AcademyHealth

Research Insights

Using Evidence to Design Benefits

Summary

Whether evidence-based research fuels the broad reforms in health care delivery that are essential to improving quality and reining in health care costs will depend not only on the strength of research efforts but also on the development of effective strategies to integrate evidence into decisions about how people use health care. Evidence-based purchasing programs rely on a broad variety of benefit design strategies, including strategies for determining "essential" or "core" benefits. They can provide ways to link insurance design to provider performance, e.g., adherence to evidence-based practice. Evidence-based benefit designs create incentives—in the form of either financial incentives or enhanced services—that drive consumer behavior. The goal is to encourage people to use services that are effective and provide clinical benefit for the money spent. As the application of evidence-based designs advances, payers and policymakers will face trade-offs between the specificity of benefit structures and administrative efficiency. "Getting it right" can be technically difficult and expensive as well as politically problematic. Evidence to-date suggests the need for research to address concerns related to establishing expectations about the standards for evidence in support of decisions about what insurance should pay for, determining how to expand the use of evidence to broader categories of health benefits, and developing a better understanding of how different types of incentives work with different populations.

Introduction

Health insurance in the United States plays a critical role in how health care works—for better or worse. What insurance pays for can affect when, where, and how people use health care and, consequently, health care outcomes. Historically, insurance has provided some level of protection from the costs associated with the community standard for reasonable, appropriate health care. The 2009–2010 debate over health care reform focused on the role that insurance should play in addressing critical problems of health care access, costs, and quality.

Clinical effectiveness and outcomes research, including comparative effectiveness research (CER),[1] can help clinicians, consumers, health

Genesis of This Brief:

At its annual National Health Policy Conference (NHPC) in Washington, D.C. in February 2010, AcademyHealth convened a panel of experts who are the forefront of efforts to use evidence about medical effectiveness, including comparative effectiveness research, to design better—i.e. higher quality, more cost-effective – health benefits. Clifford Goodman, Ph.D., vice president, The Lewin Group; Sam Nussbaum, M.D, executive vice president and chief medical officer, WellPoint, Inc.; and Kevin Volpp, M.D., Ph.D., director, Center for Health Incentives, Leonard Davis Institute of Health Economics participated in the panel. Peter Neumann, Sc.D., director of the Center for the Evaluation of Value and Risk in Health at the Institute for Clinical Research and Health Policy Studies at Tufts Medical School, moderated the discussion. This issue brief builds on the presentations and discussion at the NHPC session.

care organizations, purchasers, and policymakers make informed decisions that can improve health care.[2] Evidence-based health care draws on a wide range of research, including clinical trials, cost-effectiveness studies, comparative effectiveness studies, and population-based outcomes research. CER is playing an increasingly important role in efforts to reform health care by identifying the health care technologies and services that produce the best health outcomes. Yet, whether evidence-based research fuels the broad reforms in health care delivery that are essential to improving quality and reining in health care costs will depend not only on the strength of research efforts but also on the development of effective strategies for integrating evidence into decisions about how people use health care.[3]

In current practice, the application of evidence-based benefit design often combines direct and indirect incentives for both providers and consumers. For analytical purposes, however, the differences between the two are important. The structure of health benefits can focus primarily on offering incentives for clinicians and provider organizations to "do the right things" or it can focus directly on consumers, by crafting benefits and cost-sharing that encourage them to choose insurance plans that are providing high-value care, to use health care that has been shown to be effective, or to forego care that is ineffective or of marginal benefit. Approaches to designing benefits focused on providers can be structured as "evidence-based purchasing," while the term "evidence-based insurance design"[4] refers to approaches that focus primarily on structuring cost-sharing to promote the use of services or technologies that provide benefit for the money spent.[5]

This brief draws on some of the leading-edge initiatives in the public and private sectors and on emerging insights drawn from recent work, including behavioral economics research, ongoing technology assessment programs, and experience with innovative benefit designs adopted by large group insurance carriers. Together, the evidence to date points to some key areas for future, research and raises broader concerns that may need to be addressed if evidence on effectiveness and quality is to be a driving force in health care reform. These include establishing clear expectations about the standards for evidence that can support decisions about what insurance should pay for, determining how to expand the use of evidence to broader categories of health benefits, and developing better understanding of how different types of incentives work with different populations.

Figure 1 : **Using Evidence to Design Benefits: CMS Findings on Genetic Testing for Warfarin Anticoagulation Response**

With input from the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), the Centers for Medicare & Medicaid Services proposed limited coverage—that is, coverage restricted to participation in qualified clinical trials—of genetic testing to predict individuals' response to the anticoagulant drug warfarin.

