronstin, Steve Blakely, Jim Jaffe, Deborah Holmes, and Alicia Willis joined Ray in a team effort that assured a successful meeting. Our presenters must all be thanked as well for the contribution they made on that day and to this book of proceedings. The law firm of Arnold & Porter donated their excellent meeting facilities for the event, and a grant from The Commonwealth Fund made the development, publication, and distribution of this book possible.

Full responsibility for the contents, however, rests with the EBRI team that produced it. The views expressed in this book are solely those of the authors and participants. They should not be attributed to the officers, trustees, EBRI members, its staff, or its Education and Research Fund. In publishing this book, EBRI-ERF is making no effort to influence the passage or defeat of any legislation. Comments on the contents of the book, and suggestions for work that we might undertake in the future, are encouraged.

Dallas L. Salisbury  
President and CEO  
salisbury@ebri.org  
November 2003



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## About the Authors

**Carolyn M. Clancy, MD**, serves as Acting Director of the Agency for Healthcare Research and Quality (AHRQ). Since 1997, and immediately before assuming the role of Acting Director in April 2002, she was the Director of AHRQ's Center for Outcomes and Effectiveness Research (COER).

Dr. Clancy is a general internist and health services researcher, and a graduate of Boston College and the University of Massachusetts Medical School. Following clinical training in internal medicine, she was a Henry Kaiser Family Foundation Fellow at the University of Pennsylvania. She was also an assistant professor in the Department of Internal Medicine at the Medical College of Virginia in Richmond prior to joining AHRQ (then named the Agency for Health Care Policy and Research) in 1990.

Her major research interests include women's health, primary care, access to care, and the impact of financial incentives on physicians' decisions. She holds an academic appointment at George Washington University School of Medicine (Clinical Associate Professor, Department of Health Care Sciences) and serves as Senior Associate Editor, *Health Services Research*. Dr. Clancy is a member of multiple editorial boards (*American Journal of Public Health*; *Journal of Evaluation in Clinical Practice*; *Journal of General Internal Medicine*; and *Medical Care Research and Review*).

Dr. Clancy has published widely in peer-reviewed journals and has edited or contributed to five books. Her work in women's health was recognized by an award from the Women's Caucus of the American Public Health Association. Active in multiple professional organizations, she has been recognized as a leader within the Society of General Internal Medicine. Before becoming the Director of COER in 1997, Dr. Clancy served as Director of

the Center for Primary Care Research. There she helped develop the U.S. Public Health Service Primary Care Policy Fellowship and led research initiatives on the interface of primary and specialty care, the impact of health care reforms on primary care, and the evaluation of strategies to implement clinical practice guidelines in primary care practice.

**Daniel M. Fox, Ph.D.**, has been President of the Milbank Memorial Fund, the nation's oldest endowed foundation in health care and public health, since 1990. Prior to that he was a faculty member and administrator at Harvard University and then at the Health Sciences Center of the State University of New York at Stony Brook. He has served in State government in Massachusetts and New York, and as an adviser to, or staff member of, several federal agencies. Dr. Fox holds A.B., A.M., and Ph.D. degrees from Harvard University and is a member of the Institute of Medicine of the National Academy of Sciences and of the Council on Foreign Relations.

In addition to articles in journals of health affairs, social science and history, Dr. Fox has written *Power and Illness: The Failure and Future of American Health Policy* (1993 and 1995); *Engines of Culture* (1963 and 1994); *The Discovery of Abundance* (1967); *Economists and Health Care* (1979); *Health Politics, Health Policies: The Experience of Britain and America 1911 1965* (1986); and *Photographing Medicine: Images and Power in Britain and America since 1840* (1988). He co-edited *AIDS: The Burdens of History* (1988); *AIDS: The Making of a Chronic Disease* (1992); *Five States That Could Not Wait: Lessons for Health Reform from Florida, Hawaii, Minnesota, Oregon and Vermont* (1994); *The State, Politics and Health* (1995); *Home-Based Care for a New Century* (1996); and *Treating Drug Abusers Effectively* (1996).

**Paul Fronstin**, Ph.D., is a Senior Research Associate with the Employee Benefit Research Institute (EBRI), a private, nonprofit, nonpartisan organization committed to original public policy research and education on economic security and employee benefits. He is also director of the Institute's Health Research Education Program. He has been with EBRI since 1993.

Dr. Fronstin's research interests include trends in employment-based health benefits, the uninsured, retiree health benefits, employee benefits and taxation, and public opinion about health care. He earned his Bachelor of Science degree in economics from SUNY Binghamton and his Ph.D. in economics from the University of Miami.

**Marjorie Ginsburg**, MPH, is founder and Executive Director of Sacramento Healthcare Decisions (SHD), a nonprofit, nonpartisan organization established in 1994 whose purpose is to bring the public's voice into health care policy and practice. She received her BSN from the University of Maryland and a Masters of Public Health from UC Berkeley. Prior to moving to Sacramento in 1990, she spent 15 years in management and administration of community-based geriatric services in San Francisco.

**Jessie Gruman**, Ph.D., is the President and founding Executive Director of the Center for the Advancement of Health, a Washington-based policy institute originally funded by the John D. and Catherine T. MacArthur Foundation and the Nathan Cummings Foundation to translate health research into effective policy and practice. Her career has focused on the application of scientific knowledge to effective solutions to the problems of health and illness.

Since its start in 1992, Dr. Gruman has built the Center into a well-funded nonprofit, ensuring that evidence on social, behavioral and economic factors are used in to prevent, manage, and treat disease. The Center is governed by a board of nationally recognized experts from the health, research, health care and media sectors. In addition to continued support from the MacArthur and Cummings Foundations, the Center currently receives funding from the Robert Wood Johnson Foundation, W.K. Kellogg Foundation, Soros

Foundation, the Burroughs Wellcome Fund, the American Cancer Society, and other major national health philanthropies.

Formerly at the National Cancer Institute, Dr. Gruman directed the initial phase of the American Stop Smoking Intervention Study for Cancer Prevention (ASSIST). Prior to government service, she served as the national director for public education at the American Cancer Society and the manager of health promotion at the AT&T corporate headquarters.

Dr. Gruman graduated from Vassar College and received her Ph.D. in social psychology from Columbia University.

**Mark Helfand**, MD, MS, is a nationally recognized expert in evidence-based medicine, Dr. Helfand directs the Oregon Evidence-based Practice Center, based at Oregon Health & Science University in Portland. The Oregon EPC is one of 13 EPCs in North America funded by the Agency for Healthcare Research and Quality. Dr. Helfand, who has an MPH in health resources management and an MS in health services research, also maintains a practice in general internal medicine at the Portland Veterans Affairs Medical Center and is associate professor of medicine and medical informatics and outcomes research at OHSU. He has been an author on more than 25 evidence-based reviews and has received federal, state, or private funding on 28 grants and contracts. He has recently directed work on drug class reviews for the State of Oregon for their Practitioner-managed Prescription Drug Program.

**James Jaffe** has been the EBRI Director of External Affairs since April 2002. Trained as a journalist, he spent more than decade working for the House Ways and Means Committee dealing with tax, health, and trade issues. He has also worked for the Internal Revenue Service, the Center on Budget and Policy Priorities, and Powell Tate, a Washington public relations firm. He has a B.A. in history from Antioch College and an M.S. in journalism from Columbia University.

**Jeffrey Charles Lerner**, Ph.D., has served since 2001 as President and Chief Executive Officer of ECRI, a nonprofit agency and Collaborating Center of the World Health Organization. Prior to this, he held the position

of Vice President for Strategic Planning for 18 years. He played the key role in setting the course for ECRI's transition from its origins as a medical device evaluation laboratory to a broader health services research organization that assesses clinical procedures and drug therapies in addition to medical devices. ECRI's technology assessment information programs are now used worldwide by ministries of health, U.S. federal agencies (such as the Social Security Administration, Medicare and Medicaid programs, FDA, CDC, and AHRQ), state governments, private health plans (such as Kaiser Permanente), clinical specialty societies (such as the National Kidney Foundation and the American Academy of Pediatrics), hospitals, and other professional constituencies and by consumers directly.

Dr. Lerner has conceived of, secured funding for, and implemented numerous programs in technology assessment. For example, he was the first Center Director of ECRI's Evidence-based Practice Center (EPC) under the Agency for Healthcare Research and Quality, and Coordinator of the Technical Expert Panel of the National Guideline Clearinghouse (a project sponsored by AHRQ in cooperation with the American Medical Association and the American Association of Health Plans). He also served a member of the Medicare Coverage Advisory Committee (MCAC) until 2003 and is currently on the Advisory Board of the U.S. Cochrane Collaboration Center.

He has, over the past 25 years, made major presentations to government agencies and professional organizations worldwide and has written articles, editorials, and book chapters such as "The National Patient Library: Evidence-based Information for Consumers," which appeared in the winter 1998 issue of the *International Journal of Technology Assessment in Health Care*.

Dr. Lerner received his M.A., M.Phil., and Ph.D. from Columbia University, where he was awarded three University President's Fellowships and other honors. His B.A. is from Antioch College, and his business training is from the Wharton School. He also studied abroad at St. Andrew's University, Scotland.

**Richard Mathis**, Ph.D., CHE, has managed Medical Policy Research and Development for BlueCross BlueShield of Tennessee (BCBST) for

the last six years. During this time BCBST became one of the first health plans to publish their Medical Policy Manual on the Internet. The BCBST Medical Policy Manual now serves as an important Internet reference for various organizations, and has received recognition in an article published by *Health Affairs*, from Best Ethical Strategies in Managed Care (BEST), and from researchers associated with universities such as Stanford.

Dr. Mathis has published articles and made national presentations on various aspects of health care, most recently in the field of Evidence Based Medicine. His book, *Prayer Centered Healing*, published in 2000, received an award as the best book on spirituality for that year. He is a Diplomate of the College of Healthcare Executives and a Certified Healthcare Manager. He received his Ph.D. in political science from the Johns Hopkins University in 1987.

**Susan L. Prows**, Ph.D., MPH, directs consumer health research initiatives at FACCT. She has extensive teaching and research experience in theory development and the practical application of findings in population-based programs. She is a former New Orleans public school teacher and administrator, community nutrition educator, and recently directed the health policy research unit for the Office for Oregon Health Policy & Research. Current research projects at FACCT focus on developing scientifically defensible, provider-level profiles of adherence to disease-specific treatment guidelines.

Dr. Prows holds an MPH from the Tulane University School of Public Health & Tropical Medicine and a Ph.D. from the University of Massachusetts School of Public Health.

**Dennis E. Richling**, MD, became the President of the Midwest Business Group on Health (MBGH) on February 1, 2003. MBGH is a coalition of employers working together to provide leadership and knowledge to continuously improve the quality and cost effectiveness of health services. Members include both public and private employers of all sizes in an eleven-state region. Prior to this, Dr. Richling was the Assistant Vice President of Health Services and Chief Medical Officer of Union Pacific Railroad, a position he held February 1989 to January 2003. In this

capacity he was responsible for the medical and health-related services that were provided to approximately 50,000 employees throughout the 23 state operating territory of Union Pacific. The Health Services Department manages over 450 company sponsored fitness facilities, a multi-site health risk intervention program, vocational rehabilitation services for injured and ill employees, a medical consumer education program, an alertness management program, and the medical surveillance programs for the railroad.

Dr. Richling is a graduate of Creighton University School of Medicine. He continued his post-graduate training at Creighton, as well. He practiced Emergency Medicine in Omaha for six years, before joining Union Pacific as Assistant Medical Director in 1986. He graduated from Harvard Business School after completing the Program for Management Development in 1997. He also served as a 2002 fellow on the Secretary's Primary Health Care Policy Fellowship.

**Diane C. Robertson**, ECRI Editor-in-Chief and Senior Clinical Writer, has 25 years of experience in writing and editing on cutting-edge clinical topics, health policy, regulatory, and health services research issues. Ms. Robertson is responsible for many of the reports and publications developed under ECRI's Health Technology Assessment Program: *Windows on Medical Technology*, *Executive Briefings* (concise digests of ECRI's full-length, in-depth technology assessments); *Health Technology Assessment News*, a monthly internationally distributed forum for health services research and policy issues; *Health Technology Trends*, a monthly newsletter on emerging technologies; *Health Technology Forecast*, ECRI's new online database reviewing and predicting the impact of health care technologies now under research and development; and TARGET, a database of technology reviews of new health care technologies emerging on the market.

Ms. Robertson authored ECRI's comprehensive *Patient Reference Guides* on high-dose chemotherapy and autologous bone marrow transplantation for Metastatic Breast Cancer. *Should I Enter a Clinical Trial?* The *Patient Reference Guide* on HDC/ABMT for metastatic breast cancer was accorded the 1996 Rose Kushner Award for excellence in medical

writing on breast cancer by the American Medical Writers Association. The *Patient Reference Guide* on clinical trials has been adopted for use with patients and training patient advocates and researchers at numerous national cancer centers and research institutions, including the University of Pittsburgh, Mayo Clinic, and Cleveland Clinic. She holds degrees from Moore College and Temple University.

**Steven H. Sheingold**, Ph.D., is Director of the Division of Operation and Committee Management, Office of Clinical Standards and Quality, Centers for Medicare and Medicaid Services (CMS). He and his staff are responsible for the operation of the Medicare Coverage Advisory Committee, providing analytic/methodologic support for national coverage decisions, conducting post-coverage analyses of Medicare claims, and providing various other support activities to Medicare's coverage processes. In previous positions with CMS, Dr. Sheingold was responsible for developing and analyzing databases for implementing prospective payments systems, including Medicare's recent system for hospital outpatient services. He has also been responsible for developing capacity to support coverage decisions making with evidence-based methods.

Prior to joining CMS, Dr. Sheingold was a Research Scientist for Battelle's Human Affairs Research Centers and a Principal Analyst for the Congressional Budget Office. He has published articles concerning reimbursement systems, cost effectiveness analyses, performance measurement and technology assessment in Journals such as *Health Affairs*, *Journal of the American Medical Association*, *Medical Care* and *PharmacoEconomics*.

**Lois A. Vitt**, Ph.D., is Chair and Founding Director of the Institute for Socio-Financial Studies (ISFS), Middleburg, VA. She has a background in business and finance for both entrepreneurial companies and investment banking firms, and she is a consultant to financial services companies and community organizations. She is Editor-in-Chief of the *Encyclopedia of Financial Gerontology* and the forthcoming *Encyclopedia of Retirement and Finance: Revised and Expanded Edition*. She has conducted research on consumer decision

making, financial literacy education, consumer health finances, the finances of retirement and aging, and financial instruments and organizations.

Dr. Vitt conducted studies for the Employee Benefit Research Institute (EBRI) on Consumer Health Care Finances and Education, and she also directed *Personal Financial and the Rush to Competence: Financial Literacy Education in the U.S.* for the Fannie Mae Foundation. She has developed interdisciplinary curricula and taught undergraduate and certificate courses in the social psychology of money and finance and the finances of aging for American University and Catholic University of America. Dr. Vitt pioneered the development of real estate financing vehicles for the capital markets, and her research on the beneficial effects of homeownership has been presented to audiences around the world. She received an Executive MBA from the Lubin School of Business at Pace University. She earned her M.A. and Ph.D. in sociology at the American University in Washington, DC.

**Paul J. Wallace, MD**, has combined past experiences in academic medicine and clinical medical oncology and hematology practice with work in quality improvement, especially in the areas of guideline development and evaluation of emerging medical technologies. Since 1997, his full-time focus has been administrative and development endeavors in the application of evidence based medicine within Disease Management, Measurement of Clinical Performance, technology assessment and use of the Electronic Medical Record.

Dr. Wallace has been a member of the Northwest Permanente Medical Group since 1989, where he directed the Clinical Practice Guidelines Program from 1994 to 2000. He joined the National Kaiser Permanente Care Management Institute (CMI) in Fall 1999 as the Senior Director of Clinical Integration, and became the CMI Executive Director in June 2000. He also participates with the Kaiser Permanente Interregional New Technology, Guidelines and Diversity Committees, is on the Medical Advisory Panel for the Blue Cross and Blue Shield Technology Evaluation Program, serves as a Board member for the Institute for Medical Knowledge Implementation, and participates as a Commissioner with the

National Center for Information Therapy. He also serves on the Medical Coverage Advisory Committee for the Centers for Medicare & Medicaid Services (CMS).

**Ray Werntz** was President of the Consumer Health Education Council (CHEC), a program of EBRI-ERF from 1999 to 2003.

Previously, Mr. Werntz was Vice President of Compensation and Benefits for Whitman Corporation in Rolling Meadows, IL, where he was a strong proponent of health and financial education for employees and their families. In addition to his over 30 years' experience as a human resources executive, he has been active on many boards and in other private- and public-sector organizations established to address health care delivery, quality, education, and access.

A native of Chicago, he has a B.A. and M.A. in history and philosophy from De Paul University and a J.D. from John Marshall Law School.

**Thomas H. Wood, MD, MMM, CPE, FAAFP**, is the Clinical Software Architect and Product Manager at Milliman Care Guidelines, a division of Milliman USA.

Dr. Wood has 25 years of clinical practice experience, across all socioeconomic groups and all payment mechanisms. He has been a solo practitioner on an island in Alaska and a regional medical director in a large, urban, multi-specialty group. He received his undergraduate degree from Yale and his medical training from the University of Washington and Virginia Mason Medical Center. He earned a Masters in Medical Management from Carnegie Mellon. He is a Clinical Assistant Professor in Family Medicine at the University of Washington.



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## ***Executive Summary***

**By James Jaffe, EBRI**

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While doctors accurately point out that medicine is both an art and a science, most experts agree that America's health care system would better serve all of its constituencies—providers, patients, and payers—if more of the medicine practiced were grounded in science. In other words, the best health care to both give and receive is that which is known to actually work—if it can be proven that a particular procedure or treatment is effective.

But, for a host of reasons, extending the influence of so-called “evidence-based medicine” is a daunting challenge. The question of whether to focus on providers (as has historically been the case) or on patients (as is one goal of the new consumer-choice health plans) is a complex and controversial one.

Underlying these issues is a more basic question: If the nation lacks the resources to provide all the health care Americans want, who will decide who gets what, and when? And what will the decision-making mechanism be?

These were among the key questions discussed by about a hundred health experts and policymakers on May 8, 2003, at an EBRI Education and Research Fund (EBRI-ERF) policy forum held in Washington, DC. The theme was: “Will Wider Use of Evidence-Based Medicine Significantly Enhance Health Care Quality and Affordability? Implications for Consumer-Driven Health Benefits.”

There was broad agreement on several points:

- Relatively little evidence-based medicine is being practiced now.
- Evidence-based medicine could have a major positive impact on health care quality.

- Evidence-based medicine could, in certain situations, simultaneously lower costs and enhance quality.

But speakers disagreed on several other basic questions:

- Might optimal care prove to be more expensive care than what is now being delivered?
- Should the focus be on the minority of the population, who run up the majority of America's medical bills, or on the healthy majority, most of whom are responsible for only modest medical expenses?
- Should the primary targets of efforts to accelerate the spread of evidence-based medicine be health-care providers or consumers?

Analysts commonly—and critically—refer to the nation's health care system as the world's largest cottage industry, in which hundreds of hospitals and thousands of physicians make millions of individual decisions about how to best care for patients. But these decisions often do not reflect the current state of scientific knowledge; old habits die hard and new practices spread slowly.

Paradoxically, this problem is exacerbated by the explosive growth and dissemination of medical research results in recent decades. This ever-rising flood of information makes it more difficult for even the most conscientious practitioner to keep up.

And while it may seem that several ongoing trends—computerization, the replacement of individual physician practices with group practices, more vocal and involved consumers, and managed care guidelines—would rapidly push medical practices in a positive direction, there is scant evidence this has occurred.

The drive for consumer-driven, evidence-based health care is based on two premises, each of which is open to challenge:

- That there is an optimum way, or at least a narrow range of options, for best dealing with any given medical diagnosis.
- That information on the preferred route can be communicated to health care providers, patients, and their families in a way that is readily accessible.

EBRI president and CEO Dallas Salisbury opened the session by contrasting the wealth of data available and the difficulty in using it well to make rational medical decisions. Summarizing an earlier discussion of evidence-based medicine (EBM) done jointly with ECRI, he said of evidence: “It very frequently is not used and, even where someone has it and might want to use it, the nature of the tools or the complexity of the tools for application are so intricate that even the individual who might wish to apply the evidence may find it nearly impossible to do so.”

Reflecting on personal experiences, he noted a surprising conflict: Physicians are hungry for new scientific data that will help them to improve their practice of medicine, but are often offended when patients seem to challenge their judgment by asking them to justify a recommended course of action, or by actually bringing new data to the session and demanding that it be addressed.

Salisbury was the first of several speakers during the program to observe that the shift under discussion challenged cultural norms that participants in the system, particularly providers, have become comfortable with. Indeed, a basic premise of managed care was that the experts could direct patients toward the “best” types of care, from both a medical and fiscal perspective. But in reality, individuals did not like the limitation of choices that this frequently carried with it.

These themes were amplified by Ray Werntz, an EBRI-ERF consultant, who spoke of growing anxiety among health plan sponsors about increasing health care costs, although employers currently are reluctant to translate their concern into strong action.

“Employers have made noise about cost transfers for years and they’ve not moved as quickly as they’ve said they would on the issue

of cost-shifting because employee health benefits are so important to the work force. They are the number-one employee benefit,” Werntz said. “Health care is vitally important to people, and the willingness and ability of employer-sponsors to mess with it—and mess with them—is muted these days.”

But Werntz noted that more than money is involved, as news reports of medical errors, patient safety, and the growing ranks of the uninsured all add to employers’ worries about offering a health benefit. “While poor quality and medical errors clearly add cost to the system, providers of care that are also struggling with the uninsured problem are asking for more, not less, money to build the infrastructure and provide the services they think will be necessary to improve quality and reduce medical errors,” Werntz said. “Cost and quality problems for employers these days are daunting problems, each in their own right.”

The experience of the past decade has left both employers and their workers unhappy. Despite changes, employers are still troubled by chronic significant cost increases. And while employers have not been able to keep costs as low as they would like, the changes they’ve made in pursuit of this goal have left many workers feeling that the burden is being shifted to them, and that they’re being forced to use preferred providers they lack either confidence in or comfort with—or both.

## ■ Definitions: Are Cost, Quality Linked?

Bruce Taylor, director of benefits planning, health, and welfare plans for Verizon Communications, noted that his company spends \$2.7 billion annually on health care for workers and retirees, and that the only larger expense is payroll. Not surprisingly, he spoke of the communications revolution that makes it easier for health practitioners in all areas to quickly learn about advances in medicine. But, he added, the availability of a technology doesn’t guarantee its use; with health care, “no one wants to pay or utilize or be exposed to things that are less than the best.” Taylor described various techniques Verizon is using that it believes will simultaneously increase quality and control health care costs, which he acknowledged will take some time to evaluate.

“We’re convinced that buying high quality the first time and only once has to cost less money.”

He was cautiously optimistic: “I think we’re at the beginning of a very long journey and I don’t think we should be dissuaded along the road. The good news is that consumers hear the message,” he said.

Richard Mathis, BlueCross BlueShield of Tennessee’s manager of medical policy research and development, defined EBM as “the conscientious, explicit and judicious use of current evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.”

But that immediately raises questions about clinical expertise and how to deal with many areas where high-quality evidence is lacking. In these situations, the insights of clinicians can prove invaluable, he noted. And while the specific cost savings from evidence-based medicine are sometimes difficult to quantify, blocking the spread of useless and expensive procedures yields a clear payoff. An example is high-dose chemotherapy for breast cancer that was not only very expensive but also ultimately acknowledged to be ineffective, Mathis said.

Evidence pushes in two directions: Limiting the use of very expensive but less-than-helpful new technologies, while also encouraging broader use of clinical guidelines and treatments that might add to costs. Mathis cautioned that there is no way to make simple either/or decisions about whether a given practice is worthwhile, citing “half-way technologies” that prolong life but don’t cure a condition—a “quality” outcome that “may cost more money to take care of down the road.” This can become even more complex when consumers are added to the equation, since they tend to have a different understanding of evidence, cost, and quality from medical professionals. “Quality for consumers is more treatments, more money spent. Quality for consumers is having more choices. Quality is being in a waiting room with people who earn more money than you do. Quality is the right to sue,” Mathis said.

He predicted that consumers hit with higher deductibles will have to think more before accepting recommended remedies and

will need new tools to help them make a more systematic evaluation of options than is now the case. He’s “looking at some treatments and rating them according to a *Consumer Reports*-type model,” Mathis said, which means not just providing guidance about what may or may not be covered in their insurance, but also “just what do you want to spend your money on and is it really worth it?”

Paul Wallace, executive director of the Kaiser Permanente Care Management Institute, said the growing interest in EBM was “something that will allow us to continue to both test and evolve what really still is a hypothesis, that evidence can be the foundation by which we can actually make some sense out of this mess that we call health care.”

He observed that everyone wanted “value,” but that different constituencies in the system had differing definitions of value, creating a “dissidence of defining things differently.” He went on to cite Kaiser’s David Eddy, who defines evidence-based medicine this way:

- Being clear about what’s known and what’s not.
- If something works, do it.
- If something doesn’t work, or causes harm, don’t do it and actively discourage it.
- When unsure about the efficacy of a step, be cautious.

Wallace said that at Kaiser Permanente, this is called making the right thing easier and there is a conscious effort to acknowledge the patient perspective, which can be described as: “I don’t care how much you *know* until I know how much you *care*.” He warned: “If people aren’t treated well coming into the medical office, disabuse yourself of the notion that you can engage them in a shared decision.” Wallace also stressed the need to focus on the small number of patients with chronic conditions who require a disproportionate share of health spending. Citing a favorite example in such discussions, he noted that nearly 10 percent of Kaiser’s total costs went to care for diabetics. For patients with this condition, Kaiser has held spending constant over the past five years while simultaneously enhancing the quality of care, Wallace said.

## ■ What's Happening?

Lerner, president and CEO of ECRI, argued that the movement toward defined contribution health plans gives employers an incentive—and perhaps even an obligation—to provide employees with evidence of what health care works and what doesn't. He cited two examples of products ECRI has created to provide such evidence.

*Should I Enter a Clinical Trial?* is a pamphlet published in 2002 that provides guidance to patients in making this complex and difficult decision. An earlier effort, published in 1996, asked the question of whether bone marrow transplants were efficacious in dealing with breast cancer and concluded, despite the popularity such treatments then had, that they were not. ECRI then convinced advocacy groups to fund publication of this conclusion. In doing so, they came to realize that what the public—and the news media—find interesting isn't necessarily what's most helpful. Most news stories in the press about breast cancer, for instance, involved women between ages 30 and 50; there were few stories about women over 70 with the disease, although it is much more common within the older age group. What the press is most interested in communicating may not be the information that health experts believe most needs to be shared, Lerner said.

He also talked about the challenges of communicating to a lay audience. People readily understand that a disease will strike one person in 10. But saying that 10 percent of the population will get the disease—the same message in different words—leaves people confused. Context is also important: For instance, is the probability of dying from a specific disease more or less than, say, getting hit by a bus?

But Lerner noted that evidence-based medicine is still a largely unexplored field—as are the methods of informing people about it. “We don't have a lot of experience in evaluating the effectiveness of disseminating patient information to providers and we have even less experience in disseminating evidence-based information to the public,” he said. “And we have still less experience in evaluating what the effect is of doing this.”

Nonetheless, proponents of various treatments are going this route, making it more

important that impartial information be available and understandable. “It's one thing to have the information,” he concluded. “It's another thing to learn how to present it.”

Jessie Gruman, president of the Center for the Advancement of Health, summarized research in the area and the difficulty in presenting results in a way that patients will find helpful—which often means translating group statistics into personal probabilities in an accessible fashion. “We actually know quite a bit about how to communicate risk, but what we know is couched in such a way that it's so qualified that it's kind of risky to even say that we know a lot,” she said.

Gruman also pointed out that different participants in the system tend to define “consumers” in very different ways: “Those people who use ‘consumer’ in its *economic* sense assume that consumers can and will make rational choices among available options, while those using it in the *political* sense believe consumers should have excellent and affordable choices available and also should be protected from either having no choices at all or from the circumstances which would lead them to make bad choices.”

She then summarized eight broadly held views about consumer education (including “providing the right information will lead to changes in behaviors and choices”) and then cited research suggesting that each was at least partially untrue. Citing the types of complex decisions that could be left to unsophisticated consumer patients, Gruman warned: “To the extent that consumers are expected to take on these roles without support, there's risk of abrogating the social contract between physicians and patients, between public decision makers and the people whose health they seek to protect, and, most broadly, between the health care sector and the society that it's supposed to serve.”

Steven Sheingold, director of the Division of Operation and Committee Management, Office of Clinical Standards and Quality, in the Centers for Medicare & Medicaid Services (CMS, the agency that runs the Medicare and Medicaid programs), suggested that technology moves faster than evaluations, partly due to pressures from patients who are, understandably, seeking immediate relief. “As a result, our physicians who want to treat us and we as patients or family members may have accepted

some technologies in a less-critical manner than may have been appropriate,” he said. This means, he added, that there are “accepted” technologies in use that are based on evidence that by today’s evidence-based systematic reviews would not rate very high in quality. “Later on, we did some higher quality randomized trials and found that these things either didn’t work or, in fact, were harmful.”

What’s best in terms of care provided by the system may not necessarily be optimal for individual patients within the system, he said, which raises an equity issue: If the rich have the option of selecting a procedure that has only a 1 percent chance of success, does society have an obligation to offer similar care to those who cannot afford it?

Despite general support for the concept of evidence-based medicine, insurance plans (including Medicare and Medicaid), which may effectively limit the menu of options by making reimbursement decisions that consider costs as well as outcomes, may be using criteria quite different from what individuals would use. “How much surgical risk should we be willing to accept to get a certain quality of life improvement? On the individual level, this may be completely a different calculus. The individual patient and the payment system may take a very different view of what constitutes ‘adequate’ evidence,” Sheingold said.

Aligning these two perspectives is a major challenge, he added, and if evidence-based medicine is to work “to improve the value of health care, we have to bridge the gap between the population decision and the individual decision at the point of treatment. And we need to find ways to package scientific information to be useful to physicians and patients.”

So while it makes sense for the system to reject a treatment that helps 10 percent and harms 50 percent, uncomfortable patients may find a 1-in-10 chance of improvement attractive.

Finally, there is confusion and even ambiguity about the role that cost plays in evaluation. Does a commitment to evidence-based medicine suggest that insurers have an obligation to pay for anything that is medically effective, even if the cost is extremely high and the benefits are quite limited?

Thomas Wood, of the clinical guidelines division of Milliman USA, stressed the importance of measuring things that really matter. “Information about quality is poor, and

actually if you look at most of these report cards [provided beneficiaries], they’re about service—not quality. And when you have poor measurements, people make decisions based on reputation.”

But providing something more sophisticated than a poll on reputation is a challenge. Milliman tried to translate some of its proprietary guidelines for providers into materials that could help consumers. Wood said their feedback about the guidelines was that they were written at the 8th grade level, “and that’s too high—that it should be written at the 3rd grade level.”

Effective marketing is difficult. Consumers have easy access to a wealth of Web sites, but for the layman it’s difficult to separate the wheat from the chaff. And even sites that are generally viewed as presenting good information in an accessible fashion can have only a modest impact on behavior. For instance, the Pennsylvania Health Care Cost Containment Council publishes information on hospital performance doing cardiac surgery. Four years after they began issuing such ratings, only 2 percent of surveyed patients were aware of them, and less than 1 percent used their data in deciding which surgeon to select. No one ventured a guess about what upper limits might achieve over time or whether there was, perhaps, a “tipping point” when the utilization of such data might become normal behavior.

Milliman is assembling and evaluating research on these issues, but such research is increasingly dependent on potential profits. “If you can’t patent something, if you can’t corner the market on something, there’s no business incentive to having a study, no matter how valuable that information might be to the public,” Wood said.

Within the existing system, there will always be those trying to sell new expensive remedies that are always claimed to be better than those they seek to replace, he added, but there seem to be no economic incentives for coming up with remedies that are cheaper and better.

## ■ How to Learn?

Carolyn Clancy, director of the Agency for Healthcare Research and Quality, seconded a view expressed earlier that getting people to

use evidence already available was a major problem. “We’ve done a much, much better job in terms of *production* of evidence than we have in terms of *using* it or making it usable and navigable for people, whether they’re clinicians or consumers trying to figure out how to get a common surgical procedure done,” she said. “It’s astonishingly rare when you have a question to actually find a site that helps you get right to the answer to your question, or it’s at least entirely serendipitous.”

Dennis Richling, president of the Midwest Business Group on Health, warned that good intentions weren’t enough. “I see some companies spending money on prevention programs that are not well integrated or not based on systematically based evidence, where you might as well take the money you’re spending and put it in a big pile in front of the building and burn it, for as much good as you’re going to get out of those kinds of services,” he said. “The evidence is pretty strong that fragmented activities that do not follow the evidence really don’t work.”

Richling participated in developing *The Guide to Community Preventive Services*, a systematic review of population-based interventions to promote public health, sponsored by the U.S. Department of Health and Human Services and coordinated with the Centers for Disease Control. He deals daily with experts and consultants in health promotion, and expressed concern over recommendations made by those are unaware of this important work.

Mark Helfand of Oregon’s Evidence-Based Practice Center talked about the work he’s done as a member of the U.S. Preventive Services Task Force, and about the inevitable push to accentuate the positive in research results—especially when the effort is sponsored by someone looking to make a profit from wider use of the therapy being tested.

And the process isn’t terribly sophisticated in delivering guidance about marginal benefit, “whether it’s a big, moderate-large or small benefit,” Helfand said. “The best we can do is try to translate what it says in the literature into some gross estimate of the benefits minus harms, either on an individual or an aggregate basis. It’s far from precise and it’s far from usable” by individual consumers.

## ■ Do Consumers Care?

Susan Prows, director of the Foundation for Accountability (FACCT) in Portland, OR, focused on some basic questions about quality of health care: How do consumers define quality health care? Who do consumers hold responsible for assuring quality health care? What do consumers expect from their doctors? And what information do consumers want? The answer: “We have found that consumers think that good quality means a good doctor and that bad quality is a bad doctor,” she said.

Consumers want to have a collaborative relationship with their physician, but “they really have no idea that there are things called guidelines and quality indicators,” Prows said. Nevertheless, she added, consumers would like to know what those are and how they relate to them and their medical conditions. Prows currently is involved in research on maximizing use of reliable Web sites, including the one (Compareyourcare.com) operated by FACCT.

Marge Ginsburg, executive director of Sacramento Healthcare Decisions, discussed a project her group sponsored on how consumers would prioritize limited health care resources. Her group is working on a computer simulation program that allows consumers to optimize their health insurance.

One central message is that “we Americans love to have choice and we really don’t want that compromised if we can help it,” she said; patients accept the need for guidelines to provide a shared standard of care, but “they don’t want to feel like they are relegated to some little algorithm.” Guidelines get more respect if they are prepared outside the health plan that uses them and are not construed solely as ways of saving money.

Finally, Ginsburg said, patients want assurances “that dollars saved through using guidelines need to go to patient care and not to stockholders.” Listing consumers’ expectations, she concluded that when people have health insurance, “they really expect that everything except cosmetic surgery is going to be covered,” and also that when an individual is seriously ill, “they want everything to be done to help that individual to survive.”

Lois Vitt, director of the Institute for Socio-Financial Studies, which tries to help make consumers financially literate, argued

that patients “need the belief that they can successfully navigate the health care system.” Right now, she added, “they don’t have that belief.”

For instance, she said, few patients would challenge a physician recommending an MRI by asking whether a CAT scan would be adequate and more cost effective for the task at hand. “We’ve learned that consumers don’t know very much about the coverage they already have. They don’t know how the health care system works. They don’t know the connections between coverage and lifetime health,” Vitt said.

Daniel Fox, president of the Milbank Memorial Fund, concluded the policy forum with three key points:

- Health care evidence is getting better and becoming more widely available, even as the stakes (and costs) are rising in the U.S. health care system.
- Evidence informs—but does not determine—individual health care decisions.
- Not all that’s claimed to be “evidence” actually is evidence.

Fox noted that as a result of the science of research synthesis, there can be a common understanding of which health care practices actually work. But for systemic reviews to be produced and be effective, he added, there must be good quality trials to synthesize results, and infrastructure funding to produce those reviews—both of which are currently lacking. And for the movement toward evidence-based medicine to be successful, Fox said, the growing demand for trials and infrastructure “needs to be accompanied by broad education of the media, the public, the professions, and the purchasers.”



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## **Overview**

Making Coverage Decisions: Chapter 1

Consumer-Driven Evidence-Based Health Care:  
Chapter 2

## ***Making Coverage Decisions***

by Paul Fronstin, EBRI, and Diane C. Robertson, ECRI<sup>1</sup>

(This paper was originally published in the May 2003 *EBRI Notes*, vol. 24, no. 5)

### ■ **Introduction**

A return to double-digit increases in health benefit costs is fueling interest in new structures for employment-based health benefits. It is also fueling discussions about whether the best available evidence, based on rigorous evidence reviews, is used in making coverage decisions and how these decisions affect the cost of providing health benefits. Evidence reviews based on the relatively new science of research synthesis will play an increasingly important role not only in the practice of medicine but also in the business of health care, according to speakers at ECRI's 10th Annual Conference on Healthcare Policy, Law, and Methodology on October 29 and 30, 2002, in Plymouth Meeting, PA. Conference cosponsors included the Consumer Health Education Council, the Employee Benefit Research Institute, the Leonard Davis Institute of the University of Pennsylvania, and the Milbank Memorial Fund. Employers, insurers, providers, and regulators questioned whether the health care debate would focus more on cost—at the expense of quality and value in health care—as costs continue to rise, particularly during a foundering economy.

### ■ **Evidence-Based Medicine**

“Traditionally, mention of cost-effectiveness in health care decision making was heresy, but cost always filters into the question,” said Grant P. Bagley, M.D., J.D., former director of the coverage and analysis group in the Health Care Financing Administration (now Centers for Medicare & Medicaid Services, or CMS) and

now a partner in the law firm of Arnold and Porter. Evidence is required to make these decisions, and a major obstacle is first overcoming antagonism to evidence-based medicine (EBM), he noted. “Everyone is in favor of evidence-based medicine as long as you use *their* evidence and come to *their* conclusions,” said Bagley. To further the acceptance of EBM, Bagley called for greater inclusion of all interested parties—perhaps patients and beneficiaries themselves—in EBM and the coverage process.

“What is the business case for worrying about value in health care?” asked Dallas L. Salisbury, president and chief executive officer, Employee Benefit Research Institute. To date, the business case for health care quality has not been made, said Salisbury, and most employers have based their health care purchases on issues of cost and satisfaction. Although using evidence could help guide health care purchasing based on quality, most employers have little experience evaluating research evidence and putting evidence-based conclusions into practice, he noted.

As the largest health care purchasers in many jurisdictions, state governments are turning to EBM to make rational health care decisions while also providing political cover, said John M. Colmers, program officer for the Milbank Memorial Fund. “Private payers observe states to see if some health care policy and its coverage aspects work,” he noted. “Private payers observe what the public response is to state coverage decisions, such as repealing coverage of a certain technology or

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<sup>1</sup> ECRI (formerly the *Emergency Care Research Institute*) is an independent nonprofit health services research agency based in Plymouth Meeting, PA.

adding prescription drug coverage,” said Colmers.

Sharon Levine, M.D., a pediatrician and associate executive director for physician and professional services, The Permanente Medical Group, Inc., explained that Kaiser Permanente uses evidence in making coverage decisions but places the locus of authority on the treating physician rather than on insurance executives. “We’ve created as much autonomy as is available in U.S. health care—Kaiser puts the responsibility on doctors to be accountable for both the quality and cost of health care,” said Levine.

Kaiser uses evidence-based technology assessments “not to deny the use of new technology, but to use new technology in the most practical and clinically appropriate way,” said Levine. In one evidence-based example, Kaiser determined that Cox II inhibitors (prescription drugs) offered limited, if any, benefit for relieving arthritis pain and inflammation compared with other nonsteroidal anti-inflammatory drugs (NSAIDs), which cost substantially less. Because evidence failed to show that Cox II inhibitors did not eliminate the risk of gastrointestinal bleeding, were not proven safe in high-risk patients, and offered no benefit to low-risk patients, Cox II inhibitors are prescribed for only about 5 percent of Kaiser Permanente patients, compared with about 46 percent of patients nationally.

Levine believes that improving the evidence base for making coverage decisions can help relieve cost pressures. “It’s easy where there is clear evidence of harm or lack of benefit,” she noted. However, evidence often does not exist for new technology, and if available, evidence frequently does not address the cost of new technology and drugs, said Levine.

Among the proposals that panelists suggested for improving the dearth of available evidence on emerging technologies, where it is often most needed, were:

- Shifting more National Institutes of Health funding from basic laboratory research to applied clinical research, to enable better coverage decision making.
- Creating a national procedure for studying emerging technologies and collecting evidence to inform decision making on these technologies.

## ■ Methods of Medicare Coverage Policymaking Create Inconsistencies

Discrepancies in Medicare coverage policies exist because of the different ways in which local and national coverage policies are made (Medicare is the federal health care insurance program for the elderly and disabled). A panel of speakers involved in different aspects of Medicare coverage decision making and implementation at both levels reviewed the problems that these discrepancies can create and proposed solutions.

Panel moderator Susan Bartlett Foote, J.D., division head and associate professor, Division of Health Services Research and Policy, University of Minnesota School of Public Health, said that national coverage decisions tend to focus on the effectiveness of a particular medical technology and the equity in extending national coverage to that technology to make it available to a wider patient population. Local medical review policy (LMRP), on the other hand, deals with the timeliness and flexibility of extending coverage and the responsiveness to local conditions, said Foote.

She also reviewed findings from a recent survey of LMRP contractors that found that 87 percent of responding contractors had no written process for making policy, while 92 percent had no process for reviewing data on technology. While manufacturers try to influence LMRPs the most, they have the least influence with them, and patients in large part were not active in trying to influence local policies, she said. LMRPs and national coverage decisions (NCDs) tend to be developed from very divergent positions, said Sean Tunis, M.D., M.Sc., acting deputy director, Office of Clinical Standards and Quality, and acting chief clinical officer for CMS. Technologies are considered for NCDs when companies file a request for consideration of their technology or when local Medicare carriers request that an NCD be made. Under Medicare’s “reasonable and necessary” statutory requirement for coverage, CMS considers the evidence on new technologies with the following goals in mind before making an NCD, Tunis explained:

- Having sufficient knowledge and data about how well a technology works.

- Avoiding the promotion of procedures that are ineffective or may harm Medicare beneficiaries.
- Directing limited resources so that they produce a net health benefit.

LMRPs tend to be enacted first, with the intention of studying the technology later, said Tunis. In practice, such studies are difficult to conduct once a technology has been diffused, and adequate evaluations are rarely done because prospective studies require time and funding. If manufacturers obtain coverage on a local level for new technologies, there is little incentive to carry out further studies. Moreover, manufacturers can put together funding from numerous localities, allowing them to diffuse the technology more broadly even in the absence of an NCD. And if studies are carried out after coverage is granted and a technology is found to be less effective than first believed, it is very difficult to remove coverage, Tunis explained.

Charlotte S. Yeh, M.D., medical director for Medicare policy at National Heritage Insurance Company, the local Medicare carrier for New England and California, described the difficulties of carrier medical directors (CMDs) in making local policy, but also noted benefits to making LMRPs. Yeh is one of two people (the other is a nurse) who review technologies and make LMRPs for two large regions in which the carrier provides Medicare coverage. The carrier in these regions covers five states, 2.4 million beneficiaries and 80,000 providers, and processes more than 25 million beneficiary claims annually.

“When CMDs started in 1993, they were to assure program integrity and utilization review, not to make coverage policy,” she explained. Yeh said that CMDs lack the resources and time to carefully weigh the available evidence. “We are given no budget for technology assessment activities even though we’d love to have those kinds of resources,” she said. Instead, they rely on consensus from their 200 care advisory committee (CAC) members, who represent all the medical specialties and states in the two regions, and on input from public hearings. Relevant CAC members have periodic teleconferences to discuss what they know about particular technologies and make recommendations to the CMD. LMRPs give local CMDs the ability to make flexible

coverage decisions that consider geography (i.e., coverage area), local practice patterns and culture, and the volume of patients. Once an LMRP is made, CAC members carry that message to providers. LMRPs, however, cannot conflict with statutory requirements, regulations, or national coverage determinations.

To balance the flexibility of local decisions and national coverage consistency, Yeh suggested setting a threshold for converting local decisions to national ones. “If perhaps 40 percent to 50 percent of local carriers cover a certain procedure, then perhaps we should set a standard national coverage policy for this technology,” said Yeh. However, she believes LMRPs are necessary because they allow the flexibility that she feels the system needs due to differences in laws, licensure, and scope of practice across states; local standards of practice; the rate of adoption of new technology; beneficiary demand; and provider interest in and capability of using technologies.

## ■ Less May Be More

Douglas L. Wood, M.D., vice chair of the department of internal medicine at the Mayo Clinic and chair of both the Minnesota Medicare Carrier Advisory Committee and the Department of Health and Human Services’ Secretary’s Advisory Committee on Regulatory Reform, expressed dismay at the variation in Medicare coverage and reinforcement of practice created by 9,000 LMRPs. “LMRPs have many unintended consequences and much unfulfilled promise,” he declared.

Although LMRPs ostensibly are intended to improve health care quality while containing costs, there is no direct evidence that LMRPs actually reduce aggregate health care spending or utilization, said Wood. In fact, he believes that LMRPs discriminate against beneficiaries by increasing out-of-pocket expenses for some, create burdens on physicians through significant paperwork, and have no effect on spending and quality of care. “If we could devise LMRPs that would improve and standardize care, then that would be beneficial,” said Wood. “That seldom occurs in reality, however, so we need to figure out a way to achieve those goals.”

Wood noted, for example, that Minnesota has relatively few LMRPs, relatively low overall Medicare beneficiary spending per capita, and

ranks fourth-highest in the nation in quality-of-care ratings. In contrast, Missouri has hundreds of LMRPs, higher spending, and much lower quality-of-care ratings. To streamline the coverage-review process, Wood recommended that CMS develop a simple, understandable, consistent, and nondiscriminatory preauthorization system to alert physicians and beneficiaries about what services would likely be covered. He believes that CMS should eliminate most LMRPs and restrict them to new medical technology or important local delivery system or policy needs. “What is not local is the scientific basis for medical practices and the requirements for training,” he asserted. Furthermore, Wood advised that CMS establish an effective appeals process to complement NCDs or create templates for payment policies that all CMDs would follow.

## ■ Reconciling LMRP and NCD Policymaking

In the continuing policy debate over the proper balance between national and local Medicare coverage, Foote recommended that coverage decisions maximize value on both sides by allocating coverage decisions to national, local, and shared areas based on the technology under review and needs of beneficiaries. Foote suggested that coverage of breakthrough medical technologies would best be addressed through NCDs for which technical expertise would be more readily available to consider questions of equity among beneficiaries and efficiency. Coverage issues that deal with managing how various medical technologies are used would be handled locally, Foote noted. Local and national coverage policy would converge when product extensions, new clinical indications, and process improvements come under review, Foote proposed. Under this combined approach, LMRPs would be flexible enough to respond to local needs while encouraging innovation. In cases in which wider coverage for an evolving technology becomes appropriate, LMRPs could prompt development of NCDs when certain conditions are met, Foote said.

## ■ Opportunities for Stakeholders to Collaborate on Health Policy

Who has what interest in improving the quality and cost of health care in this country, and who can benefit in the future? This was the crosscutting issue, noted Daniel Fox, Ph.D., president of the Milbank Memorial Fund. Fox synthesized the panel presentations and described the opportunities for collaboration to solve the problems identified by stakeholders.

The two main areas that Fox identified for collaboration among businesses, employers, the government, private payers, and consumers center around issues of how to apply “evidence” for health technologies and assess the best mix of spending by employers, the government, and consumers. “‘Best mix’ means achieving the optimal affordable health of the populations that make up this country,” said Fox. “Dallas Salisbury introduced this issue by asking if there is a ‘business case’ for health. That is, do firms benefit from what they spend for employees’ health coverage? Is there a return on a firm’s investment in health care and health promotion?” said Fox, who then added his own questions. “What if evidence shows that there is a business case for spending on health for large firms in some industries but hardly ever for small firms and never for very small ones?”

“Put another way,” he continued, “what if employer spending for coverage benefits society because it contributes to the health of employees and their dependents in our highly mobile society but doesn’t do much for firms’ earnings? What if health coverage is like defense and domestic security—something that is more efficiently paid for by taxes? What if it turns out that it is better for the economy—that is, better for employment and earnings—to use taxes and consumer spending to pay for health care? On the other hand, what if the opposite is true—that coverage based on employment combined with public programs for particular populations is the most effective way to serve the public interest?”

As he urged the audience to collaborate, Fox noted, “We have talked about coverage in

this country for a long time. We have, however, never had a national discussion that is based on good evidence about the effects on the national economy and health status of particular policy approaches to coverage. The second major opportunity for collaboration is to use evidence in ways that maximize quality and outcomes in ways that are cost-effective.”