- "CMS found no evidence that genetic testing can replace PT/INR [prothrombin time/ International Normalized Ratio Testing] for titrating and monitoring warfarin therapy…. [W]e propose that the evidence is insufficient to determine that pharmacogenomic testing to predict warfarin responsiveness improves patient-oriented health outcomes related to the underlying indication for warfarin anticoagulation or adverse events related to warfarin therapy itself. In addition, we propose that the evidence is insufficient to determine that pharmacogenomic testing to predict warfarin responsiveness leads to changes in physician management of beneficiaries' anticoagulation therapy that would result in positive outcomes."[1]

- Noting that the testing offers promise, CMS proposed "coverage with evidence development" in which Medicare would cover the test only for beneficiaries enrolled in an RCT [randomized clinical trial] meeting certain specifications, one of which is "[t]he research study protocol must explicitly discuss subpopulations affected by the treatment under investigation." Such RCTs would provide further evidence that could inform a revised coverage determination.

Other research continues on how genotypes affect sensitivity to warfarin and how well genetic tests predict safer and more effective doses of warfarin, including a large, multicenter RCT designed to determine whether genetic information provides additional benefit to what can be accomplished with traditional clinically based warfarin information alone.[2]

[1] CMS. Proposed Decision Memo for Pharmacogenomic Testing for Warfarin Response (CAG-00400N), May 4, 2009.
[2] Shurin S.B. and Nabel E.G. Pharmacogenomics--ready for prime time? New England Journal of Medicine, Vol. 358, No. 10, March 6, 2008, pp. 1061-3.

Source: Goodman C., The Lewin Group. Presentation slide from session on "Using Evidence to Design Benefits," AcademyHealth National Health Policy Conference, Washington, D.C., February 9, 2010.

Evidence and Health Insurance

In the United States, the use of effectiveness and outcomes evidence to shape the scope and generosity of health benefits has been slow to take hold. The complicated array of systems and rules that govern public and private health coverage and the opposition to limitations on coverage on the part of some health care providers and consumers confound efforts to change how insurance is designed.[6] But rising costs are driving federal and state government agencies as well as various organizations and consortia—both domestic and international—to build on the foundation of technology assessment and clinical effectiveness research to find better ways

to increase the quality and effectiveness of health care.[7]

Evidence can help providers and policymakers shape how health care is used in several interrelated but operationally distinct ways. For example, health plans and third-party payers can use evidence on outcomes, comparative effectiveness, safety and efficacy,[8] and cost-effectiveness[9] to determine whether to cover particular treatments or technologies.

Public and private payers in the United States have devised different strategies for integrating evidence into their payment policies. Some larger insurers and health plans have established institutional arrangements and dedicate funding for programs that provide them with comparative effectiveness evidence. For example, the Technology Evaluation Center (TEC) founded in 1985 by the Blue Cross Blue Shield Association works with organizations in the public and private sectors to generate comprehensive evaluations of the clinical effectiveness of medical procedures, devices, and drugs. Since 1993, Kaiser Permanente has used the evidence from TEC assessments to help develop its health plan's clinical policy decisions and clinical practice guidelines.[10] WellPoint draws on CER evidence and on input from panels of experts convened by medical specialty societies from across the United States to assign existing and new treatments and drugs to one of four value tiers.[11]

Policies based on CER regarding the appropriate use of a treatment or technology and the reimbursement of associated costs can directly and indirectly affect the behavior of both providers and consumers. In some countries, national health care systems draw directly on comparative effectiveness and outcomes research when determining the benefits to be covered by insurance. In the United Kingdom, the National Health Service uses reviews by the National Institute for Health and Clinical Excellence (NICE) as the basis for its coverage decisions. In Germany, the Federal Joint Commission draws on the work of the independent Institute for Quality and Efficiency in Health Care; in Australia, the Pharmaceutical Benefits Scheme develops CER data. In these latter two countries, a negative recommendation stating that evidence does not support the use of a drug or technology is binding and prevents public insurance programs from covering the technology or treatment in question.[12,13]

In the United States, both public and private health care systems are developing increasingly sophisticated systems for reviewing evidence about new medical technologies.[14] The Centers for Medicare & Medicaid Services (CMS) has set out criteria for reviewing and evaluating information on the effectiveness and appropriateness of medical items and services that are covered or may be covered under Medicare. The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) judges the strength of available evidence and makes recommendations to CMS on specific clinical topics.[15]

Recommendations about coverage are not limited to a simple "yes" or "no." Increasingly, researchers, payers, and manufacturers are working collaboratively to develop policies that will permit the "managed entry" of new products under controlled conditions that involve ongoing testing and evaluation. For example, manufacturers and public payers have established data requirements for clinical trials to ensure the reporting of data needed to evaluate the process and outcomes of care in "real-world" settings[16] (Figure 1). At the same time, researchers are developing methods to produce sound experimental and observational data in a timely and practical manner.[17]