Fox cited six general issues for collaboration that would enhance the interests of business, labor, and government. The sixth issue, he warned, was very controversial. These issues are as follows:

1. Determining what health services different populations require.
2. Learning more about the determinants of health, an area of research in which he said the research community has not yet been asked to listen hard to policymakers in the public and private sectors.
3. Evaluating the quality of plans and providers. (Evaluation should include how plans and provider organizations appraise evidence about both new and accepted interventions, how they implement the results of their appraisal, and the results of implementation for patients.)
4. Studying the effects of various types of cost shifting and cost sharing on access, cost, and, most important, patient outcomes.
5. Evaluating the effectiveness of interventions. (Immediate value would be added by setting standards of evidence; setting standards for evaluating the quality of evidence reviews; defining processes by which reviews inform clinical policymaking on local, regional, and national levels; finding ways for federal and state regulators to create incentives for professionals and systems to use the best evidence in everyday health care practice; and pressing for federal funding for the infrastructure that is needed to speed the production of evidence, especially well-designed clinical trials and evidence reviews that meet high international scientific standards.)
6. Addressing antagonism and resistance to the use of the evidence to inform policy.

“Collaboration is essential on the sixth issue because the antagonists of the use of best evidence to inform clinical and finance policy are powerful, often wealthy, and always very smart,” said Fox. “The work before us requires attention to manufacturers, professionals, and consumers. We need to reduce or neutralize resistance from manufacturers of drugs and devices. We must address resistance of health professionals by aligning incentives, provoking the emulation of appropriate peers, and supporting innovators in education, especially of physicians. Finally, we must help consumers understand that the best evidence is the best guide to their care, just as it is the best guide to clinical and reimbursement policies. The best way to get this message to consumers may be to improve how the media covers the announcement of alleged advances in medicine—that is, to work with health reporters and editors to communicate the practical power of evidence.”

## *Consumer-Driven Evidence-Based Health Care*

by Ray Werntz  
EBRI Consultant

### ■ Introduction

Health care has been a big part of my life for over 30 years. Working for a large, Chicago-based employer before joining the Consumer Health Education Council (CHEC), I built benefit “systems,” chaired a state health care data commission, served on a hospital board, and worked with health care advocates. At the Employee Benefit Research Institute (EBRI), I learned to respect fact-based information and its value to decision-makers—especially employers who provide the lion’s share of health care and retirement security for millions of Americans. With this as background, and with apologies to Charles Dickens, I think this may be the “worst of times and the best of times” for those of us who are committed to high quality, accessible, and affordable health care for all Americans.

### ■ Rising Health Care Costs

There are good reasons for concern. Private-sector plan sponsors, employers who provide health care for about two-thirds of the American people, are in their third consecutive year of double-digit cost increases. Increases of this magnitude are likely to continue because it is hard for employers to isolate and neutralize the underlying and controllable causes of inflation. As a result, employers are searching for ways to pass on some of these increases to their employees by means of higher premiums and co-payments, “tiered” hospital and pharmaceutical benefits, and a wider range of benefit formats.

However, while employers appear to be more candid about their cost-shifting plans, these days, their actions still don’t seem to jibe

with these intentions, according to our research. The reason probably lies in the well-documented influence of health benefits—the benefits ranked highest in importance by employees—on employee recruitment, retention, and satisfaction.

A short time ago, the Kaiser Family Foundation reported that Americans are more concerned about health care costs than about housing costs, stock market losses, terrorism, or job loss. Because affordable health care is so vitally important to people generally, it is no surprise that employers’ actions seem to lag their expressed intentions.

### ■ Quality Problems

Adding to employers’ frustrations over mounting health care costs and other financial pressures on their businesses is a steady stream of reports documenting poor quality health care and medical errors that exacerbate the cost problems and compromise their employees’ health. For example, just a short time ago, the Institute of Medicine reported that “serious and widespread quality problems exist throughout American medicine. In small and large communities alike, in all parts of the country, and with approximately equal frequency in managed care and fee for service plans.” The RAND Corporation was more specific in a recent study of care provided to more than 13,000 patients. It found that in over 45 percent of the cases, processes for basic care based on national guidelines or medical literature were not being followed, and concluded that these shortcomings constituted serious threats to the American public’s health.

Nevertheless, despite the human and financial toll exacted by poor quality health care and medical errors, health care providers have conflicting priorities. With the economy in

a slump and growing numbers of patients without health insurance, providers feel hard pressed to invest in the information infrastructure and process changes necessary for the safe and appropriate delivery of medical care to patients. At a time when employers want to pay less for care, providers are asking for more.

## ■ Consumer-Directed Health Benefits

Seemingly uncontrollable costs, work force morale, and deficiencies in quality are all daunting problems for employers. But as they converge, they become much more problematic. Do employers try to solve one problem at the expense of another? Alternatively, is it possible to stabilize and manage costs without destabilizing employee relations, jeopardizing care quality, or compromising the peoples' health? In other words, might there be a clear, causal relationship between health care value and quality that will lead to more affordable health benefits that employees will welcome?

Some think the answer to that question may lie in employers' current experiments with consumer-driven health benefits. EBRI has been tracking consumer-driven health benefits for some time now. The proponents of the numerous benefit formats classified as consumer-directed claim that this approach will promote greater consumer knowledge, assertiveness, and financial discipline in the use of health care. At the same time, experts in the area of quality improvement uniformly endorse education that increases consumers' involvement in decisions affecting their care.

Twenty years ago, when the business community began its romance with managed care, hopes were high that more efficacious care processes, management, and coordination would correct what were often characterized as suboptimal encounters between doctors and patients. An obvious inference to draw from the end of the romance between employers and managed care and the rise of consumer-directed benefit formats is that consumers will be expected to assume more of the role formerly assigned to managed care.

A recent article in *Health Plan Magazine* described the new benefit formats as the "devolution" of health care. Devolution in this

context means the transfer of decision making power over the who, what, where, and when of health care from the benefit plan to the plan participant. The hope is that these new, more flexible benefit formats, supplemented with accurate and understandable care and cost information and education, will "empower" participants to decide among more varied benefit arrangements, providers, and care options and take greater financial responsibility for the consequences.

Employers who adopt these new formats are not certain of their effect on costs, but some believe that consumer-driven benefits may slow the rate of inflation over time. Many expect that, by knowing more about the costs as well as the medical consequence of diagnosis and treatment alternatives, participants will eventually be able to decide for themselves which are cost effective and which are not.

Probably the most important question raised by requiring individuals to play a more active role in their health care is whether or not the migration of care decisions from care management experts to consumers will affect the quality of care that is received in the future. I believe part of the answer lies in how changes in benefit formats requiring more consumer discretion and accountability will affect the translation of evidence-based screening, diagnosis, and treatment standards into the care delivered to individuals.

## ■ Evidence-Based Medicine

EBRI plans to continue its investigation of evidence-based medicine (EBM) in the context of its years of research on employee benefits trends generally and, more recently and specifically, consumer-driven health benefits. EBRI's interest in EBM grew out of a collaboration with ECRI<sup>1</sup> last year that examined of the influence of EBM on coverage decisions made by employer plan sponsors. The collaboration with ECRI is continuing, with a plan to explore the extension of EBM research, designed for populations, to individuals.

However, this discussion will concentrate on how the wider use of EBM might enhance the quality and affordability of health care

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<sup>1</sup> See chapter 1.

services in the context of our experience with emerging consumer-driven benefit strategies. We believe that our findings will be of value to all of EBRI's constituencies, and hope that those in the benefits community will factor the more positive effects of EBM into their benefit plan strategies.

Our investigation starts with a look at the basics—what do we mean by evidence-based medicine? What are the prospects that higher-quality care, driven by EBM, will cost less than poor quality care? Will EBM save money in the short term, slow the rate of future inflation, or increase the real and perceived value of health care? On the other hand, how difficult will it be to apply population-based evidence to individuals? We know new evidence often stimulates demand for expensive care. How resistant will physicians and other providers be to change? Who decides whether to follow the evidence and who will pay for it? There is a lack of evidence in many areas, and research shows low levels of health literacy in at least one-third of the population.

We also need to identify the sources of evidence and assess its availability to individuals and plan sponsors to help accelerate its dissemination. But, most of all, we must look at consumers themselves, especially as their roles in health care change. Are they ready and able to understand and use evidence as they choose care for themselves and others who depend on them? Will they accept cost effectiveness as a determinant of the care they think they need? Will better information about costs and efficacy suffice or must we do more to respect personal health values and preferences in future educational programs? Some of the answers to these questions might be found in the words of Honor Page, in a letter she wrote to me. Honor is the mother of an eight-year-old child with cystic fibrosis. She knows firsthand what it means to make care decisions based on good evidence and live with the consequences:

*My name is Honor Page. I would like to share my experiences as a mother of a chronically ill child as some food for thought. I hope this is helpful for those of you involved in designing and funding health care.*

*My daughter, Annie, was born with a genetic disease called cystic fibrosis (CF). Over time, this disease will take away her ability to breathe. Like many who face*

*chronic illness, our lives were turned upside down by an unexpected diagnosis. We were thrust into assimilating medical information and terminology, shown necessary physical therapy skills, taught nutrition strategies and started on a multidrug regimen. Our family has been on this journey for six years now, and we have learned a great deal about being consumers of health care. I would like to touch on three areas I feel would give hope and better outcomes to patients and their families— patient education, patient-centered care, and transparency around standards of care.*

*What is the key to living well with chronic illness? In my opinion, it is the desire to survive coupled with a true understanding of your disease and its treatments. Successful management of chronic illness depends on daily hard work. It's not fun taking endless pills, enduring physical therapy sessions, following diets and exercise programs, giving up things you enjoy, and coping with an illness that never goes away.*

*We are fortunate to have a CF Foundation accredited CF Clinic at our local Children's Hospital. I believe the Care Team there feels they have educated families and designed the best care plans possible. And yet, have you ever left a doctor's appointment and had trouble remembering all that was said? Have you tried to learn important information as fear washes over you? Our typical office visit doesn't have time built in for, "Did you understand what we talked about last time?" "Are you clear on what's happening inside your child's lungs?" Being sent home with numerous pamphlets and books doesn't mean families will learn. Educating patients and families in a way they can understand is essential in managing chronic illness.*

*Annie's daily care requires two 30-minute physical therapy sessions, medication every time she eats, three inhaled medications, and encouraging her to consume hundreds of extra calories. I have met CF families that chose not to do some or all of these treatments because it's very difficult and, for now, their child seems fine. Do these families really understand how these treatments work to keep their children well and slow down the progression of the disease?*

*Probably not. Are they telling the staff of our CF Clinic that they are not doing treatments? Probably not. What are the barriers to them caring for their child – and who will help them? This scenario may be common in many chronic illnesses.*

*Patient-centered care—what would that mean to you if you were chronically ill? Patient-centered care gives the patient a voice and a role in decision making. Our CF Clinic is currently working on adding a specialist to the care team (at no extra cost). Someone who knows the patient’s abilities and preferences best—the patients and their families. How can this improve health care? One personal example: Annie’s physical therapy sessions often resulted in tears. Many days I would hear “Mommy, it really hurts when you pound on my chest—do we have to do this?” It was heartbreaking, but I knew we had to work to keep her lungs from clogging with mucus, so we persisted. After two years, our CF Clinic told us of three or four other methods we could utilize. We knew which of these options would work for our family. I wish we had been given options earlier. Informed patients involved in care decisions can lead to better compliance with treatment plans. It is the patient and family who will live with the results of treatment options and outcomes. What would you like your care to look like if you or someone you loved was chronically ill?*

*What is the best treatment for cystic fibrosis, or any other chronic illness? Is your doctor treating the disease like his or her partners? Or like other physicians in town, in the country, in the world? Evidence-based medicine can offer some answers. For diseases with well-funded research there may be a good body of scientific evidence that can be used to design best practice guidelines. How do you know if your physician is using best practice guidelines?*

*What if your illness has little evidence of best care? Who has the best outcomes? Organizations that fund disease research often collect data for accreditation purposes. Sites that participate submit non-identified patient data. If this data is accurate, a research organization has a picture of where patients are doing the best. What are they*

*doing better at these “best sites”? Could these practices be shared? Are there other sources to determine best outcomes? Currently, this type of information, to my knowledge, is not shared with the public. Why? There are concerns about competition, potential legal ramifications, and the insular nature of the medical community. These concerns are hard to understand as you watch your child struggle to breathe. If sharing this information publicly is impossible, then it is my hope that organizations with this type of knowledge will reach out and cause quality improvements within their fields.*

*Thank you for your interest in improving health care and in one family’s experience. Like so many others living with chronic illness, we will continue on our journey—grateful for each day and working for many tomorrows.*

## ■ What Lies Ahead

I began my comments with a short summary of the myriad of problems besetting employers as they develop their health benefits strategies. But there is hope. We could be on the threshold of better times. We are getting better at preventing, diagnosing, and treating disease. We know more about health and health care each day. We have the technology to synthesize and disseminate what we know and connect each of us to better care processes. The hope lies in the science of medicine and new discoveries with regard to better diagnostics, therapies, and care processes and supporting technologies. The realization of that hope depends on our willingness as policymakers, analysts, plan sponsors, and consumers to take the steps necessary to support translation of this knowledge into individual medical encounters.

No one knows yet who is most capable of making difficult care decisions—caregivers, care managers, or consumers. Most likely the level of participation will depend on individuals and their personal situations. Nevertheless, I believe it is inevitable that each of us will do more and pay more to get the care we think we need.

I like cruising high-end audio stores on weekends and listening to good music on the latest and most expensive equipment. Most of

the time I don't buy anything because I have better uses for my money. I understand value in personal terms when it comes hi-fi technology. Talking to my doctor in his office and getting some other things done because something doesn't feel right is an entirely different matter. Yet, as difficult as these encounters are, I see them as an investment. Health has more to do with the important things in my life—such as being a father, a grandfather, a spouse, and a breadwinner—than a pair of new speakers.

## ■ Conclusion

We know that the value and quality of health care can be better for all of us. But we have relied for too long on those who provide health care and pay for health care to make it better. We have fallen short. While it is easy to be skeptical about consumer-driven health as simply glossed-up cost shifting, it is here for 1.5 million Americans now and it is growing. Ongoing changes in benefit formats, the Internet, and a better understanding of the determinants of health and quality health care won't allow consumers to remain passive about their care anymore.

One final point. Consumer-driven health benefits are much more than a new trend in health care financing. Actually they are not even really “new.” Higher deductibles and co-payments were employers' first reaction to the inflation spike in the early 1980s. Managed care, flexible benefit plans, and medical savings accounts followed close behind. The difference between today and 20 years ago is that we seem more convinced that better decisions by consumers is good for them and good for the health care system.

Health care is more than trained professionals, evidence-based processes, and technology. While better, more understandable information about what works is essential, more is necessary if we expect consumers to do and pay more when they need health care. If employers and the medical community expect to be taken seriously by consumers, then they must earn consumers' trust. Health care exists for only one reason: to serve sick and injured human beings.



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## **Evidence-Based Medicine and Its Connection With Cost and Quality**

Thinking About Evidence, Costs, and Quality: Chapter 3

The Different Faces of Health Care Today: Chapter 4

## Thinking About Evidence, Costs, and Quality

by Rick Mathis, Ph.D.  
BlueCross BlueShield Tennessee

### ■ Introduction

Thinking about evidence, cost, and quality together is an extremely important and timely exercise. I want to back up a minute and think about how these three issues became so important. Evidence-based medicine (EBM) has been an integral part of medicine since the first randomized control trials started about 50 years ago. More recently, EBM has become an idea that is gaining in popularity. It's even being discussed in the popular media. We are starting to see new applications of the idea. In health plan administration we are seeing concepts such as evidence-based medical management and evidence-based referrals. The thinking is that what we do should have some good evidence to support it.

The second issue, health care costs, represents an ongoing economic concern that's been around at least since the 1960s. It is, of course, the central issue as we try to determine as a nation whether we can continue to sustain ever-increasing health care costs.

The third issue, quality, is similar to EBM in that it has been around for some time. Like EBM, it is also receiving increased attention as far as health care is concerned. Edward Demming and others were instrumental in getting industries in general to focus on quality. Now we see both intense and popular interests in health care quality through such efforts as the Institute of Medicine publications and the recent Leapfrog initiative.<sup>1</sup>

### ■ Definition of EBM

The first task of this presentation is to define EBM. One of the best definitions is from a book by David L. Sackett and others entitled *Evidenced-Based Medicine: How to Practice and Teach EBM*. This book defines EBM as the

“integration of best research evidence with clinical expertise and patient values.”

According to Sackett, the practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research. There are a couple of interesting things going on with this approach. Clinical evidence means looking at such factors as the results of randomized controlled clinical trials. But there is a recognition here that we can't rely on such trials alone. We also need to draw from clinicians who are working out in the field. This is important particularly given that not every medical treatment benefits from a formal clinical trial. Using the experience of physicians and other health care professionals helps to fill such gaps.

At BlueCross BlueShield of Tennessee, for example, the Medical Policy and Research Department benefits greatly from technology assessment organizations such as the Technical Evaluation Center (TEC), ECRI, and Hayes. But we seek input from other mechanisms as well. Occasionally we will put together panels made up of external clinicians from our networks and ask them what their experience is with a particular technology. This helps in such instances when the technology has been around for a long time but has not received a great deal of formal study. In such instances we try to balance the evidence with clinical experience.

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<sup>1</sup> *The Leapfrog Group, composed of more than 140 public and private organizations that provide health care benefits, works with medical experts throughout the United States to identify problems and propose solutions that it believes will improve hospital systems that could break down and harm patients. It provides important information and solutions for consumers and health care providers.*

## ■ The Importance of EBM

Why is EBM important? For one thing, many health benefits contracts with policyholders specify that medically necessary services will be covered while investigational services will not be. Investigational services refer to those services that have not been proven to work. So, by definition and by contract, we are obligated to use approaches such as EBM to make coverage decisions. Beyond this are safety issues. There are medical treatments that harm as well as help. Looking at the evidence helps to determine if there are treatments that should not be covered because they are potentially dangerous. There is one other issue that I think is worth mentioning. This is more in the realm of ethics, perhaps, and involves the idea of stewardship. As all resources are limited, we need to make sure that we make the best use of our health care resources. Focusing on those treatments that work, and not on those that have not been proven to work, helps us to make wise use of limited resources.

## ■ EBM and Health Care Costs

One question under discussion has to do with the relationship between EBM and health care costs. Let's take a quick look at the relationship between new technologies and health care cost increases. One study indicates that as much as 22 percent of health care cost increases can be attributed to new technologies and treatments. I've seen other figures, but whatever it is, new technologies and treatments certainly contribute a great deal to health care cost increases.

Can EBM help here? My belief is that it does have an overall dampening effect. The use of EBM does keep a lot of ineffective treatments from taking place. This saves money as far as limiting ineffective services as well as dealing with complications that result from both ineffective and unsafe services. It's hard to put a dollar figure on this, but I'm sure this effect is fairly large. We certainly know that, as a nation, we would be paying a lot more for health care if we paid for every last treatment, good or bad, that came along.

## ■ EBM and Quality

The next thing I'd like to do is look at the relationship between EBM and quality. There is some overlap here. The Institute of Medicine sees quality of care as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. We see here many of the components of EBM. Desired health outcomes are measured using the same kind of science that goes into measuring the outcomes of clinical trials. The goal is to see what works and to encourage the practice of what works. But that's not the only thing. According to this definition, quality also involves professional knowledge. That is consistent with what we've already said about getting input from clinicians about what is best for patients. Again, evidence and experience are blended. The Institute of Medicine recognized this in *Crossing the Quality Chasm* by encouraging services based on the best available scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit.

EBM and quality share many of the same concerns. Both focus on positive health outcomes and use scientific methods as the best means of determining that. We've seen that EBM likely has a dampening effect upon costs. How does health care quality impact costs? Will all quality interventions necessarily lead to lower health care costs? I tend to see this as a mixed bag. There are certainly areas where quality decreases cost. Immunizations, for example, have clear cost benefits. Clinical practice guidelines, which "quality" institutions are to use in treating specific conditions, are also proving to be cost-effective. You could argue, however, that some quality programs actually increase costs. There were some articles in *Health Affairs* about a year ago indicating that smoking cessation programs might actually increase costs. Smoking cessation may effectively stop a percentage of smokers from smoking, which may in turn increase the life expectancy of these individuals. Yet they are still likely to be sick and will, therefore, require more money to treat as they live longer.

## ■ Halfway Technologies

Another aspect that makes both EBM and health care quality a mixed bag has to do with what are known as halfway technologies. These are technologies that prolong life, but don't really cure the individual of the condition. Here I'm thinking of AIDS treatments, as well as treatments for advanced stages of cancer. There are a lot of ethical issues here but the reality is, from a purely economic perspective, keeping sick people alive longer actually costs more money. When treatments come along that are curative, of course, this issue goes away.

## ■ Practical Realities

I would like to mention a few practical realities as well. One is that even if health care quality can save money, the health care system is typically slow to embrace new innovations. Of course, that's why Leapfrog came about to begin with. It takes awhile for any large system to adopt change, and the health care system is no exception.

Another issue is that EBM and quality mean different things to consumers than they do to health care professions. Evidence to consumers is likely to be whatever they have seen on television or in brief news reports. These tend to report all of the positives of a new treatment and none of the negatives. As far as quality is concerned, consumers think very differently about this. One writer from Harris Interactive sees quality for consumers as meaning that they have more access to more treatments. It also means having more choices, being in a waiting room with people who earn more money than they do, and having the right to sue. Lastly, and more hopefully, quality is evidence-based medicine and community health applied systematically. So there may be some hope here. The fact is that consumer-driven health care will likely change consumer perceptions of EBM and quality. Their perceptions will be more in line with health care and industry professionals.

What does this mean? Evidence, costs and quality are here to stay. As consumers bear more of the cost, they will become more attuned to evidence and quality. One approach BlueCross BlueShield of Tennessee is using is to develop consumer decision tools to help

bridge the gap between consumer and professional understandings. We've developed a medical value index that you can find at [www.TennesseeHealth.com](http://www.TennesseeHealth.com) by going to the medical technology area. What you'll find there are assessments of medical treatments that are written at the consumer level. We have about 10 of these assessments developed at present, and look to develop many more.

## ■ Conclusion

EBM, quality, and costs are three of the most important issues facing health care today. Unfortunately, I don't think EBM and quality will have a huge enough impact on costs to keep costs down. I do believe that EBM and quality are going to continue to have a large role to play in health care. No matter how the cost issue is addressed, we are still going to want to have access to treatments that work and to avoid treatments that are harmful. And we're also going to want more standardized approaches to conditions so that the quality approaches (i.e., those that produce the best outcomes) are used.

## *The Different Faces of Health Care Today*

by Paul J. Wallace, MD  
Care Management Institute, Kaiser Permanente

### ■ Introduction

I think that evidence-based medicine is being discussed more broadly today, whereas it used to be more the province of academic endeavor. It currently is being discussed in consumer circles, and it is being discussed actively by purchasers, particularly by health benefits professionals. This will allow us to continue both to test and evolve what is still a hypothesis: that evidence can be the foundation on which we can actually make some sense out of this mess that we call health care. In addition to the observations in this book concerning what evidence-based medicine is and why we need it, I think it also is critical to think about how we actually endeavor to imagine that evidence can be integrated into practice. And then there is even a step beyond that, which is what I tend to think of as the “how to do the how.” Once you have the pilot, once you have done the study, how do you actually take an idea and leverage it in a very complex system such as what we have in health care today? I want to discuss how we are trying to approach, more than anything else, “how to do the how” within Kaiser Permanente.

### ■ Background

I started out as a researcher doing basic science research, and then I practiced internal medicine, hematology, and medical oncology for the better part of 15 years. For the last several years, my practice has migrated to population-based care and administrative and design work, thinking about how we can leverage evidence in systems of care. Kaiser Permanente is the largest not-for-profit integrated health care system in the country. We take care of about 8.5 million members in eight regions, nine states, and the District of Columbia. At Kaiser

Permanente we have about 140,000 employees, and we purchase health care for well over a quarter of a million people. So we also have a very significant vested interest in understanding things from the benefits perspective, too, because we are purchasing health care for the people who work with and for us. That perspective is one that I hope we can learn more about: How do we continue to define and refine value from a broader and broader perspective?

### ■ The Different Faces of Medicine Today

First, a brief anecdote about discussing evidence-based medicine with medical students. At the Medical School at the Oregon Health Sciences University, we were talking about this approach to medicine, and I used one of the metaphors that I have drawn on in clinician-based talks for a long time: We’re not Marcus Welby anymore. Most of us grew up with the image of Marcus Welby as a sort of all-knowing oracle. I was not thinking about the fact that in his career, Marcus Welby saw something like 150 patients, one patient a week, 26 weeks a year for several years. But when I mentioned Marcus Welby, I saw a sea of blank faces in front of me—which in reality had probably been there for a few years but I hadn’t noticed—and I finally said, “Does anybody here have a clue who Marcus Welby is?” This sea of faces was made up of 50 percent women and about 30 percent people of color (which was dramatically different from my medical school class, which was about 95 percent male and largely white). There were three people in the audience who had actually even heard of Marcus Welby, and all of them had a father who was physician. One poor woman had actually been subjected to

tapes of Marcus Welby by her father, and she was still there, which I thought was remarkable, too. This experience showed me how much the face of medicine is changing. And that is a good thing.

This change applies to patients as well, and frames a huge opportunity for us. For example, a Kaiser Permanente member in Northern California named Bonnie T. has diabetes. She is the face of medicine today. The problems that we confront as we deliver medical care today often involve chronic conditions. Bonnie T. doesn't look miserable; in fact she looks like she is living a healthy life with diabetes. Indeed, she is healthy. She's not lying in a hospital bed with IVs in her arm. The issue is how can we actually support her in terms of keeping her functional, i.e., able to contribute in a work environment? How do we understand what her perspective of value is?

Bonnie is supported in her care by her care team, consisting of her care manager, her dietician, her psychologist, and the office assistant who puts her in the room when she comes in. Also on the team is the clinic manager, the medical director who had to rationalize hiring these people to support Bonnie's care.

These, too, are the different faces of medicine today, and each of them has a different perspective on value. Bonnie's perspective on value has to do with her own personal performance. Her physician's perspective on value may be described by things like hemoglobin A1C. The person who fills out and writes the check for these peoples' salaries has a perspective that looks at how each one actively contributes to the value proposition of the care that is delivered. That is what I think we have to be mindful of: We all have different perspectives of value, and we have to recognize the fact that, if we are going to understand value, there is a 360-degree view that we have to at least acknowledge. My belief, and I think it's being actively tested, is that if we want to migrate from where medicine has been to where it needs to be, it is going to take all of the different components that have differing perspectives of value.

I think we learned in the 1990s that these perspectives are going to include that of the clinician, who will probably resonate most with the classical dimensions of quality that we've talked about for a long time, as well as that of

the purchaser, who obviously brings a very critical and increasingly articulated concern with understanding the return on investment. But we also go forward at great peril if we don't also begin to understand and dissect the consumer and patient perspectives of value. If we don't consider all of these together, I think we are not going to get there.

If you want to take into account all of these different views of value, what common language can you begin to use so that all of the individuals can actually communicate with each other? My strong belief is that language has to include the evidence, and it has to be such that people can actually talk about value without the dissonance that occurs when things are defined differently.

That is why the definitions of evidence-based medicine that I find most helpful are ones that you can test in different arenas, that you can test for these different perspectives. Dr. David Eddy, who has been a thought leader for many of us who have had the opportunity to work with him at Kaiser Permanente, has looked at this in a couple of ways. He says evidence-based medicine is no more or no less than being clear about what is known and what isn't known—and doing that in a credible and disciplined way. And that can lead to a quite practical approach, from the individual perspective, the patient perspective, and the system perspective. If something works, you should do it. That adds value. If something doesn't work or it causes harm, you should not do it. You should actively discourage it. And finally, if you are not sure, you should at least be cautious. And you should be thoughtful about what you are learning along the way and realize that there are multiple stakeholders in this decision. I think part of the dissonance that we have gone through in the last decade was a result of trying to make unilateral decisions when there were really shared interests. The challenge is going to be to develop a floor where people can make shared decisions. When you begin to think about individual and system competencies going forward, the "how to do the how," we are talking about a different set of skills for both clinicians and consumers, and we are also talking about reinforcing these in different ways as we design and purchase products.

## ■ “Making the Right Thing Easier”

Within Kaiser Permanente, the mantra that we have used to help guide our thinking is “making the right thing easier.” This has two important components, the first of which is basically the academic foundation of evidence-based medicine. It is identifying the right thing. It is understanding what works and what doesn’t work and trying to be clear about it. But there is more, too. It is about thinking, with rigor and understanding, about how to build these things into systems in such a way that they actually work. How do you use measurement to guide the management of these processes? How do you identify processes that work and make sure that you diffuse them? And ultimately, one should always keep in mind that this is about the member, and members come in many different sizes and shapes. If you haven’t figured out how to deliver culturally competent care, you should disabuse yourself of the notion that you’re going to be effective, particularly as the face of health care and the people you’re caring for change daily.

The second part is where people can become fully engaged to do something that makes the right thing easier. Because if you make it easier, it’s more likely to happen. And this is about systems. We are drawn to technology systems—and technology systems are an absolutely critical underpinning of moving medicine forward—but if you forget that every technology that has ever come along has been a means as opposed to an end, you do so at your peril. Because what technologies do, ultimately, is change how people do their work.

To me, this is a very exciting time. There is an urgent need to change how we do our work. There actually is a means at hand around information technologies that alter all of the transaction thoughts that we have ever had about sharing or leveraging information. There’s a good reason why Marcus Welby held the information he needed in his head: It was too expensive for him to get it any other way. He bought a textbook every four years, he pulled it off his shelf, and that met his needs, partly because that was how quickly the information changed. But that’s all different now. We also have to raise our expectations to leverage those things that are available.

## ■ Different Perspectives

A saying that I like, which is really a good checkpoint for the patient perspective, is, “I don’t care how much you know until I know how much you care.” If people are not treated well when they come into a medical office, disabuse yourself of the notion that you can engage them in a shared decision. The issue is delivering on service—service has to be the first thing that is accomplished if you want to accomplish evidence-based medicine. To me, that is the learning from the member perspective. Clinicians and everybody else needs to understand that. That is my belief.

Once you have achieved this first level of need, members are very interested in the evidence. In fact, it may be the member who brings evidence-based medicine to the office. For five or more years now, members have been bringing in information they download from the Internet. It is they who brought the Internet into the medical office. It wasn’t the clinician saying, “I have to have the Internet in my office.” In fact, some clinicians fought tooth and nail against having the Internet in their offices. However, most of them now see the patient more as a partner, and they actually learn from what the patient brings in.

It is also very important to ensure that clinicians have access to information. So, like many other organizations, we have invested in leveraging the Internet, and it is now quite feasible to have on the clinician’s desk anything that you used to be able to get in a medical library. Our clinicians now have full-text search for every journal, and they have access to essentially every textbook right on their desktop. Thus, we have to eliminate the transaction costs that used to be involved with walking down the hallway or having to go to the hospital to get necessary information. However, this in itself is not ultimately sufficient. We have to integrate this innovation into the clinical encounter.

## ■ Electronic Medical Records

When we first implemented medical electronic records in the Kaiser Permanente’s Northwest Region, we thought that we couldn’t put the computer in the exam room because it would

interfere with the clinician-patient relationship. Instead, we put it in the clinician's office. You can imagine how meaningful a member's experience is when the clinician is running back and forth between his office, where the computer is, and the exam room, where the patient is—and what effect going back and forth between offices has on patient-clinician communication. We ultimately found that putting the computer in the exam room makes the “right thing” easier.

So there has been some real learning in how to situate the technology, but I would reassure you that it is a big plus from the patients' perspective to know that their clinician knows them and knows their past history. It also creates the opportunity to share information at critical points in care. This has value in ensuring that the right things get done. It actually makes the right thing easier. For example, if a patient comes in who has diabetes and is a smoker, and if she hasn't had her hemoglobin A1C checked, why wouldn't she take the opportunity to schedule that? And why would the clinician be expected to do that if the office assistant who brought the patient into the room could do it? In fact, why wouldn't the orthopedist who saw that patient earlier in the day order the test (assuming the result would get back to the right person)?

There's an important counterpoint to this, though, which is that if you actually make it easier, it had better be the right thing. We often sort of cavalierly think, we'll just build all this stuff in and we'll make a few million alerts and everybody will be jumping up and down. Workflow is very precious to the clinician, so if you're going to interrupt a clinician's workflow, you'd better be sure that the item in question is a critical item for your patient. How are you going to know what's a critical item for the patient? It goes back to the evidence. Again, a common language is needed if such issues are to be worked out.

## ■ Spending

The third perspective is health care spending. A look at different percentiles of health care spending indicates that a small set of people spend most of the health care dollars. We are increasingly recognizing that these are mainly people who have chronic conditions. Yet the revenue comes from the other group of people:

those who pay to be covered and basically don't use any service. The social proposition of insurance is based on the fact that the people will continue to be in the system. As we begin to think about product designs to support the people who are the largest users of medical services, one of our challenges is going to be to ensure that what we are doing has its basis in improving the health of the population. We need to be thoughtful about how we ensure that the people who need services receive them and that the services are actually appropriate in terms of screening, but we also need to keep the dollars in play.

When you look at the cost of chronic conditions in our system, this is incremental cost. It is above and beyond regular services. We know that about 10 percent of our cost structure is made up of caring for diabetics, the incremental cost of caring for diabetics. That is an astounding amount of money. But there is also an outstanding amount of opportunity. I think progress is being made. You can leverage activity to improve quality by creating evidence-based tools. This has been our experience with trying to improve the control of glucose and also trying to decrease the risk of cardiovascular disease in diabetics. The outcomes from this, we believe, are beginning to show effect. This is preliminary. We have to see the trend over a few years; nevertheless, we are seeing fewer strokes, heart attacks, and amputations.

The other thing that I would bet you are seeing is fewer days away from work. There also are other conditions, such as depression and allergies, that have huge impacts on productivity and that lend themselves to population-based approaches.

We have done some analysis of the incremental costs of chronic conditions over time. If you correct for inflation, the absolute dollars that we spend per member with diabetes are now the same as we spent five or six years ago. And the quality is better. Now what we have to wrestle with is whether that is an adequate increase in value to meet the needs of a benefits purchaser. I think it is adequate for Bonnie T. Certainly, clinicians feel good about this. But what do we need to do to make everybody feel good about this? We are seeing the same trend across other chronic conditions. It doesn't mean costs are going down, but it does mean that dollars are being diverted from

what used to be hospitalizations, which could be termed over-use, to areas of under-use such as lipid management and glucose management.

Our belief is that over time we actually will see more of a dividend from this, but I also believe that any cost savings that we see from what we're doing now will probably be buffered in the opposite direction by the cost of new technologies. These new technologies may actually improve people's health. In fact, I believe they do improve people's health. So we also have to realize what a dynamic and moving target this is.

Kaiser Permanente has 450,000 members with diabetes. If we take the leading improvements in performance in Kaiser Permanente and extrapolate them over our entire diabetic population, we would expect to see, over five years, many people who are going to be at work because they aren't having heart attacks, aren't on dialysis, can still see, and don't have neuropathy. So, it really is about this face of care. It is about trying to come up with a paradigm that actually engages all of the different players, and it is about having meaningful conversations about how we move forward. Our belief is that understanding value really has to take into account all of these perspectives.



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## **Reality Checks**

Communicating With Patients: What You Don't Know Can Hurt You: Chapter 5

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Delivering Evidence-Based Knowledge at the Point of Care: Chapter 8

## ***Communicating With Patients: What You Don't Know Can Hurt You***

**by Jeffrey Charles Lerner, Ph.D.  
ECRI**

### ■ **Introduction**

This discussion is premised on the belief that when using defined contribution health plans, businesses have an incentive and, arguably, an obligation, to ensure that employees have access to understandable, evidence-based patient information on clinical procedures and drug therapies and the medical technologies that support them. We make an argument in three parts: First, business already involves itself in attempting to improve the quality, safety, and cost-effectiveness of the health care delivery system. Second, evidence-based information is being used by various constituencies, including the medical device and pharmaceutical industry, to influence employees' care choices. Third, evidence-based research needs to be developed in a way that is tailored specifically for patients and their families and disseminated to them effectively. The three arguments are discussed briefly below.

### ■ **Business Involvement**

Business has a longstanding involvement in the health care delivery system. It has provided insurance coverage for many decades, with a notable upsurge after World War II. It has also played a key role in supporting efforts to improve patient safety, such as through the highly publicized Leap Frog Group.<sup>1</sup> Programs and experiments to reduce costs of care have been widespread, at least within the community of larger employers. It has not been uncommon for employers to provide information to employees on their personal health care, such as through health promotion programs.

Providing evidence-based patient information, however, would set a precedent. The vast majority of evidence-based information is designed for professionals such as coverage decision-makers in health plans and public-sector insurers, as well as for the physician community. It usually takes the form of systematic reviews (sometimes called technology assessments or evidence reports) and evidence-based clinical guidelines. Patient versions of this professional material are sometimes produced, but this is much rarer. Under defined contribution health plans, or consumer-directed care, as they are sometimes called, the locus of decision making is the layperson rather than a health care professional. That is, the patient controls how money is spent for health care services in a much more direct way than he or she does under traditional or managed care insurance models.

### ■ **Evidence-Based Medicine**

“Evidence-based medicine” is catching on as a popular phrase that does not always reflect careful work based on systematic reviews of

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<sup>1</sup> *The Leapfrog Group, composed of more than 140 public and private organizations that provide health care benefits, works with medical experts throughout the United States to identify problems and propose solutions that it believes will improve hospital systems that could break down and harm patients. It provides important information and solutions for consumers and health care providers.*

clinical literature and data. However, whether in its pure form or in a more popular version, it is becoming familiar. For example, a press release entitled “Landmark Study Proves Oral-B® Power Toothbrush Technology Superior in Reducing Plaque and Gingivitis,” issued January 11, 2003, states, “The comprehensive study, conducted by the Cochrane Collaboration, a British-based nonprofit health research group, reviewed data from all available published studies conducted between 1964 and 2001, involving more than 2,500 participants.” The same systematic review is cited in a full-page ad in the *New York Times* (17 April, 2003, Sec. A: 21). Evidence reviews prepared for the U.S. Agency for Healthcare Research and Quality (AHRQ) have been cited in advertisements from the herbal supplement industry. It is reasonable to assume that the number of examples will increase as the scientific community increasingly accepts the validity of systematic reviews as a critical step forward in health services research as well as in a variety of other scientific fields. This trend is described in *How Science Takes Stock: The Story of Meta-Analysis* by Morton Hunt (Russell Sage Foundation, 1997).

## ■ Guidance for Patients

Given the extraordinary amount of information targeted to patients to influence their medical decision making, it is important for those who believe in evidence-based medicine to provide scientifically valid guidance to patients. Under defined contributions, the business world would be wise to support these efforts because better medical decision making is likely to improve employee health and reduce costs to employers. It is an information tool for defining effective care and, where appropriate, less costly care. But the information must be accurate, trusted, and understandable. These are difficult goals to achieve. In the experience of the author’s organization, ECRI, they are necessary ones.

ECRI began producing evidence-based patient information in the 1990s, beginning with a patient reference guide for women with metastatic breast cancer who were considering undergoing high-dose chemotherapy with bone marrow transplant or stem cell rescue. In the early 1990s, ECRI produced technology assessments on this therapy, which was touted by some oncologists as a cure or life-extending

therapy for desperately ill patients. ECRI’s technology assessment was met with disbelief or active opposition when it concluded that patients on this therapy lived a shorter time than those who underwent standard chemotherapy regimens. ECRI also reported that there were high death rates from the initial therapy itself, which meant that patients were not living long enough to die of breast cancer. Because the information was unacceptable to many professionals, ECRI partnered with a select group of breast cancer and women’s health advocacy organizations to develop its patient reference guide in 1996. The guide presented results of ECRI’s technology assessment in lay language, along with guidance for patients on how to discuss the therapy with their physicians. The guide still appears on ECRI’s Web site at [www.ecri.org](http://www.ecri.org), under the Patient Information tab.

Bone marrow transplant for breast cancer was the most visible of the hotly debated, expensive technologies that were met with coverage denials from managed care organizations during the 1990s. Although the results of ECRI’s technology assessment were confirmed by randomized-controlled clinical trials published in 2000, some five years after the technology assessments were published, public opposition to coverage denials was a powerful influence in undoing the philosophy of strict managed care prevalent in that era. It is more than just an irony that this undoing was, in part, over an ineffective technology.

Many political lessons can be learned by various constituencies in the health care community from this experience, but there are also lessons that can be learned about disseminating patient information. ECRI garnered the support of the National Breast Cancer Coalition, the National Women’s Health Network, the Boston Women’s Health Book Collective, and other advocacy organizations, not only because of its technical competence but also because it was a trusted source of information. ECRI’s strict conflict-of-interest rules, designed to ensure independence, were very appealing to these advocacy organizations. Among these rules were and are that neither ECRI nor any of its staff has a financial interest in the sale of any medical technology. ECRI and its staff accept no royalties, gifts, finders’ fees, or commissions from the medical device or pharmaceutical industries, and they are not

permitted to own stock in, or undertake consulting work for, such industries. All of ECRI's 250 employees have their income tax returns audited yearly before submission in order to verify conformance with these rules. New rules were developed during the bone marrow transplant debate so that the technology assessment staff could not invest in health insurance companies. Complementing these rules to prevent financial bias were and are internal processes to prevent intellectual and emotional bias on the part of the research staff.

## ■ Communicating Risk to Patients

ECRI learned a great deal about the technical presentation of information to patients as a result of producing the bone marrow transplant guide and subsequent work, such as a patient reference guide entitled *Should I Enter a Clinical Trial? A Guide for Adults with Life-Threatening or Serious Illness*, which was published in 2002. One of these lessons is that, in presenting information, it is important to communicate risk in ways that can be understood. For example, lay people grasp frequency better than probability. An example of this phenomenon is that lay people can more easily grasp the concept that 1 in 10 people will experience an outcome than if this fact is presented as people having a 10 percent chance of experiencing an event. Or, take this example: "1 in 10 people will experience an event" versus "you double your risk if you go from 1 in 20 to 1 in 10." In this example, the "1" in "1 in 10" is the absolute risk, while "double your risk" is the relative risk. Relative risk sounds more dramatic if the initial risk of an event occurring is low. If the initial risk of an event occurring is high, then relative risk sounds smaller than absolute risk. For example, a 12 percent increase in a risk (the relative risk) sounds smaller to most people than saying your risk goes from 8 in 10 to 9 in 10 for an event.

There are many other issues in communicating risk. For example, it is important to give people anchor points for understanding. Many people can understand that the chance of an event is greater or less than their chance of being in an auto accident because they are familiar with auto accidents.

Similarly, visualization of a risk can be very important. It is hard to imagine a liver enzyme, but it is easy to imagine a person turning yellow.

But even when these concepts are used so that statistics can be presented more clearly, numbers and risks can be difficult for many patients to understand. Numerical information alone is harder for most people to understand and use than, for example, multimedia information like that in direct-to-consumer advertising on television. In other words, both the medium and the message matter. Although many researchers reject the notion that they have the responsibility to communicate clearly with the public, they will ultimately fail to get their messages across if these messages are drowned out by more powerful media.

## ■ Conclusion

In summary, very significant challenges lie ahead if employers and other interested groups wish to provide patients with evidence-based information. These challenges include communication in a pure form as well as the conflicting messages delivered through sophisticated media. The science of communicating with patients is underdeveloped. The resources going into providing evidence-based patient information are slim. The author believes that it is crucial to develop the science of creating and disseminating evidence-based patient information if we, as a society, wish to place the locus for medical decision making upon patients and their families.

## Evidence-Based Medicine and Consumers

by Jessie Gruman, Ph.D.  
Center for the Advancement of Health

### ■ Introduction

There's an old saying that just because you have furniture doesn't mean you're an interior decorator, and just because you behave doesn't mean you know anything about behavior. I want to discuss what we do know about the behavior of consumers, and I would like to address myself to two main questions. First, what do we know about how consumers view evidence-based medicine? And second, what is the evidence-based view of consumers?

In an Internet discussion that I joined recently, Daniel Fox<sup>1</sup> put up an interesting quote and asked what participants thought about it. It was from Jerome Groopman, an oncologist who writes often for the *New Yorker* magazine about situations he encounters in his practice. In this quote, he recounted a story of a patient, a young woman named Maxine, who had cancer. He talks about presenting her with the evidence for the different options that were available to her among the chemotherapeutic regimens. And he explained that statistics don't say anything about any particular individual, only about groups. There can be wide variability in the behavior of any cancer among individuals because each of us is different. He wanted his patients to be informed. When Maxine said she understood there was a good chance of remission, that was accurate. It could last months or it could last years. Putting precise numbers on it at this point wouldn't tell us anything about Maxine.

This statement is at the core of evidence-based medicine generally and is particularly central to the idea of consumer engagement and demand for evidence-based information.

Understanding and acting on risk means that individuals ask, "What does risk mean for me? What do all these studies of aggregate means in different populations tell me about what I should do next?"

### ■ Risk Information

As it happens, we know quite a bit about how individuals understand and make use of risk information. But before I begin that discussion, I'd like to broaden the focus so that we are not just talking about making decisions about specific medical procedures or embarking on a specific therapeutic regimen, such as "Should I have prostate surgery or not?" Or, "Should I take this course of antibiotics or that one?" I'd like to expand the consideration of how people act in response to evidence to include questions such as "Should I stop smoking or not?" "Should I use this smoking cessation product or not?" "Should I do the Atkins diet or should I walk around the block every night?" "Should I choose one physician over another or one benefits plan over another?"

All of these are health decisions and all of them, we hope, over time will be guided by evidence. Here is a list of some of the major lines of research that have been undertaken in the behavioral and social sciences as well as in the health services arena. Some of them may be familiar to you. For others, there are lines of research that have nothing to do with health per se but have to do with understanding risk:

- Shared decision making.
- Informed decision making.

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<sup>1</sup> See Chapter 15.

- Social learning theory.
- The health belief model.
- Risk perception.
- Risk communication.
- Theory of reason by action.
- Behavioral economics.
- Health communications.
- Quality of life.
- End-of-life decision making.

For each of these lines of research literally hundreds of articles and doctoral dissertations have been written. And there is great variety among them. Some are highly theoretical. Some are not. Some are embedded in the assumptions of others and others are independent. Some use behavior as the outcome. Others measure understanding or intent to act as the outcome. Some use the language and constructs of a specific discipline, such as sociology or psychology, and some are completely ecumenical and have no discipline associated with them at all. Some isolate risk information and focus on how individuals respond to risk per se, and some examine the idea of risk in a larger context.

The common thread is that they are addressing people’s fogginess about what risk means, generally, and what risk means to them as individuals. This fogginess is often shared by health care providers who are trying to help people understand their own personal risk. But taken together, all of these theories demonstrate a lack of *concilience*. This is a term that E. O. Wilson resuscitated a few years ago in a book by that name. Concilience is the idea of linking fact-based theory across disciplines to create a common groundwork for explanation. Consilience, he notes, is lacking in the behavioral and social sciences, and he attributes this lack of a common set of fact-based principles to the slow progress in understanding human behavior generally.

The point is that we know quite a bit about how to communicate risk but what we know is couched in language so qualified that it is risky to even say that we know a lot. As part of the Internet discussion string I mentioned before, Jeffrey Lerner<sup>2</sup> said, “There’s a tendency to be platitudinous about how group statistics should inform individual decisions. But there are not and never can be numbers that allow

individual prediction. Every moderator that is added—sex, smoking history, and so on—narrows the comparison population, but it will never take one to the patient’s level. The unsolved problem is how we convince both physicians and patients of this simple but very uncomfortable truth and how we help them to work with group statistics, since that is all we have.”

We know a lot about how people respond to the unsolved problem that Jeffrey Lerner noted. This problem is that, like most of the evidence for medical intervention, the evidence about risk perception and behavior is not synthesized and presented in a way that will allow us to set in place practices, programs, and policies to help people make sense of population-level risks and then to use this information as a guide for actions to improve their health.

## ■ Who Are “Consumers?”

A larger but related question has to do with who these people are that we want to help make decisions based on evidence. Who are these “consumers?” They’re individuals; they’re patients; they’re mothers, fathers, sisters, brothers, daughters, sons. We call these people, these non-health professionals, *consumers*. I’d like to talk about some of the meanings that cloud the use of that word to describe individuals acting in this role. This builds on some work that I’m doing with a colleague, Shoshanna Sofaer of the City University of New York

One of the things that we, among others, have noted is that the meaning that people assign to the word *consumer* has a kind of Tower of Babel aspect:

- Purchasers use the word *consumer* to distinguish their own role from that played by individuals who choose among the options that the purchaser makes available, i.e., health insurance products or delivery systems or providers.
- Insurers, including managed care plans, also use the word *consumer* to describe a subsidiary purchaser in the market place. For these stakeholders, consumers are viewed largely as economic actors making a choice.

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<sup>2</sup> See Chapter 5

- Advocacy organizations, including national groups like AARP, Consumer Coalition for Quality Healthcare, use *consumer* to describe a political constituency whose interests they hope to protect and enhance.
- Public policymakers both in the legislative and executive branches use the term in a similar manner, often or interchangeably with such terms as *citizen* or *the public*.
- Clinicians often resist the term *consumer* and prefer *patient* or *client* as more consistent with their own self-identity.
- Public health professionals as well don't often use this term. They typically view individuals as those whose behavior they are trying to change. Their audience is high-risk groups, target populations. They want to affect their behavior with health promotion interventions or information campaigns and so on.

We identified two underlying themes that vary across these various uses of the term *consumer*.