Evidence-based policy is also helping shape coverage policies for state-financed programs. For example:

- Established in 2006, the Medicaid Evidence-based Decision Project, housed at the Center for Evidence-based Policy at the Oregon Health & Science University, is a collaborative effort that supports 11 participating state Medicaid programs by providing rapid reviews, comprehensive reports, systematic technology assessments, and related information and technical assistance. The participating states use the evidence and reports to inform coverage decisions including non-coverage decisions for arthroscopy of the knee for osteoarthritis, some types of low-back pain treatment, and negative-pressure therapy for specified conditions.[18]

- The Washington State Health Technology Assessment Program (HTA) has conducted assessments resulting in public insurance programs' non-coverage of a variety of services, including upright/positional MRI and discography tests and surgical procedures for knee arthroscopy and lumbar fusion.[19]

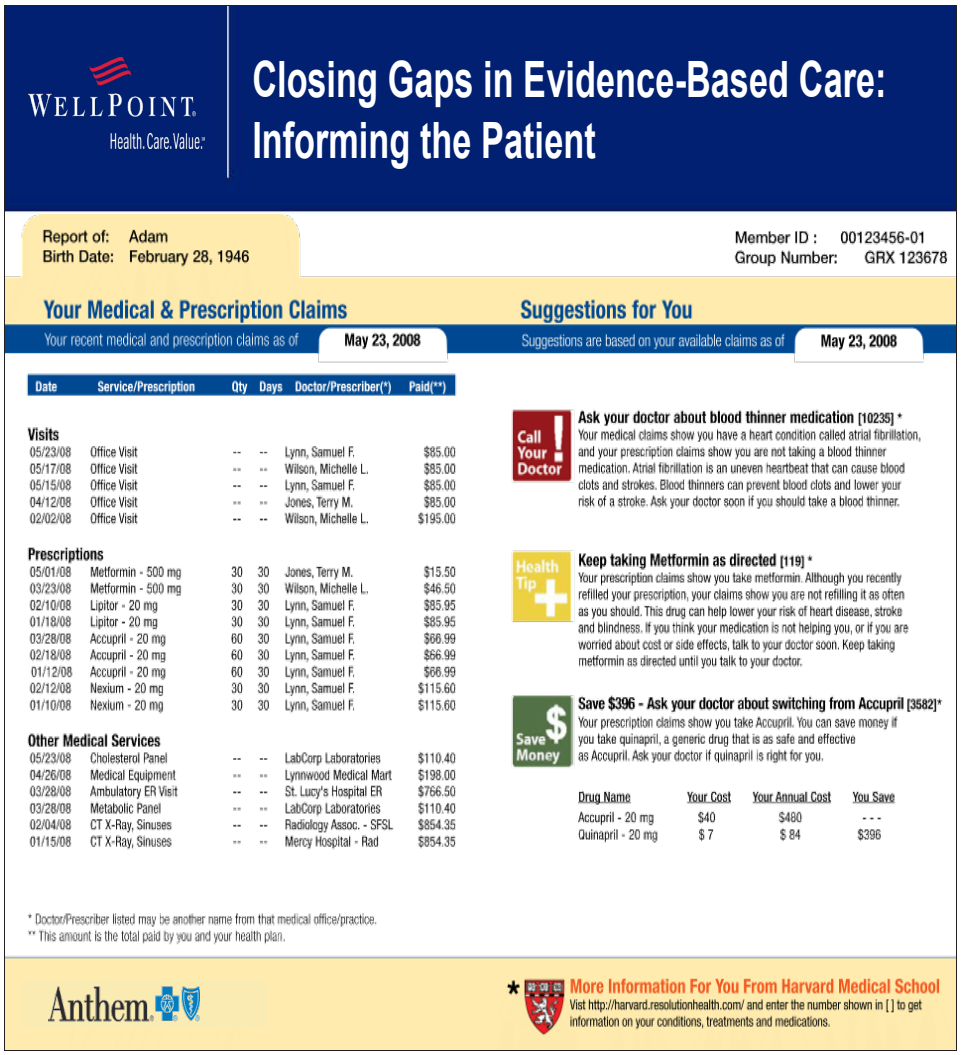
In the private sector, an increasing number of organizations are collaborating to review data on effectiveness. Newly formed groups are developing the capacity to perform comparative effectiveness studies for clients interested in improving quality and controlling the costs of coverage. Some focus primarily on prescription drugs but also on devices and imaging technologies; others focus on approaches to preventing illness or managing chronic or high-cost medical conditions. While private insurers are concerned about coverage policy, they often follow Medicare's lead when deciding about non-coverage of technologies or treatments.[20] Private insurers' independent decisions to exclude

a particular technology or treatment regimen based on CER can, however, be controversial—both politically and technically—if insurers base their decisions on an evidence base that differs from that used by other large payers, particularly public payers. If necessary, private insurers can adopt financial incentives that drive clinicians and consumers to use more effective services rather than less effective, lower-quality services.