The first is that there is variation in the perspective between those who view consumers as marketplace actors and those who view them as political constituencies. The divergence creates confusion, in particular in discussions about choices people make about health and health care. Those people who use *consumer* in its economic sense assume that consumers can and will make rational choices among available options, while those using it in its political sense believe consumers should have excellent and affordable choices available and also should be protected from either having no choices at all or from the circumstances that would lead them to make bad choices.

## ■ Are Individuals Active or Passive Receivers of Information?

The second crosscutting theme is whether individuals are viewed as passive recipients of information and services or active participants in maintaining and improving their health. This distinction is more of a continuum. It is critical in designing efforts to support people in making use of evidence in their decisions about

health. The distinction translates into the difference between informing people about the consequences of poor health behavioral choices and how they can make better ones and creating laws and ordinances that either forbid or discourage unhealthy behavioral choices or offer greater access to positive choices. For example, in tobacco use, the difference between media campaigns against teen smoking versus strict enforcement of minor access laws. For diet, for example, it would look like widespread accurate food labeling versus removing school cafeteria vending machines. While these strategies don't have to be mutually exclusive, they can be. For example, there are those who view the accurate labeling of food products as sufficient, in the belief that individuals are going to make their own choices and bear the consequences—*caveat emptor*.

The assumptions about consumers' appropriate and feasible roles ultimately have far-reaching consequences for our ability to communicate effectively with individuals. We are all consumers in some very fundamental sense. We all make choices about health and health care. But what we are referring to here is individuals as consumers, with very specific aims about what we expect them to do. We expect them to use evidence to guide their decisions. I think our collective notion of *consumer* in this discussion rests on some pretty strong assumptions. I have identified eight of them, as follows, and leave it to the reader to decide whether there is evidence to support each of them:

- Almost all people can and will participate positively in maintaining and improving their health and the health of their immediate family. Those who cannot almost always have someone who will serve as a trusted proxy for them. So it is assumed that everybody's going to be able to participate.
- Individuals have choices about their health care and exposure to health risks.
- Providing the right information will lead to changes in behaviors and choices.
- Emerging communication technologies provide needed information to virtually everyone.
- The evidence that individuals need and want in order to be able to make informed

choices about health and health care is available.

- Effective strategies are available to guide the transformation of evidence into information. There is adequate knowledge about how to present and disseminate this information effectively to all individuals in a given subgroup to insure optimal comprehension and use.
- Individuals will be more likely to acquire this information and use it to make rational decisions if they perceive themselves to be at greater financial and health risk.
- Clinicians are willing and able both to provide this information and to encourage their patients to seek and use such information.

To me, these are the assumptions that underlie the idea of consumers as people who are going to make use of evidence to drive their health and their health care.

We actually looked for the evidence to support each one of these assumptions and found substantial evidence that undermines each one of them. Some are dramatically contradicted by the evidence and some only partially. Some are not supportable now but may be in the future, and some simply are not going to change.

When used as a catchall term to designate the public at large, that is, to mean those who have no professional role in health and health care, I think that the term *consumer* is problematic. It carries with it assumptions, expectations, and implications for institutional policies and programs that are inconsistent with what is known about human cognition, motivation, and behavior. It misrepresents the current state of knowledge and evidence about information and technical capacity. And finally, these assumptions about consumers could be used to justify policies that expect individuals to take actions of which they are sometimes physically and mentally incapable. For example, consider the challenge faced by a low-skilled worker in assessing the relative merits of three diverse benefits options in relation to the multiple needs of a family. Similarly, these assumptions could be used to justify policies that assign people the responsibility for evaluating and acting on complex information

for which they are simply not prepared. For example, deciding which chemotherapeutic regimen is right for them in the face of multiple co-morbidities.

To the extent that individuals are expected to take on these roles without support, there is a risk of abrogating the social contract between physicians and patients, between public decision makers and the people whose health they seek to protect and, most broadly, between the health care sector and the society that it is supposed to serve. Under the cover of virtuous language that connotes egalitarianism and individual autonomy, powerful health stakeholders, including clinician, insurers, and purchasers delegate responsibility for health decisions to those who do not have the resources to be guided by even the best evidence.

## ■ Conclusion

The answer to the first question I posed earlier, “What do we know about how individuals understand and act in response to information about risk?” is that we know a lot. While the information that we have is not organized in a way that we can use it, we do actually have a tremendous amount of knowledge about how people understand process and act in response to risk. But the answer to the second question—“What is the evidence-based view of consumers?”—is that the answer to the first question is only a small piece of what we need to take into account as we devise strategies and practices that will help people to make optimal use of what is known about health and to make decisions and act on those decisions in ways that will enable them to live for as long and as well as they can.

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## ***Approaching the 10-Year Anniversary of Evidence-Based Coverage Decisions: Reality Checks***

**by Steven H. Sheingold, Ph.D.  
Centers for Medicare & Medicaid Services**

### ■ Introduction

I have referred to the approaching 10-year anniversary of evidence-based coverage decisions in the title of discussion, and other contributors to this book provide a number of estimates concerning how long evidence-based medicine (EBM) has been in practice. But it was perceptible that sometime between the publication of those influential articles in *Journal of the American Medical Association* in the early 1990s and 1995–1996 nearly all health plans, public and private, started to think of their coverage processes (what can be paid for) as evidence based (Rettig, 1997). So now may be a good time to look at what we have learned and how we can improve the use of EBM for coverage decision making.

A remark by Jessie Gruman,<sup>1</sup> another contributor to this book, that just because you have furniture, you're not an interior decorator reminded me of an experience I had on returning home recently. My wife had been redecorating our downstairs. The rationale for the project was that she wanted to make a comfortable place for me to watch television—although I had not been consulted on any of the details. The contractors had started the painting and she asked, “Well what do you think”? Upon inspection of the color scheme I said to myself, on the upside it's bold and imaginative, on the downside I think I am going to have nightmares from being in this room. Now my wife is brutally honest so I looked at her and asked if my opinion counted. She said, “No”—to which I responded, “In that case I have no opinion.” I think this story is relevant to a discussion coverage decisions at the

population level, in that we do not want to make the mistake of ignoring input from the patients and physicians who will use similar information to make individual treatment decisions and whose support is critical to meeting the objective of an evidence-based medical care system.

### ■ The Current Health Care System

As a background to discussing the use of EBM it is typical to refer to an all-too-familiar set of facts about the U.S. health care system: Our costs are much higher than those of other countries; our health-related outcomes rank poorly relative to these same countries; we have identified a quality “chasm” in our system; and costs have once again begun to rise at rapid rates. The diffusion and use of medical technologies play a significant role in all of these cost and quality issues. Clearly, very innovative, very creative pharmaceutical and device companies and academic medical centers generate our new technologies. A reasonable hypothesis based on recent history, however, is that our willingness and ability to innovate and diffuse new technologies has exceeded our willingness and ability to produce the right information on how to use them appropriately. As a result, our delivery system is subject to those characteristic problems that are referenced in the quality literature: the underuse, overuse, and inappropriate use of services. And what that means is that, despite the great breakthroughs we have had in areas

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<sup>1</sup> See Chapter 6.

such as transplantations, bypass surgeries, kidney dialysis, etc., we probably don't get the best value from the health care resources we utilize. That is, the outcomes per dollar we realize may be too low because so much of what we do may not be appropriate or effective. Lawrence Brown summed it up very nicely in this one sentence: "Medical technology is a blessing often enjoyed wastefully" (Brown, 1988).

## ■ The Use of Evidence-Based Medicine

The rise of EBM, particularly from the purchasing or the health plan perspective, is understandable. The following excerpt from a paper by John Eisenberg (1999), a former director of The Agency for Healthcare Research and Quality, summarizes the trends that led to the adoption this framework for health plan decisions:

*The continued proliferation of new technologies in a period of constrained health care spending, some without adequate evaluation, some even after its application, has been extended to the point of misuse or overuse, resulted in the demand for better information to guide decisions.*

A friend who teaches EBM in Great Britain always reminds students that the philosophical base of evidence-based medicine dates back to the skeptics of post-revolutionary Paris. Eisenberg (1999) provides a short history of a dangerous new innovation called the stethoscope from when it was first introduced in the early 19<sup>th</sup> century to its final acceptance by the medical community after nearly a half-century of skepticism.

One way of looking at today's application of evidence-based medicine may be as a return to such skepticism. The aging and prevalence of chronic diseases in our population has increased our expectations of what technology can do. When we become ill, or family members become ill, we look to new technologies for solutions. These expectations have probably been enhanced by the successes that I have already mentioned. And so the physicians who treat us, and we as patients or family members of patients, have accepted some technologies in

a less critical manner than may have been appropriate. There are a growing number of recent examples of technologies accepted in practice that are based on evidence that would be considered of lesser quality by today's evidence-based systematic reviews. These were later the subject of well-designed trials and found to be either ineffective or harmful. Therefore, health plans have adopted evidence-based coverage processes to avoid promoting procedures that cause harm, limit payment for ineffective services, foster clinical research, and provide better information to the public. In addition, EBM allows for a more open and explicit framework to engage the public within the decision-making process.

## ■ The Application of EBM

Substantial progress has been made in the application of EBM. Understanding of its concepts and principles has become much wider over the last 10 years as a result of the considerable amount of training received by clinicians, policymakers, and other stakeholders. Those who are promoting technologies are considering study design issues much earlier in the technology pipeline. In addition, there has been a rapid increase in the number of randomized trials conducted and published, and it is reasonable to hypothesize that there has been a beneficial impact on technology use.

There are still some areas in which more progress is needed. To some extent, the political and legal arenas remain an obstacle to widespread use of evidence-based medicine. Those who don't like the answers they get can still use these avenues in an attempt to change decisions. There is nothing wrong with a reconsideration process, indeed one is essential, but courts and legislative bodies may not be the proper venues for resolving scientific issues. In the case of high-dose chemotherapy with bone marrow transplantation, it should be remembered not only that we paid for a service that turned out to be ineffective but also that the political and legal decisions actually delayed the research that demonstrated the treatment's lack of effectiveness (Mello and Brennan, 2002). Finally, reaching patients and gaining their understanding will be a key to widespread acceptance of EBM. I like this quote

from a paper by a former Sen. Durenberger (D-MN) and Susan Foote (2001):

*The public has a greater appetite for the promise of cures than for the ambiguity and uncertainty of scientific breakthroughs and the limits to the art of medicine.*

In other words, patients don't have a lot of patience for the scientific issues; they want treatments, and we must understand this in our decision making.

In addition, we should recognize and improve upon how EBM is perceived. On the face of it, we are all believers in evidence-based medicine. It has been said that everybody believes in evidence-based medicine as long as you use their evidence and come to the conclusion they want you to reach. Proponents of particular technologies have told me that they believe in evidence-based medicine, and that services should be evaluated by randomized trials—but not their service because they know it is effective. This type of thinking reminds me of a quote by Woody Allen “I am not afraid of dying, I just don't want to be there when it happens.” I think for EBM to work, everybody has got to be there in terms of having a more consistent view of evidence.

## ■ Reality Checks

In terms of reality checks, we have had a considerable amount of learning over these last 10 years about developing process, reviewing evidence, and making improvements. It is interesting to note that in 1995 the *Journal of Medical Ethics* published an article that discussed three principles for purchasers adopting evidence-based medicine (Hope, 1995). First, cost cutting is not the primary objective of EBM. Second, avoid systematic bias by recognizing that it is easier to produce evidence for some products and services than for others, and you don't necessarily want to bias medical care by only accepting those with the best evidence. Finally, recognize that there are other values that are important to patients. Although not explicitly stated, the Medicare coverage process employs such principles for each decision.

We also recognize three potential impacts of each decision we make using evidence. First is the impact of the decision on that specific technology and the patients who might use it.

Second is the impact of each decision on how we make future decisions—that is, there has to be consistency. And finally, how we examine evidence and translate the analysis into decisions affects expectations concerning the types of evidence that should be available for future coverage requests. That is, each decision provides information for those who are putting technologies in the pipeline in terms of developing research that will yield high-quality evidence. It should be noted that maintaining consistency among decisions, yet still recognizing that there are differences between technologies regarding the feasibility of producing the highest quality evidence (the second ethical principle mentioned above), presents a considerable challenge for decision makers.

As has been discussed, there are at least two levels at which EBM can be applied. There are population-based decisions such as coverage and there are decisions that the physicians and the patients have to make related to a treatment regimen. Although these two decisions may involve very different considerations, values, and ways of weighing information, they are related in two important ways. First, coverage decisions affect treatment decisions through their financial impact. Second, the coverage decisions may affect clinical decisions through the information they provide to the public. As we have developed a process that puts very detailed information about our decisions on the Internet, it has become apparent that proponents of technologies are concerned not only with the decision itself but also with the information conveyed in the supporting documentation.

When undertaking each coverage determination, we must consider several factors. These include: what outcomes are most appropriate for evaluating the particular technology (e.g., mortality, quality of life, hospitalizations); whether the quality of evidence is sufficient to draw conclusions about these outcomes; and what are the relative magnitudes of risks and benefits that should make for positive or negative coverage decisions. In comparing risks and benefits, we generally take the population perspective. On the individual level, there may be a completely different calculus. The individual patient and physician may have very different views of what constitutes adequate evidence. Moreover,

due to different individual risk preferences, there may be a different calculation of when the relative risks and benefits are acceptable. Indeed, armed with information from the Internet and their television, patients are now coming to their physicians with their own thoughts about what is effective and what they want provided.

I think that reality check number one is that if EBM is going to be widely accepted as a means of improving the value of health care, we will need to bridge the gap between the population decision and the individual decision at the point of treatment. We need to find ways to package scientific information to be useful to physicians and patients. We also need to find ways to provide patients a voice in what is inherently a very technical process. How do we bring patients into our Medicare Coverage Advisory Committee process and our technology assessment process? These processes are critical to the coverage decision but they are, in the final analysis, very technical. Providing informed patients a voice in that process is very challenging. And finally, with regard to involving patients, I raise an issue that is more difficult in the United States than it is in most other countries. How do you introduce the language and educate patients about sharing limited resources? David Eddy wrote a wonderful article years ago about the individual decision and its impact on society, using high-dose chemotherapy with bone marrow transplantation as an example (Eddy, 1991). It is an extremely difficult issue to bridge, but it may be necessary if we are going to develop a high-value medical care system.

The second reality check is closely related to the first. Getting an increasing amount of evidence from clinical trials that are designed to tell us what we want to know may be a double edge sword. I want to emphasize, however, that the beneficial edge of that sword is going to be sharper. We are going to have more information to make better decisions. But we are also going to have information that will highlight the differences described above between population-based coverage decisions and individual patient decisions. When you have very poor evidence, there is generally less detailed information as a source of disagreement. Well-designed clinical trials can provide a wealth of details about risks and benefits to various groups and subgroups of patients. For

example, the results may demonstrate that, within some groups of patients, only a very small percentage (e.g., 10 percent) will achieve a clinically meaningful benefit, while the other patients either will have no change or suffer harmful effects. From the population perspective, even without considering cost, this technology does not seem to provide good value since only one out of 10 patients improve. On the other hand, a patient who is suffering ill health may be very willing to take that one in 10 chance. I think we should be prepared to at least address these differences.

Another article on ethics and evidence-based medicine (Mike, 1999) describes two imperatives for the application of EBM. One is to create, disseminate, and use the best evidence possible for phases of medical decision making. The second is to create awareness of, and come to terms with, the irreducible nature of uncertainty. And so reality check number three, critical to our coverage process, is that we must set standards and expectations for the highest-quality evidence and still recognize that we are not going to have perfect data on which to base every decision. To make the best decisions possible, we must learn to account for these uncertainties. In this regard, it is important to consider three reasons for the uncertainty inherent in the decisions we make. First, even when relatively high-quality evidence is available, it seldom provides all the answers that decision makers would want about the use of the technology. Second, for some technologies and patient populations it is not possible to get the best evidence. Conducting the research that would provide the best evidence may be unethical, or not technically feasible, such as for rare disease populations. Finally, some technologies of interest have already come to market with less than optimal evidence, although we hope that consistent application of EBM will substantially reduce such cases in the near future. For now, we look at all sources of evidence and consider how well the studies were conducted, what can be concluded from them, and what other factors might be relevant to the particular circumstances. Most importantly, these decisions must be detailed in a manner that continually maintains the expectation that improved research and high-quality evidence will yield a much greater chance of positive decisions in the future.

Reality check number four, therefore, is a consequence of the uncertainty inherent in making coverage decisions. That is, evaluation is not a one-time event. We have tended to think of three phases in the life of an item or service in medical care: experimental, accepted in practice, and obsolete. Research and evaluation are most associated with the experimental phase. In order to make informed decisions, it may be necessary to continually evaluate services as they diffuse into clinical practice, using methods such as registries, provision in selected facilities, and analyses of claims data. In these cases, we need to find methods and partnerships to balance the issues of evaluation, reimbursement, and access so that it is fair to everybody involved. You cannot expect any item or service that demonstrates some effectiveness to stay in limited clinical trials for extended periods of time.

Finally, reality check five raises one of the most difficult social and policy issues we may face in the near future. That is, in the absence of cost-effectiveness considerations, is evidence-based medicine an incomplete framework for making medical care decisions? Many believe that without these value considerations, in fact, we are not going to make sufficient movement toward providing higher quality and affordability. And some have even argued that EBM alone could be problematic if it carries an implicit promise that any magnitude of effectiveness demonstrated by good research will guarantee reimbursement, regardless of the cost. There are likely to be a number of clinical trials showing that certain products provide some effectiveness for some patients, but do these products bring value in their use to the health care system? Until we can consider this issue explicitly, it is possible that we are using an incomplete framework.

## ■ Conclusion

I will conclude with something else from Woody Allen. In one of his early 1970s movies, he propositioned one of his leading ladies and of course she said no because “sex without love is such an empty experience.” He immediately responded, “Yes, but as empty experiences go, it’s right up there.” For now, evidence-based medicine without cost-effectiveness may be an incomplete framework, but as incomplete decision frameworks go, it’s right up there.

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## *Delivering Evidence-Based Knowledge at the Point of Care*

by Thomas H. Wood, MD  
Milliman Care Guidelines

### ■ Introduction

I work for Milliman USA, an actuarial consulting firm formerly known as Milliman and Robertson, or M&R. Milliman was founded in 1947. The Guidelines division has been publishing care guidelines since 1990, with roots that go back to the early 80s, when Dick Doyle developed guidelines at Sharp in San Diego. Milliman believes in empowered and informed patients, and we have published a guideline product for consumers.

The topic for this discussion is a reality check: Is this the time to throw consumers into the market? Do adequate information tools exist to allow consumers to make informed purchase decisions?

I've been a provider for 25 years, with seventeen years on an island in Alaska; so I know primary care medicine. I've been a manager of providers in large health organizations. I am now on the vendor side. I've also been a consumer of health care.

I like to reflect on the goal to frame my thinking and the benefit/expenditure graph in Figure 8.1 helps me. This graph is a power curve for health care benefit plotted against health care resources. As an analogy, this same graph could depict the health benefit of exercise, as exercise level is increased. At Point A on the graph, the subject arises from the couch and begins to walk. The first input of exercise yields the fastest increase in health care benefit, as shown in studies. At Point B, the subject is power walking or jogging, with further increase in benefit, but diminishing returns. Point B represents the greatest spread between the resource input and the benefit

output. At Point C, health benefit has peaked. At Point D, health is declining, with increased exercise resulting in injuries.

In looking at health care resources, Point A represents the introduction of sanitation, immunizations and basic antibiotics to an underserved population, resulting in the steepest improvement in health outcomes. At Point B, the "Economists' Ideal," input and output slopes are parallel. Point C is where most physicians and patients want to be, at the point of maximum health benefit. Point D may be the suppliers' ideal, at the point of maximum use of resources, but before harms outweigh benefits.

### ■ Consumer-Driven Purchasing

In thinking about the issue of defined contribution, there are several ways to view the relationship between employer and employee. One view is a financial arrangement; a contractual relationship. The employer provides a set dollar amount rather than a set benefit. The employee is left with the universe of purchase choices. Beyond the financial relationship, I see a support relationship between the employer and the employee. In the defined benefit world, the employer has provided some expertise to sort through the myriad, disparate plans; exercised some quality assessment; and provided a subset of qualified plans for the employee to choose from. The loss of this supportive, oversight role by the employer is a risk in moving aggressively to consumer-driven purchasing.

In considering the task of making purchase decisions in health care, one must realize that health care is far from a perfect market. In 1776, Adam Smith published the *Wealth of Nations* and defined a functioning market: perfect information, low barriers to market entry and exit, small suppliers, and homogeneous products. We have learned that information in health care is not perfect. Jeff Lerner<sup>1</sup> has discussed the power of advertising over decision making. Information about quality has been meager and service is substituted for quality on most report cards. When measurements are poor, people make decisions based on reputation. The second Adam Smith requirement is low barriers to market entry and exit; in health care these barriers are high, with limited training positions, requirements for licensure, high facility and technology costs, certificate of need, etc. The third Adam Smith requirement is smallness, but we've seen a lot of consolidation on the provider side and now in the health plan market. The fourth requirement is homogeneous products, but we know that plans are very different from one another and packages vary widely. This is a very imperfect market to throw a consumer into.

The market appears more complex and daunting when you look at what has been learned from the "Small Area Analysis" work done by Jack Wennberg. Wennberg found at the time of his study that Boston consumed twice the health care resources that New Haven consumed, with no measurable advantage in health outcomes (Wennberg et al., 1987). Additional studies show that two communities can have a fivefold variation in consumption, without increased benefit. It's difficult for an individual consumer to digest this information and make informed decisions. It is easier for governments or plans or larger organizations to access and process this information.

We've heard about underuse, overuse, and misuse of health care resources, and these all represent potential harm to the patient. The goal is elimination of unwanted variation; "unwanted" implying some autonomous choice on the part of the patient. The variation to avoid is that based on location of training, happenstance of professor, or avarice of the practitioner. Decisions should be based on the current best evidence. Don Berwick talks about "knowledge always on call" and providers

becoming "knowledge brokers" in the future, leading to more perfect knowledge and a better functioning market (Berwick, 1999).

## ■ The Evidence

Can patients follow the evidence? Can physicians follow the evidence? There are a thousand new articles in the medical literature every day. Preliminary data often grab the headlines, but when they are modified, adjusted or refuted later, that often lands on the back page.

Milliman's goal is to take all of these thousands of evidence sources and put them into something that is digestible and usable by providers, or by consumers. We're now in the eighth edition of our proprietary guidelines, with nine volumes and 10,000 citations. We've got a full-time clinical faculty that is constantly reviewing the literature, a panel of outside experts, a formal feedback process, and a training mechanism to help people use the guidelines appropriately. This is not an easy tool for the average consumer.

Figure 8.2 shows part of a guideline on asthma. You can see that this is not for the average consumer. There is technical information that is best viewed with some clinical understanding. A companion product for a consumer takes the same information and provides it in consumer language. It is written at the 8th grade level, and we have been told that it should be written at the 3rd grade level.

Commercial interests occasionally influence evidence. We have greatly privatized health care research in the past 10 to 15 years, and to a great extent that is beneficial. A huge amount of money has gone into research and we see tremendous advances in pharmaceuticals and disease treatments. There is a risk to the privatization of health research and it was illustrated recently in the *Journal of the American Medical Association* (JAMA). An anti-hypertension trial called "CONVINCE," with promise of providing useful information, was aborted mid-trial, for "business considerations." The company supporting the trial didn't feel it was in their business interest to continue funding the trial. A JAMA editorial contained this quote: "The responsible conduct of medical

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<sup>1</sup> See Chapter 5.

research involves a social duty and a moral responsibility that transcends quarterly business plans or the changing of chief executive officers.” The company, however, does have a fiduciary responsibility to its stockholders.

Studies can be stopped because of commercial interests, but studies often are not started because of absent commercial interest. If a company can’t own the market through a patent, there’s no incentive to fund an effectiveness study, no matter how valuable that information might be to the public. One such intervention is bone ultrasound for delayed fracture healing. The guideline states that the current role remains uncertain and that no prospective double-blind trials comparing ultrasound versus conventional therapy are reported. There is no incentive to study an intervention that is in the public domain.

## ■ Information and Behavior

Given the information that is available in health care, does that information change behavior? We have evidence that physicians have responded to information. Figure 8.3 is from one of our clients, VIA Health, reported in December 2000. They used a tool called CareGuideQI that presents the guidelines at the point of care or decision, and tracks variances against the guidelines. This is information about avoidable hospital days that is fed back to the physicians. For instance, a patient may be ready to go home but the discharge order is not signed or the physician doesn’t make rounds in the afternoon, thereby missing an opportunity to let the patient go home. It may be Saturday morning, with one physician rounding for a group of five and that physician’s policy is to never discharge a colleague’s patient. That patient will have to wait until Monday morning. Even before SARS, hospitals were not a healthy place for the well. When you feed that information back to physicians over a period of a few months, they dramatically change their behavior.

What about consumers and evidence? There’s a ton of evidence out here. I put “glycohemoglobin,” a fairly technical term, into Google and I got 5,800 responses. Of these

5,800 hits, what is the wheat and what is the chaff? Is any of it good? Which of these 5,800 articles should I read if I’m trying to make a decision? As a consumer, it is very difficult to wade through this information.

Figure 8.4 shows a web page that looks like the *Consumer Reports* format that we all love. The demographics of *Consumer Reports* are probably not a cross-section of society. I suspect it’s a more educated and curious subset of society. But *Consumer Reports* works. It’s a nice format with stars or little bubbles, so it’s visually friendly. But in a study, the information in at least one of these visually-friendly sites was of poor quality. The information must be both accessible and accurate.

There is good information. The ECRI site looks like an excellent source of information. I also like the Pennsylvania Health Care Cost Containment Council, affectionately known as “phc4.org.” This organization has been around since the early 1990s and they have provided the public with information from all Pennsylvania hospitals, initially about cardiac surgery. They present information about mortality rates, readmission rates, number of procedures done—the things that I as a consumer would want to know. This is very good information and very accessible, but what did consumers do with it? After four years of availability, only 2 percent of the patients surveyed were aware of the information and fewer than 1 percent actually used it in making decisions about which surgeon to choose. Hospitals, however, did make changes based on this information, and care did improve.

Paul Wallace spoke about the Kaiser approach.<sup>2</sup> Group Health Cooperative of Puget Sound, along with Kaiser, has one of the most extensive histories of providing evidence to patients and empowering patients. They have a system to support patient involvement, based on a team approach. The consumers are not thrown into an imperfect market—they are supported in their decision making.

## ■ Conclusion

In summary, health care has little in common with an ideal market, and expecting consumers to make market decisions is problematic.

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<sup>2</sup> See Chapter 4.

Neither the evidence nor the evidence-based guidelines are easy for nonclinical users to interpret at this time. There is no evidence that the general population is making informed decisions without the kind of support that Kaiser and Group Health provide. Providers have changed behavior in response to information, but there is little evidence that consumers shop based on evidence.

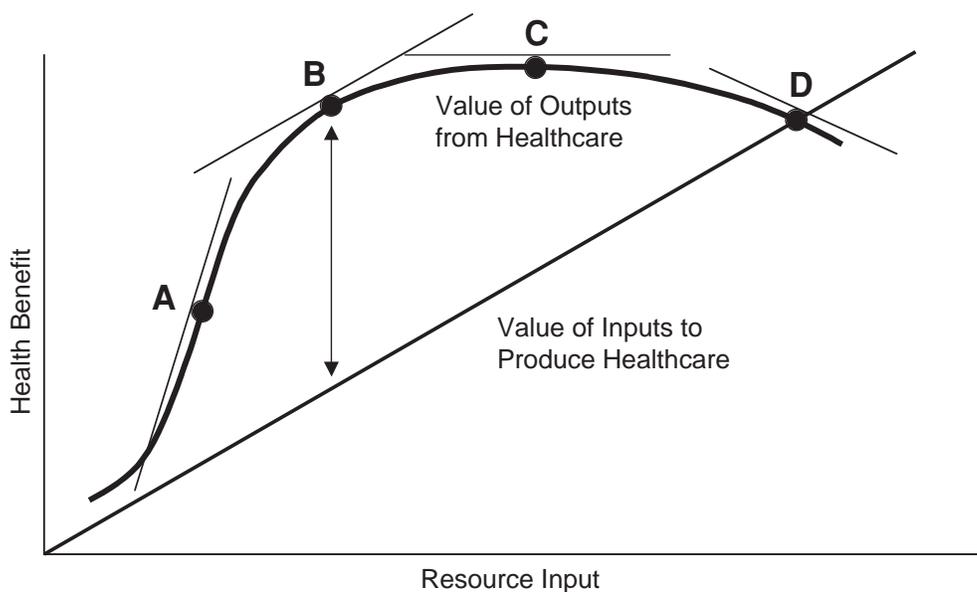
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Figure 8.1

### The Goal is Not Easy to Understand



- A = Engineering Efficiency: greatest increase in output per unit of input
- B = Output maximally greater than Input (Economists' Ideal)
- C = Maximum output (Consumers' and Providers' Ideal)
- D = Maximum input (Suppliers' Ideal)

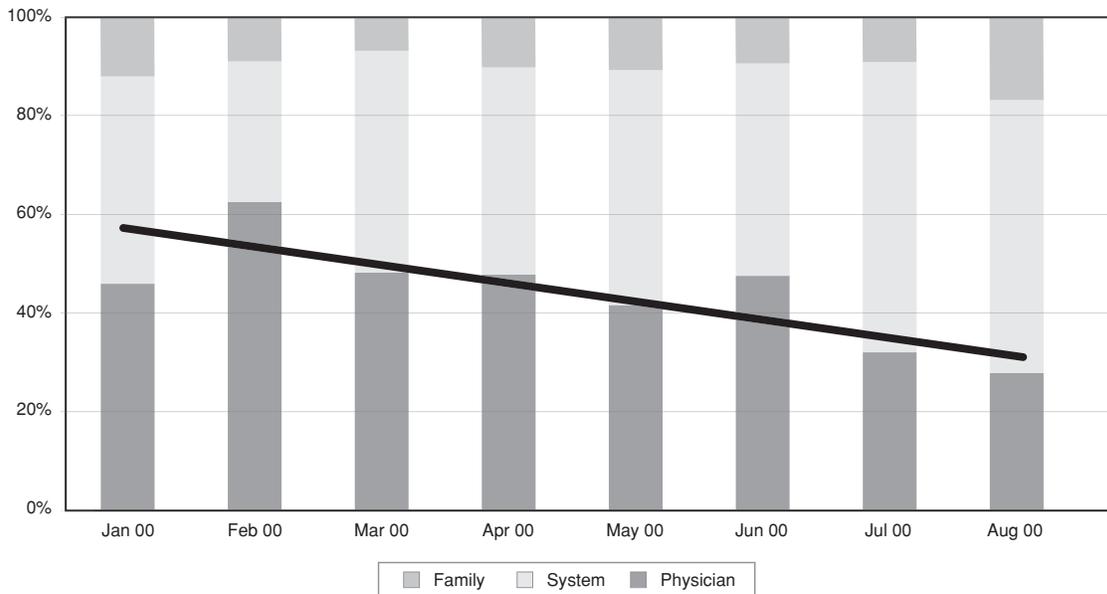
Figure 8.2

### Guidelines require some clinical knowledge of the user:

Following acute treatment and observation, admission is indicated for **ANY ONE** of the following:

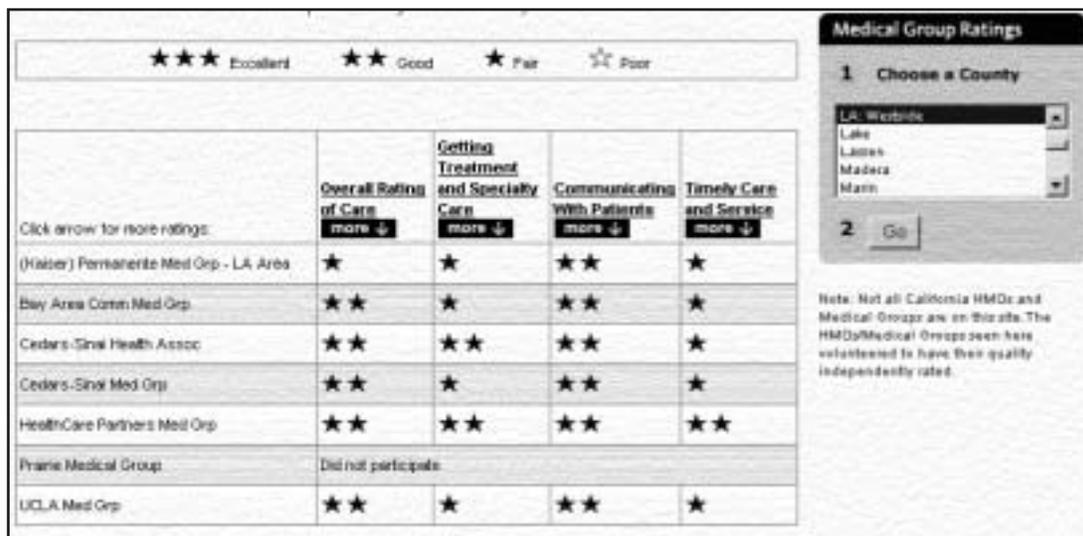
- Impending or actual respiratory arrest
- Significant respiratory acidosis indicated by **ANY ONE** of the following:
  - ▲ pH <7.35
  - ▲ PCO<sub>2</sub> ≥42 mm Hg
  - ▲ PCO<sub>2</sub> rising >5 mm Hg
- Severe symptoms (eg, continued accessory muscle use and retractions, drowsiness, confusion)
- Complicating features (eg, pneumothorax)
- Airflow measurements <40% of previous best or predicted (eg, PEFr <200 L/min)

Figure 8.3  
**Physicians do respond to information**



Decrease in physician-related causes of avoidable hospital days.  
 —VIA Health, December 2000

Figure 8.4  
**Some sites mimic “Consumer Reports”**



But, for one site studied, “...the ratings poorly discriminated between any two individual hospitals’ process of care or mortality rates...”  
 —Krumholz HM et al.  
*Evaluation of a Consumer-Oriented Internet Health Care Report Card. JAMA. 2002.*



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## **Current Sources of Evidence**

Assessing Quality of Care: Chapter 9

Evidence-Based Preventive Care: Chapter 10

Sources of Evidence: A Perspective From an  
Evidence-Based Practice Center: Chapter 11

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## *Assessing Quality of Care*

by Carolyn M. Clancy, MD  
Agency for Healthcare Research and Quality

### ■ Introduction

I'd like to consider the use of information to assess quality of care from three different perspectives. One is as the Director of the Agency for Healthcare Research and Quality (AHRQ), another is as a clinician struggling to find evidence when I see patients one night a week, and the third is as an informed spouse / consumer. My husband needs a surgical procedure for a fairly common problem for which there are at least two different procedures. Although this is a routine procedure done frequently, there is no good evidence on which is better because there haven't been any comparative trials. Moreover, there is no way to find out how patients "like me" have fared after either operation. It is very hard to find out which surgeons provide the best quality, and that information does not link to which insurers pay for which procedure, what hospital, out-of-pocket costs, etc. So while we have collectively made enormous strides in assessing and synthesizing evidence, we are a long way from making this information available to help individuals apply that information to everyday problems.

Overall, our capacity and accomplishments related to the production of evidence vastly exceeds our track record in applying that evidence or making it usable and navigable for people, whether they are clinicians, directors of research agencies, or consumers trying to figure out how to get a common surgical procedure done. Using evidence in practice and implementing a strategy to make it usable and useful to patients represents a critical frontier for all of us committed to evidence-based practice.

### ■ Sources of Evidence

We now have multiple sources of evidence. For example, two AHRQ resources that we are proud of are the National Guideline Clearinghouse and the National Quality Measures Clearinghouse. AHRQ was involved in the development of clinical practice guidelines when we were first established in late 1989, and, in response to fairly direct congressional suggestion, we shifted direction and focus in 1996. There had been considerable controversy about one guideline, in particular, and at that time the chorus of supporters was almost imperceptible. Today, that situation has changed and should be cause for celebration. When we stopped supporting the development of guidelines, what we did was to work very closely with the American Medical Association and the American Association of Health Plans to support an Internet-based guidelines clearinghouse that is exceptionally popular in the United States and around the world. Recently we added evidence-based quality measures to establish the National Quality Measures Clearinghouse. Both clearinghouses provide broad access to evidence-based practice guidelines and quality measures; both are frequently updated to reflect changes in science.

In September 2003, AHRQ will publish the first of two annual reports, one on quality of health care and the other on disparities in health care. In conjunction with the publication of these two reports we are going to try to make available a Web-based repository of tools and strategies called "qualitytools" to help a broad array of stakeholders improve health care quality. The focus of this site will be to give

interested stakeholders tools to help close the gap between evidence-based care and that which is actually provided in their setting or community. We are proud of these unique resources and gratified by positive feedback.

None of these resources, though, is sufficiently usable, i.e., we remain far from making evidence-based information both available and useful without specialized knowledge. If you go onto the Internet and look up all kinds of information, you can get all kinds of “stuff,” but it is not possible to discern its credibility or validity. The Guideline Clearinghouse and the Quality Measures Clearinghouse are good starting points because if a guideline or measure meets clear criteria, it can be posted on that site and people can make their choices about what works best for them in their situation.

But these resources still don’t quite “drill down” to the level of individual clinical decisions. They may help health care organizations dedicated to quality improvement by providing information regarding measures to track progress, current evidence, and professional consensus.

Even with all of the sites that exist, if one were to draw some kind of loose boundary around sources that we think are credible and are derived from good evidence-based principles, there are varying degrees of transparency. For example, there is a fair amount of judgment involved in many aspects of developing systematic reviews. This is not to say that it’s biased, it is just that it is not entirely clear how you go from framing—making the shift from a very broad question to the kinds of specific questions that one needs to develop to be able to do a rigorous, systematic review of the evidence.

But that degree of variability is nothing compared with the degree of variability in accessibility. There are sites with very good information that are not free, so you have to pay or subscribe in some fashion, and it is not clear that we have a common consensus about whether this is a public good. It is astonishingly rare to find a site that helps you get right to the answer to a question, or at least it is entirely serendipitous when this happens. And it’s virtually unheard for a site to state, “We don’t know. We simply don’t know this.” Why is that? One reason is that the demand for evidence-based information hasn’t reached critical mass.

Another reason is that we have not developed a business strategy for this information.

## ■ Insufficient or Imperfect Evidence

Additional issues concern the fact that for many questions there is insufficient evidence to permit clear conclusions. While the systematic review process is very rigorous, communicating the information that there is insufficient evidence on either side of a question remains a challenge. Most of us can easily say, “lack of evidence of effectiveness is not equivalent to evidence of ineffectiveness,” but we have avoided the implications of that statement. Should the implications for an intervention that is harmless be equivalent to the implications for an intervention that represents an individual’s only hope? No—but we have not yet come to grips with this challenge. Where should the burden of proof be in terms of coverage for different situations? The need to make an immediate decision in the face of imperfect evidence is also challenging. For example, it is not practical or useful to tell a patient, “I don’t know if PSA testing is a good idea, but there are some great trials in progress, so come back in five years and we’ll give you a recommendation then.”

And finally, there is a point at which evidence-based systematic reviews sometimes give the impression of being a glass half empty. Here is what is wrong with this study, here is why the quality of this study is poor, and here is why the quality of that study is poor. For people who have no other options, who are dying, or who feel like they simply have to make some kind of decision or want to do something now, this kind of review doesn’t tell them how to make the most of the information that is available.

These are technical and analytical challenges that are resolvable. The big challenge and tremendous opportunity resides in making the best evidence usable and accessible in “real time.” We can and must push to make sites usable: we must work toward making the best possible information easily available—indeed, impossible to avoid—in a way that matches the questions of clinicians, patients, and decision-makers. We can let users know about the quality of the evidence or if

there is no relevant information available. If you're going to have to make a decision and there simply is no good information, or if there is information that is good but perhaps wouldn't pass the test of a rigorous, systematic review and keep all the evidence-based medicine people happy, then we should figure out a way to make that a little bit plainer to people as well.

## ■ Conclusion

We have come a long way toward making evidence-based information available to those who provide, pay for, and use health care, but we shouldn't lose sight of the goal: assuring a more perfect match between sources of evidence and decision makers' needs for information and vastly improved navigability.

## Evidence-Based Preventive Care

by Dennis E. Richling, MD  
Midwest Business Group on Health

### ■ Introduction

I'm the president of the Midwest Business Group on Health. I was medical director or chief medical officer with Union Pacific Railroad for 14 years. I'm going to discuss one particular source of information, and explain why I think it is important. At Union Pacific, we had a robust health promotion program. We had delivered health promotion programs for more than 10 years, had some demonstrated success, and demonstrated impact on the bottom line. In that process, we applied an evidence-based approach to make decisions about population health management. I believe employers may sometimes be engaging in activities that are giving little value back to their respective organizations. In fact, I see companies engaging in prevention activities that they might as well take the money being spent, put it in a big pile in front of the building, and burn it for as much as good as will come some of those services. Many activities that are not connected to a long-term strategic effort are not necessarily giving back very much value.

### ■ The Guide to Community Preventive Services

There is a readily available source for information, the *Guide to Community Preventive Services*. This is a Department of Health and Human Services initiative, coordinated by the Center for Disease Control and Prevention. This resource has two primary

goals. It provides a standard reference for the effectiveness of population-based interventions. It answers the question, "What does the scientific evidence tell you?" It also supports a research agenda by identifying what interventions are not fully understood. Employers are engaged in intervention research within their organizations. But in the employer setting, there are many times when the various organizations are investigating the same research question. The *Community Guides* research gives us a common understanding that can contribute to a larger body of evidence about what actually works in terms of intervening in health behaviors.

The *Community Guides* are different from the *Clinical Prevention Guidelines*. The *Community Guides* are focused outside of the clinical setting. This is very relevant to employers because many of their prevention interventions occur outside the clinical setting. Employers often are focused on groups. Health care providers may or may not deliver the interventions, but it is often not a physician.

The *Community Guides* project makes recommendations based on systematic literature reviews. In order to drive the project, there is an independent, nonfederal oversight through an advisory committee. I am a member of the advisory committee. The guide tries to answer the questions, "What works to promote healthy lifestyles?" and "How do you prevent disease and injury?" The approach attempts to distill the best information and use rigor, but not allow rigor mortis. On many topics, there are no randomized clinical trials. Through the years, when I've been engaged in applying evidenced-based medicine, and trying to manage care, I found that doing something is

better than doing nothing even if the supporting data are not perfect. In some areas, a complete understanding of what is the most effective strategy may not have been achieved, but if we take the best minds and use the best information available, we can develop recommendations, which are more useful than intuition alone.

The guides attempt to thoroughly review all the information available, and make recommendations from that information. The evidence is gathered through extensive research. This is the body of the best evidence that your tax dollar has developed, reviewed, rated to identify the quality of that evidence, summarized, and then translated into recommendations. The importance of this is that it helps us to use limited resources wisely. Companies sometimes make commitments to do something to reduce at-risk behaviors by their employees, and they fail to achieve the outcomes they desired. These poor outcomes are many times predictable because the approaches are not based on the best strategies for improving health behaviors.

The *Clinical Guides* and the *Community Guides* are complementary. The *Clinical Guides* have many of the same recommendations that

are found in the *Community Guides*. The Web site is [thecommunityguide.org](http://thecommunityguide.org)

## ■ Using the Information

Along with the potential uses for this information, there are also some challenges that I think we face. When I was at Union Pacific, my staff began evaluating approaches to reduce the smoking prevalence rate. The original measured prevalence rate for smoking was about 40 percent. This is higher than the national average. We implemented programs over time, and were able to reduce the prevalence rate in our population to a little bit over 23 percent. We were forced to do our own independent research and use resources to determine the best interventions because we did not have a trusted one-stop resource. But today employers do have that resource.

If employers are making the case that we need to use evidence-based medicine in our approach to medical care, we should use it consistently in our approach to prevention activities. This is a trusted source of information for each of us to use. It is a robust system, and is continually being expanded and updated.

## *Sources of Evidence: A Perspective From an Evidence-Based Practice Center*

by Mark Helfand, MD, MPH  
Oregon Evidence-Based Practice Center

### ■ Introduction

In discussing evidence-based medicine I am going to focus on the nuts and bolts level of that miracle, that black box in between getting the evidence and making good guidelines from it. Let me start by describing Evidence-Based Practice Centers (EPCs). These centers were created by Agency for Healthcare Research and Quality in 1997, and there are now 13 centers that produce evidence reports, systematic reviews, and similar products. They work with public- and private-sector partners.

I am the director of the Oregon Evidence-Based Practice Center. Our EPC, over time, has done reports for the development of guidelines at several different organizations, including the U.S. Preventive Services Task Force, the complement to the Community Task Force. In choosing reports to do or choosing partners, I have tried to find partners that are really going to use the report, and not to do too many reports that just go onto bookshelves because no group has actually planned to use them.

We hope that, by picking the right topics and choosing partners that are committed to doing something with the information, we may have learned a thing or two about how to make the reports more useful to panels, groups, payers, providers, and patients. The key to achieving this goal is an evidence-based decision process. Throwing a systematic review into a vacuum isn't a process. When we talk about an evidence-based process, we are talking about making use of an independent, systematic review of the evidence and about employing rules for linking evidence to recommendations or decisions. We are also

talking about producing explicit and defensible recommendations.

### ■ Rules

That middle step, employing rules, is probably the key to what distinguishes a process such as that followed by the Community Task Force from those that may or may not use systematic reviews, but call themselves "evidence based." If, for example, there is no rule that says "you can't strongly recommend something if there is no evidence on it," it is not an evidence-based process. With growing frequency, groups develop guidelines or practice recommendations that incorporate some of the elements of evidence-based processes. Specifically, they use systematic reviews, and sometimes they commission very good ones. But what they end up with are recommendations for practice or guidelines that state something like, "Turn the patient every 45 minutes. Level of evidence, none. Strength of recommendation, very strong."

And while that may be a good recommendation, and the process they used has made it clear what is based on evidence and what is not, when we talk about evidenced-based decision processes, we are talking about a somewhat stronger link between the evidence and the decisions.

Programs that use systematic reviews and an evidence-based decision process include the Canadian Task Force, which began in the 1970s; the U.S. Preventive Services Task Force (USPSTF), which began around 1980; the American College Clinical Efficacy Assessment Program, which was most active in the 1980s and 1990s; the British National Health

Services' National Institute for Clinical Excellence (NICE) ([www.nice.org.uk](http://www.nice.org.uk)); the Community Preventive Services, the Institute of Medicine; and the Medicare Coverage Advisory Committee process, which is evidence-based but which addresses only a subset of Centers for Medicare & Medicaid Service's coverage decisions ([www.cms.hhs.gov/mcac](http://www.cms.hhs.gov/mcac)). The Department of Defense and the Department of Veterans Affairs have been joining forces in trying to develop their own evidence-based process.

## ■ U.S. Preventive Services Task Force

I have spent the last four or five years working with the U.S. Preventive Services Task Force (USPSTF). Two EPCs, ours and the one at Research Triangle Institute and the University of North Carolina, staffed and did reports for the Task Force, and we were able to observe what a group of individuals make of our reports and what comes out at the other end of that black box.

The Task Force is an arm of a broader effort to promote clinical preventive services. The other arm is Putting Prevention into Practice, which supplies practical ideas on implementation ([www.ahrq.gov/clinic/ppipix.htm](http://www.ahrq.gov/clinic/ppipix.htm)). Both arms are related to the U.S. Community Preventive Services Task Force. This combined effort is a key part of the federal initiative in prevention.

The mission of the USPSTF is to evaluate the scientific evidence on the effectiveness of individual, clinical preventive services. These are the everyday services—screening for prostate cancer, mammography, whether to counsel a patient to lose weight—anything that can be done in a primary care clinician's office or under the auspices of the primary care clinician's office. The USPSTF makes age-specific and risk factor-specific recommendations for routine practice. The Task Force members try to build a consensus for effective clinical preventive services by distinguishing effective services from less effective or ineffective ones, and they try to guide the research agenda for prevention by identifying gaps in current information.

The USPSTF recommendations are widely applied and used, and many organizations look

to the task force for guidance about practice, coverage, and performance measures. The Veterans Affairs' medical system and the Department of Defense rely on the Task Force recommendations as do a lot of private insurers.

When we worked with the Task Force, we produced systematic reviews for them with tables and bibliographies that have run to 50 or even 100 pages, and we include a briefer summary of the evidence (which is brief only by the USPSTF's standards!). After their deliberations, the members of the USPSTF draft recommendations, vote on them, and write a document called the "recommendation and rationale." The recommendation and rationale statement includes a section on clinical considerations, that is, how they apply their values, their clinical judgment, other considerations of equity and so on in formulating the recommendation, but which also clearly defines the link between the evidence and what they recommended.

Most people are not interested in seeing any of these products; they just want to know if the recommendation is an "A" or a "B," and that is enough for them to decide what to do. Part of that is very rational. The Task Force has a long history and an explicit process; it doesn't have a good seal of approval by anybody in particular, but it has a good track record for being evidence based.

The term *methodology* makes the evidence-based process seem more abstract than it is: In the case of the USPSTF, it is how a group of clinicians and experts in prevention decide what evidence is compelling and what evidence is only suggestive or interesting but not sufficient to make recommendations for the population as a whole. How they value different outcome measures may be the most important component of this process. In general, health outcomes, things that patients can feel, are preferred to intermediate outcomes, i.e., things that are signs to clinical findings such as lab tests, which patients can't feel and which don't really affect their functional status or their mortality directly. It is still a matter of judgment how far to go in allowing an intermediate outcome to be involved.

## ■ Evidence

Should we always require evidence about health outcomes? What if such evidence is very

hard to obtain? This is a very real, very important issue that illustrates how value judgements must be made within an evidence-based process. Imagine that you are a pediatrician on the Task Force. Should pediatric interventions be held to the same standard as those for adult medicine interventions such as screening and treatment to prevent heart attacks and deaths from coronary disease? We use the statin drugs for people to prevent heart attacks and deaths and also have operative procedures such as coronary artery bypass surgery for patients with heart disease. The statin drugs and CABG surgery have been shown in randomized, controlled trials to save lives.

But what if you are considering whether to treat children for obesity, or you are trying to decide whether to treat children who have a high cholesterol count? You are never going to find a study that followed children long enough—60 and 70 years!— to see whether the childhood treatments improved their lives as adults.

On the one hand, if it would take a 60-year-long study to answer a question, it is fair to say that anyone who claims they *know* the answer is exaggerating. On the other hand, often some judgment is needed while we are waiting for the evidence to meet a perfect but unattainably high standard.

To illustrate what the Task Force seeks from us in making their deliberations, take the example of prostate cancer. What we would be most interested in would be a study that randomized asymptomatic men to be screened with a PSA or not, a prostate screening test, and directly examined whether, in the long run, there was reduced prostate cancer morbidity and mortality. We would call that direct evidence, and it would pretty much have to come from randomized trials or from really well-done case control studies or other observational studies. That is usually not what we get; what we get is a lot of studies showing that the PSAs find many early prostate cancers, and we have some reason to think that treating early prostate cancer with radiation and prostatectomy might be better than not treating it, but even there we only have one randomized trial.

So in the absence of direct evidence, what you are really doing is taking different bodies of evidence—a group of studies about the tests,

another group of studies about treatment, a third group of studies about the adverse events of both—and trying to put it all together.

I once had a retinal branch vein occlusion in my right eye. I lost 80 percent of the vision in that eye, and so with the other eye I did a literature search and found one randomized trial of about 30 patients that showed a slight benefit to laser therapy. I called up the principal investigator at Johns Hopkins and said, “How come there was only one trial and I want to ask you questions about it.” He said, “Well, actually, the person who ran that whole trial is out there in Oregon with you. Why don’t you talk to him?” He named the doctor I had already gone to in Oregon, and so I made my own impression of the trial. My impression was that they had just rounded up some patients who had had branch vein occlusions and whose vision had not improved after some time—three or four years in the case of some of the patients. Almost none of them had had the laser surgery within three or four months of having the branch vein occlusion, and the length of time between the occlusion and the time of surgery did not seem to be related to how well the surgery worked. So the first lesson that I learned from the trial was *wait to see if it gets better before you use this information*. The other thing I learned from the trial was that the patients were generally older than I was, and I wasn’t sure how well the findings applied to me. I talked it over with my doctor (who actually did the trial). He agreed with my interpretation of the trial, but I am not sure the course of action I suggested—waiting to see whether my vision got better on its own—would have come up if I hadn’t analyzed the trial myself and asked him the question.

I was able to apply the evidence to myself because it was one study, one question, and one body of evidence. That is hardly ever the case with situations that are complex enough to lead to guidelines, and where there are dozens of studies of test results, dozens of studies of the natural history of this particular condition, some funny studies, and difficult studies of whether treatment works or not, and you have to put it all together. A very different use of evidence is involved.

In a guideline process, how do we link the quality of the evidence to the strength of recommendations? If an Evidenced-Based Center report finds the evidence is insufficient

or poor, then the Task Force cannot give it an “A” or a “B” recommendation. They have to give it an “I” (for insufficient evidence) if the evidence is poor. Only if the evidence is good or fair can they recommend the service. If the evidence is good or fair, the Task Force needs to choose between an “A,” “B,” or “C” recommendation based on their estimate of the net benefit. *Net benefit* means benefit minus harms. What you usually find is that net benefit is uncertain because no one looked carefully enough at the harms, so this is another area where we apply norms, and, for most clinicians, the norm seems to be *if there’s evidence of an effect, a benefit, and not much evidence about the harms, we’ll go with it*. I can imagine a very different norm. I can imagine us saying, *if we’re not as certain about the harms as we are about the benefits, we’re not going to recommend this or do it*.

The difference in these norms is most noticeable when there is a crisis. One of these crises that has hit the papers in the last few years is estrogen therapy, also called hormone replacement therapy. The crisis was brought about by the publication of the preliminary results of a controlled trial showing that estrogen supplements increased the risk of coronary disease and cancer.

New evidence is most likely to create a crisis when millions of people are already taking a drug or having a procedure that, when it is finally studied carefully, never really worked in the first place or has harmful effects that outweigh the potential benefits. It is one thing for experts to believe that something is true even if the evidence is shaky. It is another thing—and it is the usual thing, I am afraid—for these experts to recommend a treatment on these shaky grounds, not only to their own patients but to millions of others as well.

This particular crisis might not have happened if people had a different norm and reasoned, “Trials of a drug sponsored by industry are unlikely to really go out of their way to dig for and find long term, serious, life threatening harms. So we’re not going to take it for granted that the benefits outweigh the harms unless someone does a study that is designed to measure the harmful effects if they exist. So where there is insufficient or missing information about harm, let’s wait until there is such a study.”

The market doesn’t work that way. If the market started to work that way, the people

who do the trials, the people who fund research, would respond, because that is what the research is supposed to be doing: making the quality of evidence, and its relevance to us, the determinant of market share, of which drugs do better, which treatments do better, in the marketplace, in other words, what there is more demand for.

We could imagine that if people were more risk averse when they made their individual decisions, anything that was vague on harms (which is most of the things in medicine) would be shifted into the “I” (insufficient evidence) category and not just pushed into an “A,” “B,” or “C” category.

The “I” recommendation means there is a lack of evidence on clinical outcomes, that is, poor quality of existing studies or good quality studies with conflicting results. It also means that the confidence interval includes clinically important benefits, which means you can’t rule out this thing as really good. How do you know when you need really strong evidence of effectiveness to decide whether to recommend something?

The Task Force and other bodies that make these evidence-based recommendations have had a very high standard across the board. If there isn’t proof of efficacy in some really good studies, preferably randomized trials, they won’t recommend it. But, according to economic theory, a rational decision-maker would use a different approach in weighing risk and benefits.

First of all, in asking how strong the evidence needs to be, the answer is, if the expected utility of something is higher than the alternative, you’re going to do it. If the harms of doing it are zero, if it’s absolutely proven harmless, then even if it only has a 5 percent chance of working and it only works for one in 20 people, it is still clearly a higher expected utility than not doing it, because if it’s proven harmless, the net benefit has to be positive if there is any chance of benefit, however small that chance is.

Using a clinical scenario like this, suppose you have a child with cerebral palsy. You have tried the usual physical therapy, occupational therapy, and several other treatments, and you are in considering a surgical treatment, for example, a selective dorsal rhizotomy, that may or may not help. In this procedure, in order to relieve muscle spasticity (which is like a

permanent muscle spasm), nerves in the spinal cord that are not working are cut and killed. It is a long and complex neurosurgical procedure. The potential permanent risks are paralysis of the legs and bladder, impotence, and loss of sensation. In the short run, the child is likely to have abnormal sensitivity of the skin on the feet and legs and loss of bladder control that may last a few weeks. Because there have been many studies of this procedure, you are in a situation of weighing known risks against known harms. This is a very complex situation; people will wrestle with it and come up with different answers.

But say we are considering whether to take vitamin E to prevent prostate cancer or breast cancer, and based on the studies that have been done, you are only 20 percent sure that it has any benefit for anyone, but you are absolutely sure from these large studies that it is harmless in the dose you want to take. Why not take it? It's also cheap. The Task Force would never recommend it under these circumstances because the level of evidence is "I." If there's only a 20 percent chance it works, it's low, but an individual might very well be rational to take it, because there is no downside and there is a potential plus side.

When is cost-effectiveness needed in this kind of formulation? If all of the alternatives are equally effective and safe it is really a pure cost minimization problem—the least expensive should be selected. But when one treatment's better *and* more expensive, consumers will want to know how much the extra effectiveness costs.

We have not been very good at measuring the extra effectiveness in the first place, so it is very difficult to tell anyone how much it costs, and we haven't been gearing up to measure the difference in the magnitude of benefit precisely. The Task Force's innovation in the last four years has been to start looking at the magnitude of benefit, but, in most cases, when they get to that point, and estimate whether it's a big, moderate, large, or small benefit, it is mostly hand waving because weighing risks against benefits is not a very explicit process. The best we can do is try to translate what the literature says into some gross estimate of the benefits minus harms, either on an individual or an aggregate basis. It is far from precise and far from usable in terms of individual consumers.

## ■ The Oregon Drug Effectiveness Project

Measuring the extra effectiveness of one thing compared to another is an important part of the drug effectiveness project in Oregon. I have been working on the Oregon drug effectiveness collaboration, which has been described as creating a functional marketplace for prescription drugs, for approximately a year and a half. It is an evidence-based process, and it involves a process for selecting and refining questions that puts providers' and patients' concerns center stage.

Concerning the issue of consumers using the information from evidence, at least part of the answer is that the more they participate in figuring out what questions the systematic review ought to answer and what outcomes, interventions, and drug use should be looked at, the more relevant the information will be.

As an example, one of the reviews we did on this was about the triptans, medications for migraine headaches. Almost all of the literature on this began with studies done for FDA approval: randomized, placebo-controlled trials done in order to get FDA approval. These studies used the outcome measure the FDA said was the one that had to be used for regulatory purposes. That was pain relief at two hours. This means that the headache has been reduced in severity from severe or moderate to mild or none. It could include a lot of people who went from moderate to mild and didn't really feel that much different, or couldn't accomplish much more when they went to work, or it could include people who had a dramatic improvement from severe pain to none.

The drug companies funded a lot of great studies trying to figure out what patients really care about, what should be measured, and they came up with essentially a pallet of about 10 different measures that could all be important to patients. They did about 25 head-to-head trials comparing their triptan to some other company's triptan, looking at these measures. All this comes down to is that, because the drug companies went out and asked migraine sufferers what was important to them, the studies are a lot more responsive and meaningful to patients.

But when we presented all the evidence to our panel, there were some very important

outcome measures that were completely ignored in that literature. The most important one was, “If I’m limited to five or 10 pills a month by my insurer, I want to know how well half a pill will work.” “How many headaches can I treat with five pills?” Nobody studies that. In fact, most of the studies try to look at the best single maximum dose of one drug versus the another drug (and, often, a crummy dose of the other drug). The ideal study would be comparable doses, using the lowest dose that works. And the panelists also wanted to know, “If I’m on one of these for six months or a year, how reliable it is headache after headache?”

The process that we used—in Oregon and in Washington state—was based on the literature, and based on the filter of everybody’s values in these kinds of discussions.

Washington state decided to pick one triptan, rizatriptan, because there were a couple of studies showing that it clearly works faster than two or three of its competitors, and working fast is an outcome measure that patients clearly value.

Oregon decided three of the triptans were comparable. Their main reason was that, based on the lack of information about a couple of the outcomes and uncertainty about the reliability over months and months, i.e., the consistency of the effect, and the ability to use little cut doses of pills and make them last longer, they decided they couldn’t determine which was better.

This kind of decision making sends a clear message to the people doing the studies. There was only one reason the pharmaceutical companies did these 26 head-to-head trials. It’s market share. It’s a good thing, they’re trying to prove their drug is better than the next competitor’s. The kind of work being done in the states of Oregon and Washington sends a message back to the people doing the research that, “We will pay attention if you do better research, if you produce better evidence, and better means more responsive to what the public cares about, and to what providers care about.” And it also means consistent with the criteria we have for what a well-designed study is.

identifying what the studies ought to be investigating and what evidence they would really like to have, research will improve and will close this gap between the evidence we need and the “I” recommendations we often have. And it will have been addressed in exactly the right way: by rewarding companies that do good research with market share, and making evidence, rather than sound bytes and commercials on the 5:30 news, the basis for choosing among treatments.

## ■ Conclusion

I am going to end with a message of hope that as health care professionals and the public become more and more involved with



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## **Importance of Consumers to Evidence-Based Decision Making**

Identifying Consumer Perspectives: Chapter 12

Values-Focused Consumer Education in Health Benefits and Care: Chapter 13

Compare Your Care: A Web-Based Strategy for Consumer Activation and Physician Performance Rating: Chapter 14

## *Identifying Consumer Perspectives*

by Marjorie Ginsburg, MPH  
Sacramento Healthcare Decisions

### ■ Introduction

The perspectives of consumers are not always taken seriously by other health care stakeholders. Skepticism about consumers' ability to understand or willingness to learn the nuances of health care policy, and the penchant of advocacy groups for narrow self-interest, may have made policymakers doubtful about citizen participation in developing health policy. One consequence of this indifference has been a failure to actively engage citizens in complex policy issues.

This discussion describes what Sacramento Healthcare Decisions (SHD), a private nonprofit, nonpartisan organization, learned from consumers about the use of practice guidelines in treatment and coverage decisions. While SHD's project was focused on cost-effectiveness as a decision criterion, elements of the project overlapped with the principles of evidence-based medicine (EBM).

### ■ Engaging the Public in Complex Issues

While SHD does not assume that the values of the average citizen alone should determine health policy, meaningful policy changes require the input of those most impacted. SHD's role is to educate and involve the public in complex health policy issues and to act as a neutral liaison among diverse stakeholder groups considering policy changes. This work is usually done in three phases: 1) identifying community views and values on complex, timely health care issues; 2) proposing ways to incorporate those values into health care policy

and practice changes; and 3) developing tools and educational programs that assist consumers in making informed personal and societal choices. The centerpiece of identifying community views is conducting structured, case-based, interactive discussion groups. These discussions allow participants to struggle with and debate conflicting or competing priorities, without the bias or pressure of vested interests.

### ■ Addressing Finite Resources

In 1999, SHD began an initiative to address the reality of finite health care resources. Visible Fairness was its first project in this arena and was developed in response to work done by Stanford University's Center for Health Policy (Singer and Bergthold, 1999). Stanford's project proposed that, in an effort to develop more consistency among California health plans and medical groups, cost-effectiveness should be a criterion for defining medically necessary care. Since cost-effectiveness is, according to all accounts, rarely used explicitly in coverage decisions, this seemed an ideal time and opportunity to garner public input on the use of this controversial criterion.

### ■ Cost-Effectiveness as a Criterion

The concept of balancing cost with benefit is widely used in everyday consumer purchases (e.g., it will cost me \$50 more if I fly United instead of Southwest, but on United I can reserve an aisle seat instead of waiting in line...is this worth \$50 to me?). However, it is

not so common in most health care transactions where first-dollar coverage by health plans is still the norm for those with insurance (if this were the case for airline travel, no one would ever fly Southwest). It has long been accepted that patients do not want or expect their doctors to restrict their health care options on the basis of cost considerations. But would “cost-effectiveness”—determining if there is good value for the extra dollar spent—be an acceptable criterion, even if cost alone is not? In Visible Fairness, the concept of cost-effectiveness was illustrated through examples where, compared with an alternative, a particular medical intervention provided a small incremental benefit at a high cost. This project was designed to answer two questions: 1) Does the public believe that cost-effectiveness is an acceptable criterion for physicians to consider when weighing treatment alternatives for their patients and 2) Does the public believe that cost-effectiveness is an acceptable criterion for clinical or coverage guidelines?

To identify consumer views, SHD held 25 discussion groups of 10–12 people each. Most groups were organized and conducted in local settings such as churches, community-based organizations, work places, homes, and classrooms. Four paid focus groups were held to recruit specific population groups that were underrepresented in the other sessions. The group discussions were tape-recorded and transcribed for later analysis. A full description of the project design, results, conclusions, and recommendations is available online or in print.<sup>1</sup>

In using clinical or coverage guidelines as one way to illustrate cost-effectiveness, SHD developed a discussion scenario reflecting major components of evidence-based medicine EBM:

### ***Happy Valley Health Plan***

*Happy Valley Health Plan has contracts with several large companies to provide health insurance for their employees. These companies have recently informed Happy Valley that they cannot pay higher premiums this year for their employees' health insurance. Since the cost of medical care continues to increase each year, Happy Valley has to figure out how to provide all the medical care that its members need when the*

*insurance premiums aren't going to keep up with the cost of care. So Happy Valley decides it will try to avoid paying the cost of medical tests that have little or no proven benefit for patients.*

*Happy Valley establishes guidelines for the use of MRIs—one of the most expensive tests that doctors can order. Happy Valley knows that many of these MRIs are ordered for patients even when scientific studies have shown that the MRI is extremely unlikely to help in diagnosing certain problems. One of the most common examples of this is when an MRI is ordered for patients with uncomplicated low back pain.*

*The health plan sends its new MRI guidelines to its doctors. These guidelines indicate the types of medical problems for which an MRI test will be paid for by the health plan.*

*Do you believe that Happy Valley Health Plan should have guidelines like this?*

Yes \_\_\_\_\_ No \_\_\_\_\_ Not sure \_\_\_\_\_

Each participant individually voted yes, no, or not sure. This was the starting point for a group discussion on why people voted as they did. It was the response to this why question that led to participants' underlying perspectives and values. The themes that surfaced from the 25 meetings formed the basis of the project's results and recommendations.

## ■ **Interpreting the Results for EBM**

Although EBM was not mentioned in Visible Fairness, the Happy Valley scenario was a reasonable portrayal of incorporating EBM to improve quality and decrease cost. Given that the Sacramento region (one of the most predominantly managed care areas in the country) has many vocal anti-HMO residents, it

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<sup>2</sup> *The project report, Cost-Effectiveness as a Criterion for Medical and Coverage Decisions: Understanding and Responding to Community Perspectives, can be read or downloaded from [www.sachealthdecisions.org/vf.pdf](http://www.sachealthdecisions.org/vf.pdf) For a printed copy, e-mail [marge.shd@quiknet.com](mailto:marge.shd@quiknet.com)*

is all the more interesting that the dominant messages were not exclusively anti-health plan. The prevailing perspectives related to the use of guidelines were:

- *It is acceptable for health plans to have guidelines for when treatments are covered, as long as these are “guidelines” and not rules.*

While reluctant to have health plans “tell doctors how to practice medicine,” consumers nevertheless see some advantages to the use of guidelines, such as reducing wasteful spending, promoting high-quality medical care, and protecting physicians from malpractice claims. Many mentioned their own experience with doctors who overprescribe. But consumers believe that practice or coverage policies must be flexible, allowing for inevitable variation in patients’ circumstances. Health plan guidelines are acceptable to consumers if:

- ▲ Physicians can override them by showing a valid reason for an exception.
- ▲ Exceptions are decided through a timely review process.
- ▲ Only physicians with special expertise can override the judgment of a patient’s physician.

While many believe that the doctor is in a better position than the health plan to know what the individual patient needs, as one community member noted, “this is life (we all have to live by guidelines).”

- *If health plans establish guidelines or make coverage decisions, these should be based on expertise from outside the health plan.*

Participants have a variety of suggestions for how those guidelines or decisions should be made:

- ▲ Guidelines should be based on scientific evidence, not just on treatment expense.
- ▲ Physicians with special expertise should be involved.
- ▲ An independent body, without financial ties to the health plan, should develop the guidelines.
- ▲ Health plan members should be involved in various decision processes, such as grievances about treatment authorizations

and decisions on how health plan dollars are allocated for clinical services.

- ▲ Health plans could demonstrate that dollars saved through cost-containment efforts are being used for patient care, rather than for administrative salaries or stock dividends.

## ■ Not a Slam-Dunk

While these opinions suggest that the public supports guidelines that use evidence-based principles, there are other consumer sentiments that may conflict with standards that are too inflexible.

- *Suspicion of population-based statistics.*

Those whose personal experiences contradict population-based conclusions will give precedence to their own experience over that of researchers. Even in the absence of personal experience, there seems to be a healthy skepticism about statistics as a basis for making treatment or coverage decisions.

- *The rule of rescue.*

Often in defiance of logic or the improbability of success, Americans have an abiding belief that all efforts should be exerted to save someone when catastrophe strikes. This is especially true if the patient is a child or young adult.

- *Reverence for things new and improved.*

One of the most challenging standards of EBM may well be the requirement that sufficient data be known about a new treatment (or learned about an existing treatment) before the intervention is provided. “Waiting for the proof” may be very difficult in a culture that is notoriously optimistic and impatient.

## ■ Bringing the Public Along

Health care policy cannot function independent of public knowledge and perspective. Coverage or practice policies rooted in EBM will likely be challenged every step of the way unless consumers have a greater understanding of these standards and a more prominent voice in how they are applied. Absent a coherent

national policy on health care, health plans, medical groups, and individual clinicians can and should take an active role in involving their members and patients in the art and science of creating standards for high-quality, cost-effective health care.

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## ***Values-Focused Consumer Education in Health Benefits and Care***

**by Lois A. Vitt, Ph.D.  
Institute for Socio-Financial Studies**

### ■ **Introduction**

The Institute for Socio-Financial Studies (ISFS) is a nonprofit, nonpartisan organization that was formed in 1991. Since then, the Institute's mission has included strategic planning and nationwide benchmarking research on consumer financial education. The goal is to help organizations assess consumer knowledge and literacy levels in order to empower them to deal more knowledgeably with the financial issues in their lives.

Our work has included a nationwide study of financial education programs in the workplace, in communities, in all branches of the United States military, faith-based organizations, community colleges, and the Cooperative Extension Service Programs (CES). Other studies and publications are focused on consumer health financial education, particularly in the work place, and on what consumers know and understand about health benefits and health care finances.

### ■ **Health Benefits Models Follow Employer Shifts to Defined Contribution Pension Funds**

Consumer-driven health care benefits are being evaluated in a variety of new arrangements to help plan sponsors cope with spiraling costs. Health benefits models under consideration are less structured, give consumers more choices, and require more personal responsibility from consumers for both their health and financial outcomes. This means that many more workers

may soon be required to select, purchase, and manage their health coverage and care in the same way they are increasingly managing their pension benefits.

Self-directed pension programs, spreading computer literacy, public campaigns to increase savings and investment, and growing media interest in personal finance have all contributed to a more “money aware” public. Most people are getting the idea that they must become more responsible for their everyday and future financial well-being.

### ■ **Having More Personal Responsibility**

The central notion of being *responsible* is the idea that a person can be held accountable for something; that he or she is answerable to someone or to some social institution for his or her actions or for the outcomes of those actions. But this idea is tempered by the further notion that the condition or event for which one is accountable *is within his or her power or control*.

Americans like feeling responsible. When they know what is expected of them, and when they are given the tools and the opportunity to become successful at whatever they undertake, they accept—and even seek—responsibility. Having responsibility, feeling responsible, and being regarded as responsible by others are components of an important value held by most Americans (Vitt et al., 2002).

## ■ Providing Tools that Consumers Need

Since the mid-1990s, a growing number of public- and private-sector organizations have begun helping Americans at all socio-economic levels enhance their financial preparedness for life events, most notably retirement. The emergence of “educated, empowered consumers” in health care holds the promise, but not yet the reality, of a consumer-driven marketplace. Before consumers can successfully take on the responsibility for their own health coverage and care, they must be provided with the necessary tools:

- Literacy skills about health coverage and care.
- Knowledge about health care alternatives.
- The *belief* that they can navigate the health care system.
- Health coverage and care informed by what they value for themselves and their loved ones.

## ■ What Is Health Coverage Literacy?

Health coverage literacy is the ability to read, analyze, manage, and communicate about health coverage and health care terms, conditions, and other realities that affect general and material well-being. It includes the ability to discern benefits and care alternatives, discuss costs of coverage and care without (or despite) discomfort, plan for the possibility of a future illness or accident, and respond competently to unanticipated health events that affect personal and financial well-being, including events in the community or general economy.

Research has shown, however, that consumers often do not address health care in their budgeting or other financial planning. Many consumers do not know what type of plan they are currently enrolled in, or the quality of health care to expect under the type of plan they have chosen. In addition, consumers are not knowledgeable about health benefits in general and health care costs, in particular. They expect and accept not understanding health-related information and they ignore

what they don’t understand (Employee Benefit Research Institute, 2003).

## ■ Consumer Empowerment Through Health Benefits Education

Education determines access to occupation and income. Income, in turn, shapes access to one’s place of residence, community, social contacts and activities. Health benefits and care education can shape the life course in other, extended ways by enhancing access to coverage, the right to patient-centered care, and the ability to understand and navigate health-related finances.

After education, the second predictor of consumer empowerment is self-efficacy, which refers to a person’s belief in his or her ability to deal with different situations in a competent manner. Confidence in one’s ability to do a thing successfully increases (1) the likelihood of undertaking it, and (2) the probability of success. Many experiments have shown that a positive sense of self-efficacy can be created in those who lack it. It takes three important factors to make the shift to greater self-reliance. *Consumers can be educated to build or enhance self-efficacy in health-related decision making and other health-seeking behaviors, if these same factors are present:*

- The willingness to undertake a specific health-related action or decision that may challenge one’s sense of self-sufficiency but does not *overwhelm* it;
- The presence of supportive and reassuring others; and
- The experience of succeeding at something, with confirming feedback from others.

## ■ Financial Disconnects that Dis-Empower Consumers

Most benefits and health care service providers are focused on the bottom line. Consumers, however, are more often concerned with

assessing their needs for survival and the *human* values that transcend money and, sometimes, even health itself.

Consumers are seldom, if ever, informed about the costs of health care. They are not aware of the real price of medication for which they make a “co-payment,” nor do they think of countering a physician’s determination that an MRI is needed with a suggestion that a CT scan would save their insurance company (or themselves) money.

Consumers have little standing in a health care world that has always been structured as “top down.” They have not been taught to speak up to health care providers, to be partners in their own health coverage and care, or what to expect in connection with the *finances* of health benefits or health care.

This chasm in values perception must be bridged if the emerging health care system is to be successful, but doing so will require a much better understanding by health benefits planners and health care providers of what it is that consumers value, and how values are linked to health behaviors and to consumer health care decision making.

## ■ What Consumers Value

Values inform decisions about health, health care, and health care financing both for society and for individuals. In most cultures and for most people, financial resources for the population’s health and health care are finite, and governments, businesses, and individuals allocate health and health care resources on the basis of available money. But there are other, even more powerful motivators that transcend money. They concern life quality, reflect deeply held cultural and personal meanings, and whether consciously or unconsciously, drive nearly all of people’s behaviors and decisions.

- *Inner values* take the form of psychological or spiritual standards that individuals set for themselves. They involve people’s drives for achievement, safety and security, autonomy and control, identity—who we really are—and feelings of spiritual connectedness. In health-related experiences, these values are usually paramount.
- *Physical values* are motivating factors in how well people take care of themselves

and their environment, whether and to what extent they seek beauty and comfort, or expedience, in their surroundings, and how they fare when confronted with physical limitations and pain.

- *Social values* are inherent in people’s intimate and family relationships, in friendships and collegial connections, and in any social group where one feels that he or she “belongs.”
- *Material values* often operate in concert as two overarching financial drivers: 1) sufficiency—having enough to pay bills, to care for oneself and important others, to save for the future, to buy needed health care, to indulge on occasion, and 2) sustainability—will the money, asset, or resource last as long as the need?

All of these basic categories of values are at work, more or less, in everyone’s lives. Embedded in them are people’s requirements for equity and fairness. The *quid pro quo* for sponsors of employment-based health benefits and for health care providers who are thinking of shifting more responsibility to consumers is *education in the areas in which they intend for them to become more accountable*.

## ■ Values-Based Consumer Education in Health Benefits and Care

There is an urgent need for health benefits education based on an understanding of how personal values inform and drive health-seeking and decision-making behaviors. Programs that support the emerging models of health coverage and care, like those that support new retirement savings and pension models, will undoubtedly reward the educators as well.

We know from prior research that employer-sponsored financial education works well. Many participants in the programs we studied expressed gratitude to employers for teaching them the basics of financial management. Unfortunately, the topic that is least well covered (or well understood by consumers) involves health benefits and health care, but no other subject could be more important to their future general well-being.

Having adequate health coverage is a basic requirement for financial and personal security for most families and individuals today. But consumers also need in-depth, values-guided education about health care and health finances if they are to navigate the other financial aspects of their lives successfully. Values-based consumer health education:

- Taps into what consumer value.
- Is bottom up as well as top down.
- Is clear and respectful.
- Is motivating and empowering.
- Rewards both its sponsors and consumers.

The mobilization of the public and private sectors to increase personal financial competence is effectively creating for many Americans a sense of self-efficacy through targeted financial education. Many consumers, however, are unprepared for having even more financial responsibility shifted to them through the emerging models of health benefits and care. Moreover, they have few tools to navigate the complexities of a health care market that doesn't act like any consumer market with which they are familiar.

Health coverage literacy is essential if consumers are to be ready to assume the sort of responsibility being rapidly planned for them. It is up to plan sponsors and to care providers to help consumers prepare for the knowledge levels and the financial realities that will be needed to navigate the emerging system of health benefits by offering values-based coverage education.

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## ***Compare Your Care: A Web-Based Strategy for Consumer Activation and Physician Performance Rating***

**by Susan Prows, Ph.D., MPH  
Foundation for Accountability**

### ■ **Introduction**

At the Foundation for Accountability (FACCT) we are involved in many types of research and the promotion of policy initiatives that support a more people-responsive health care system. I've learned that this specifically refers to a system that is driven by informed, motivated consumers who help shape the system, hold it accountable for quality, and act as partners in improving their own health. I wasn't much interested in this area of health policy until I had a firsthand experience of my own.

I'll take the liberty of sharing a personal story. A year ago, I was working on state health policy issues with Governor John Kitzhaber in Salem, OR—we were trying to “save” the Oregon Health Plan from fiscal demise—when my Mom, the picture of health, was diagnosed with advanced colon cancer. In the two months previous to this, David Lansky (President of FACCT) kept approaching me, “Come work for FACCT, come work for FACCT,” and I kept saying, “I have to finish out the Governor's term, call me in January.” To make a long story short, my mom was given two weeks to three months to live as the cancer had spread to her liver and other organs. I thought, how can this be? She is one of the healthiest people in the world. Every year on her birthday she has a full physical exam, she trusts her doctor (any doctor) and does exactly what she is told to do. She has never done anything risky as far as her health is concerned, and has gone way overboard in doing all of the “right” lifestyle-type health promoting behaviors. In addition to the regular annual check-ups, she knew that smoking was dangerous before the Surgeon

General did, thought exercise was way more important than television, and knew that animal fat was dangerous before the Framingham Heart Health Study was ever conceived. But nonetheless, something had gone terribly wrong along the way. I flew to California and met with her personal care physician in Rideout Hospital in Marysville, CA, and said, “My mom has seen you every year for 25 years in the same clinic. She has continuity of care, great insurance coverage, a medical home, all of that. Weren't you screening her for early signs of cancer?” He looked at me and said, “I'm really sorry, but your mom always seemed so healthy that I never thought she needed any of those preventive and early diagnostic cancer screenings. I thought she was the picture of health.” That's when I faxed David Lansky from the hospital and said, “Tell me a little bit more about what you do to empower consumers and make their voice heard to fix the health care system.” I am now working with FACCT, heading up a research project, which, if it had been in widespread use a few years back, would have led to the early detection and cure of my mom's cancer.

### ■ **FACCT Research**

Our research at FACCT revolves around answering questions such as: How do consumers define quality health care? Who do consumers hold responsible for assuring quality health care? What do consumers expect from their doctors? What information do consumers want and need? We have done numerous surveys—online, face-to-face, telephone—and hundreds of focus groups to try to get answers to these kinds of questions.

We learned, when you boil it down to the essential elements, that consumers think that high quality health care means having easy access to a “good” doctor, and that poor quality health care is having no doctor or a “bad” doctor. Consumers, as a group, don’t tend to relate much to the clinic or office, the care system, or the various state or federal health agencies. From a consumer view, it all starts and stops with the doctor—good doctor or bad doctor. I now know that there are simple and inexpensive tools that could have been in place that would have prevented the outcome my mom experienced, the tremendous cost of her care, and the huge personal loss experienced by my dad, two sisters, and family friends. I also now know that we are not alone in our experience, that almost every family has a similar sad story to tell.

According to the research that we have done, consumers want to be partners with their doctors although they don’t know how to go about it. At least that is what they say. They want information to help them choose a good doctor, and they want information about clinical practice guidelines and quality indicators—when you tell them that such things exist. Patients/consumers have no idea that there are things called practice (or care) guidelines and quality indicators but, when they are informed, they are very interested in knowing more about how these tools can be used to improve care.

## ■ CompareYourCare

One of our research initiatives is a five-year project funded by the Robert Wood Johnson Foundation. We are in the third phase now. The consumer tool that we are developing, refining, and testing with consumers is called CompareYourCare (CYC). At [www.compareyourcare.org](http://www.compareyourcare.org) you can see an online demonstration of some of the CompareYourCare tools that are specific to various chronic diseases as well as to adult general health.

CompareYourCare is a project that will eventually allow all consumers to rate the quality of care that is provided by their doctor for all of the most common chronic diseases. Users will be able to compare the treatment that they are receiving for a specific condition with local, state, regional and national benchmarks. CYC also provides users, for their

particular chronic conditions, coaching and self-care information on communicating and partnering with their doctors. People all over the United States say they want to partner with their doctors but that they don’t know what this means in a practical sense, so CYC tools put together tailored information to give them ideas about what effective partnering is all about. CYC tools also give users self-care disease management information and tips specific to their condition and other co-morbidities.

Overall, the goals of the CompareYourCare project are to increase consumers’ awareness of what health care quality is, engage them in it, and create a groundswell message to policymakers that people want and expect quality health care. When you listen to David Lansky long enough, you think that this big public demand for quality care is going to happen at any moment, rising out of the wilderness. I have been asked if I think that large-scale consumer public demand is going to happen, and I think the answer was given to me by Marjorie Ginsburg.<sup>1</sup> She explained that since not all members of the community are critically sick at the same time, there is not enough of a groundswell going on at once. We have these little policy re-directive tremors going on all the time. Thus, everyone is chronically unhappy all the time, but I’m doubtful whether there will ever be enough of us sick enough at one time to get to where we need to be to push significant positive policy change over the tipping point.

CompareYourCare online consumer tools are built to give people detailed information on the areas where the care that they are receiving for their specific chronic condition is good or poor. All feedback messages are positive in tone. Positive messages also encourage partnership with providers using specific, theory-based health communication and behavioral techniques. But do these tools “work?” We hope so but, in order to be sure, we are involved in a series of research trials. Phase One asked the question, “Do Internet and mail surveys compare?” Phase Two, “What is the best way to bring consumers to a Web site?” Phase Three, going on right now, is a community feasibility trial in which we are learning how to—in a scientifically defensible way—put together

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<sup>1</sup> See Chapter 12.

consumer-driven, provider-level profiles of care specific to certain chronic conditions. The next phase, if we receive follow-up funding, will be a study to see what happens when we publicly disseminate these provider-level profiles to the community. Phase Five will be an evaluation of consumer use of the provider-level profiles. Does it make a difference? Do patients switch providers? Do they stay with their current provider and have different expectations for care or change the way they communicate? Are there changes in levels of “consumer activation?” Does health status change? Is there any change in cost of care?

Phase One was the implementation phase to determine whether online surveys compare with results generated from telephone surveys. We sent out 1,500 online invitations and 800 mail invitations, and we found that, although the response rates for the Internet invitations were low (about 25 percent), they were in line with the Internet penetration rate in the states where the survey data were collected. We concluded that the two modes (Internet and phone) were comparable and that online health surveys deserved the green light, at least in the research arena.

Phase Two was about real-life implementation of online surveys. We wanted to know more about different ways—effective and ineffective—to “drive” people to a Web site to get them to use the CompareYourCare Web tools. This study involved numerous research partners, different types of medical groups, a large employer, a union, and a disease advocacy group. Study participants included patients with and without chronic health conditions. In order to test ways to get respondents to the CYC Web site, we sent out personal letters, e-mails, print newsletters, and health benefits flyers. We found that response rates varied significantly by medium type. Messages from a disease-specific organization generated the highest response rates, a letter from a doctor was next highest. Letters from employers weren’t very effective. Overall, the more trusted or specific the channel is to the respondent, the higher the response rate.

For those who did respond to the survey and further provided an e-mail address—we’re cutting up the pie rather small here—the majority said they would definitely or probably recommend the CompareYourCare site to a family member or friend. About half valued the

tips and the expert information in the tool, they liked the printed information, 54 percent learned new self-care information, and about half said they would use the information provided in the tool to talk with their doctor. Eighty-two percent said they would use the ratings to actually pick a doctor, and more than 80 percent said that they would like to read other patients’ comments about their doctor. Seventy-eight percent said that they would use the CYC ratings information to pick a new doctor.

What we know so far from the first two trials is that the Internet mode is valid for gathering survey data. We believe that ratings at the physician level are possible. We can identify quality variations and problems. Just because someone is satisfied with a provider does not mean that that provider is providing quality treatment for a person’s specific health condition. We have reconfirmed that successful recruitment of a consumer to a health Web site requires the same message-channel-receiver communication strategies that are successful with other types of communication, e.g., there is no one shoe that is going to fit everybody; we have to segment our audience and use appropriate message/channel strategies for different types of receivers. We also learned that CYC Web users are extremely interested in provider ratings information and clinical information specific to their health.

When you go onto the CompareYourCare Web site, you will be given some different conditions to choose from. For purposes of this discussion I’m going to pretend that I have diabetes, so I will click on the diabetes checkup tool. The first page that a user sees is called “About You.” This part collects some basic demographic information and some comorbidity data, and asks some questions about the user’s doctor: is there one doctor that you can think of as your personal, regular doctor; and how long has this person been your doctor? Also, depending on the geographic locale, the screen provides drop down lists of physicians to select.

Next, the user goes to a screen that offers four different options. These are the four modules within CompareYourCare. There’s the *appropriate care* section that compares the care the user received at his or her last doctor visit with national treatment guidelines, in this case, specific to diabetes. The *education and*

*teamwork* section asks whether the doctor or the health care system provided the users with information and education specific to their chronic condition, in this case, diabetes. *Day-to-day living* investigates how the users cope with their diabetes in the outside world, concentrating on issues related to both physical and emotional health. The fourth module, *support and service*, asks the users to answer questions about their level of satisfaction with their experience of care. We have worked extensively with Dana Safran and her research group in Massachusetts on the testing of this unique and important instrument.

For this demonstration, users decide to go to the *Appropriate Care* section of the tool first. These are the questions that are asked about the care they received for diabetes: “At your last visit did your doctor or other health provider check your blood pressure? Yes or no?” “In the last 12 months, did your doctor or other health provider test your blood cholesterol or related substances such as lipids, HDL, LDL, or triglycerides?” Then the rest of the questions are specific to diabetes, based on national treatment guidelines for adult diabetes.

At the end of this section, the users receive the appropriate care feedback, in other words, they are presented with a graphic that compares what they said they received to what they should have received. A hundred percent is total adherence to the treatment guidelines. In this demonstration, our user got a score of 83 percent, compared with 100 percent, which is full adherence to the current treatment guidelines. The users can decide what they will do or won't do with the appropriate care score. It is our desire that they will use some of the tailored feedback strategies to talk with their doctors about their expectations, ask questions, or seek care from a different provider.

Additional information is provided on each of the key care issues, including blood pressure, cholesterol, kidney disease testing, and blood sugar. There are personalized *take charge* messages, and quotes from experts about the importance of things like diabetic foot care.

After users have gone through the modules of interest, they can click on their personalized *care guide*, go to relevant informational sites, and download a ton of good, easy-to-understand information. At the very end is a *summary checklist*. This is what users are encouraged to print out and take to their

provider at their next visit. In a graphic and positive way, the checklist details the areas where the patients received appropriate care and where they were lacking guideline-based care. Health consumers tell us that they like to have a guideline-based document like this that they can take to their doctor and say, “This is what I found out I'm getting and what I'm not getting. Let's talk about it.” It gives positive feedback messages to the provider when things were done right, and the way that it is posed is not all that humiliating when the provider wasn't doing everything that he or she should have been doing. For a more powerful negative effect, you have the daughter to go in and ring the provider's neck.

## ■ Conclusion

The CYC tools currently available are for adult primary care, coronary artery disease, asthma, adult diabetes, and depression. We will soon have tools for breast cancer, schizophrenia, arthritis, and headache. We are interested in new tool development and are always open to working with new partners to develop tools for the other chronic health conditions.

Please feel free to go to an online demonstration at [compareyourcare.org](http://compareyourcare.org) and get back to me with your feedback and any advice that you might have.



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# **Summary of Themes and Next Steps**

Summary: Chapter 15

## Summary

by Daniel M. Fox, Ph.D.  
Milbank Memorial Fund

Based on the discussions at this policy forum, I would change the title of the forum to “The Politics of Using Evidence-Based Medicine.” In this new title, politics is defined on every level, from the personal self-reflection through the interpersonal encounters through the politics that is the main industry of this town. My three points. Here is what I thought I heard:

- First, evidence about effective health care interventions is getting better and so is diffusion of this evidence. But the stakes in using—or not using—the evidence get higher, too, for everybody.
- Second, evidence informs but it never determines decisions by individual citizens, consumers, patients, their families, clinicians, provider organizations, insurers and other payers, and purchasers. Evidence informs judgment about coverage policy, what health professionals recommend, and what consumers and patients choose; it does not determine judgment.
- Third, not everything that is claimed to be evidence is indeed evidence. Lots of competing claims to virtue were made during this discussion. You will choose which claims you find most virtuous.

I will now editorialize. There has been a discussion of one set of claims to virtue that stands the test of international clinical science in the early years of the 21<sup>st</sup> century. Specifically, I refer to recent advances in the science of research synthesis. This science has made extraordinary progress in the past two decades, all over the world. The major products

of that science are called either systematic reviews or evidence reviews.

As a result of the science of research synthesis, we can now say for the first time in the history of science that the word *confidence* can mean exactly the same thing to decision makers, public or private, individual or collective, as it does to researchers. There are, however, two limitations on the production of systematic reviews. One is the absence of enough good quality randomized clinical trials to synthesize. The other limitation is the lack of infrastructure funding to produce reviews that meet the highest international standards.

Doing more syntheses and using them as guides to coverage and clinical decisions, as well as guides to making personal choices is, I’m happy to tell you, creating demand for more trials and more infrastructure. That demand needs to be accompanied by broad education of the media, the public, the professions, and purchasers.



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## ***Will Wider Use of Evidence-Based Medicine Significantly Enhance Health Care Quality and Affordability? Implications for Consumer-Driven Health Benefits***

### **■ Attendees List**

Martin Ahrens  
National Rural Electrification Cooperative  
Association

Anne-Marie J. Audet  
The Commonwealth Fund

Merton C. Bernstein  
Washington University

Stephen Blakely  
EBRI

Randy R. Bovbjerg  
The Urban Institute

Katherine Browne  
National Partnership for Women & Families

Janice Y. Burnham  
The ROC Group

Rachel Christensen  
EBRI

Gary Claxton  
Henry J. Kaiser Family Foundation

Vivian Coates  
ECRI

Sally Coberly  
National Health Policy Forum

Sara R. Collins  
The Commonwealth Fund

Benjamin V. Cooper  
Printing Industries of America, Inc.

Robert Coppedge  
Capitol Health Partners

Robert M. Crane  
Kaiser Permanente

Patsy D'Amelio  
EBRI

Thomas J. Dawson III  
Employee Benefits Security Administration

Darwin Dayan  
Pacific Maritime Association

Diana C. Dennett  
American Association of Health Plans

Louis H. Diamond  
MedStat

Vanessa Edwards  
Blue Cross Blue Shield Association

Janice Ervin  
EBRI

Steven Ferruggia  
Buck Consultants, Inc.

Benjamin Finder  
Kaiser Family Foundation

Steven Findlay  
National Institute for Health Care  
Management

Howard Fluhr  
The Segal Company

Robert B. Giffin  
Institute of Medicine

John Greene  
National Association of Health Underwriters

Jennifer Grosky  
AAMC

Kris Haltmeyer  
Blue Cross Blue Shield Association

Jean Hearne  
Congressional Research Service

Robert B. Helms  
American Enterprise Institute

Erin Holve  
Kaiser Family Foundation

Howard Isenstein  
Alliance for Health Reform

James Jaffe  
EBRI

John Kalamarides  
CIGNA Retirement & Investment Services

James Knutson  
Aircraft Gear Corporation

Peter V. Landin  
Barclays Global Investors

Nicholas D. Latrenta  
Metropolitan Life Insurance Companies

Rebecca Knoll Lawrence  
Willis North America Inc.

Jason S. Lee  
National Organization for Research at Chicago  
(NORC)

Susan Lexer  
Office of Rep. Tom Allen

John MacDonald  
The Hartford Courant

Carol Malone  
National Education Association

Janet M. Marchibroda  
eHealth Initiative

Joseph Marlowe  
Aon Consulting

David Maslen  
Aon Consulting

Lisa L. Mattie  
Milliman USA, Inc.

Anne Mayberry  
National Rural Electrification Cooperative  
Association

Paul McAuliffe  
The Federal Reserve Bank - Office of Employee  
Benefits

Peter McMenamin  
PHRMA

Dwight McNeill  
Brandeis University

Don Metz  
Health Affairs

Joe Moser  
Galen Institute

Ted Nelson  
National Rural Electric Cooperative Association

Toshihisa Okamoto  
EBRI Fellow

Bettye Page-Wilson  
Pacific Maritime Association

Stephen Pennacchio  
Merrill Lynch

Leon Piper  
Delta Air Lines, Inc.

James F. Rodgers  
American Medical Association

Joel A. Rubin  
Office of Rep. Brian Baird (WA-03)

Inger Saphire-Bernstein  
Blue Cross Blue Shield Association

Kathleen B. Sarli  
Merck & Company, Inc.

Melinda Silver  
U.S. Department of Labor

Peter J. Smail  
Fidelity Employer Services Company

Miles Snowden  
Delta Air Lines, Inc.

Scott M. Spencer  
National Rural Electric Cooperative Association

Anthony J. Tirone  
JCAHO

Laura Tollen  
Kaiser Permanente Institute for Health Policy

Tomas Valdivia  
Definity Health

Alicia Willis  
EBRI

Jill Yegian  
California Healthcare Foundation

## ■ Presenters List

Carolyn M. Clancy, MD  
Agency for Healthcare Research and Quality

Daniel M. Fox, Ph.D.  
Milbank Memorial Fund

Paul Fronstin, Ph.D.  
Employee Benefit Research Institute

Marjorie Ginsburg, MPH  
Sacramento Healthcare Decisions

Jessie Gruman, Ph.D.  
Center for the Advancement of Health

Mark Helfand, MD, MPH  
Oregon Evidence-Based Practice Center

Jeffrey Charles Lerner, Ph.D.  
ECRI

Richard Mathis, Ph.D.  
BlueCross BlueShield Tennessee

Susan L. Prows, Ph.D., MPH  
Foundation for Accountability

Dennis E. Richling, MD  
Midwest Business Group on Health

Steven H. Sheingold, Ph.D.  
Centers for Medicare & Medicaid Services

Lois A. Vitt, Ph.D.  
Institute for Socio-Financial Studies

Paul J. Wallace, MD  
Care Management Institute, Kaiser  
Permanente

Ray Werntz  
Employee Benefit Research Institute

Thomas H. Wood, MD  
Milliman Care Guidelines

America spends more than 14 percent of its gross domestic product (GDP) on health care each year. Every modern-day president has declared that he would lead action to reduce the continuous trend of growth. Each has declared that the nation cannot afford more. Yet, advances in research, technology, marketing, population age, and more continue to come together to push national health spending higher each year.

Real health care inflation is high relative to overall inflation, health insurance premium growth is at historically high levels, individuals are being asked to pay more when they seek health care services, and the Internet—more than any other advance of the modern age—has made it possible for the inspired individual to become an "informed" health consumer by placing the contents of thousands of libraries a simple mouse click away. We know, however, that not everything is on the Internet, and some of what is there may not be of actual value or may simply be wrong.

How can individuals find what is right, or best, or proven? How can the health system be moved to do a better job of testing, documentation, communication, and performance? How can individuals find what is right (or best) or proven, and can they determine what's best for them personally? Will increased evidence-based care stabilize or accelerate cost inflation?

Annual double-digit increases in the cost of providing health benefits have proven to be an engine for experimentation, testing, and adoption of new approaches. Yet, the health system and decision-making are still highly fractured. Where evidence-based medicine has been developed, it cannot always be effectively communicated, and even if communicated, it cannot always be effectively used for decision-making.

About a hundred leaders of the health sector, policymakers, employers, labor representatives, and others examined the promise, the obstacles, and the realities of evidenced-based medicine during the Employee Benefit Research Institute's May 8, 2003, policy forum: "Will Wider Use of Evidence-Based Medicine Significantly Enhance Health Care Quality and Affordability? Implications for Consumer-Driven Health Benefits." The papers contained in this book, based on the policy forum's proceedings, explore in detail the research that has been done on the topic and the implications for consumers, business, and government.

This book provides a comprehensive review of how much has been done, and also the challenges that lie ahead if "evidenced-based" medicine is to become the rule rather than the exception, and if consumer-driven health care is to allow the consumer to have full information on all possible treatments and procedures and the evidenced-based efficacy of all of them.

2121 K Street NW, Suite 600  
Washington, DC 20037-1896

(202) 659-0670  
Fax (202) 775-6312

Web Sites:

[www.ebri.org](http://www.ebri.org)  
[www.ourhealthbenefits.org](http://www.ourhealthbenefits.org)  
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