Evidence-Based Purchasing

Evidence-based purchasing can encompass a broad variety of benefit design strategies, including those used to determine "essential" or "core" benefits, but it also provides a way to link insurance design to provider performance, e.g., adherence to evidence-based practice. To date, evidence-based purchasing has largely focused on prescription drugs. Indeed, comparative effectiveness data are critical in decision-making about formularies, particularly policies about generics and drug substitutions. Eleven state Medicaid programs, along with the Canadian Agency for Drugs and Technologies in Health, currently participate in the Drug Effectiveness Review Project (DERP) housed at the Oregon Health & Science University's Center for Evidence-based Policy[21] (also the home of the Medicaid Evidence-based Decision Project). The DERP's reports have provided input for the development of formularies as well as for consumer education.

Figure 2:



Source: S. Nussbaum, Wellpoint, Inc. Presentation slide from session on "Using Evidence to Design Benefits" at the AcademyHealth National Health Policy Conference, Washington, D.C., February 9, 2010.

Oregon has been in the forefront of efforts to apply research evidence to the design of system-wide evidence-based purchasing. In 1989, the Oregon Health Plan, working with the state system that oversees Medicaid-covered services, began a lengthy process that included systematic review of available medical evidence to rate the clinical importance and effectiveness of treatments for all health care conditions. Beginning in 1994, they published a priority list of conditions based on these systematic reviews became the basis for determining which services the state's Medicaid program would cover. In 2007, Oregon adopted the priority list of benefits as the basis for an essential benefits package as part of a legislative mandate to establish a universal health plan for the state. The health plan assigned benefits to one of five tiers based on the priority ranking of the service. The highest-priority services are assigned to the "value-based tier," which includes "low-cost, evidence-based services whose utilization is encouraged to prevent downstream costs and adverse outcomes." If the Oregon reform legislation were enacted, the value-based tier would constitute the minimum set of benefits for health plans offering coverage in the state.[22] Washington State also uses effectiveness research to grade Medicaid services.[23]

Evidence-based purchasing can also inform decisions about how clinicians or provider organizations fit into a particular insurance plan. Effectiveness and outcomes research may be translated into an array of measurement criteria for use in identifying high- or poor-performing providers. In setting up provider networks, for example, payers can consider whether physician groups have implemented specific protocols or programs such as evidence-based approaches to managing clinical depression or preventive screening. The composition of networks can, in turn, affect the availability and scope of enrollee benefits.

- Several states and public/private consortia have adopted insurance programs that include tiered provider networks based in part on evidence-based measures of quality or effective practice. Among the states are Massachusetts (Massachusetts Group Insurance Commission), Wisconsin

(Department of Employee Trust Funds), and Washington (Puget Sound Health Alliance).[24] Typically, consumers who enroll in health plans that meet the standards for the higher tiers have lower cost-sharing requirements.

- Payers can use effectiveness research to help them establish criteria for "centers of excellence" or related programs that steer enrollees to particular facilities or provider groups. The Blue Cross Blue Shield "Blue Distinction" program, for example, has identified more than 1,600 centers across the United States that meet its criteria; that is, they draw on "evidence-based thresholds for clinical quality" for six procedures and conditions.[25]

- Evidence-based criteria can be incorporated into insurance payment systems by selecting the providers to be included in networks, adjusting payments to providers who meet established best practice standards under pay-for-performance systems,[26] or basing global payments on the application of evidence-based principles.[27]

Evidence-Based Insurance Benefits

Many payers and organizations that purchase insurance on behalf of employers use some of the findings from effectiveness research to address increasingly complex aspects of benefit design in areas such as pharmaceutical benefits, disease management, and preventive services. To drive consumer behavior, evidence-based benefit designs create specific incentives in the form of either financial incentives or enhanced services. The designs generally encourage consumers to use services that are deemed effective and provide clinical benefit for the money spent.

Insurers have taken several approaches to designing evidence-based benefits. For example, researchers at the Center for Value-Based Insurance Design at the University of Michigan have categorized four basic approaches that entail progressively more complex design:[28]

- **Design by service**. All enrollees using selected drugs or services pay reduced or zero co-payments. Examples include the Pitney Bowes program initiated in 2002 that reduced co-payments for asthma, diabetes, and hypertension drugs and a similar program adopted by Marriott International, Inc., for drugs used to treat diabetes, heart disease, and asthma.

- **Design by condition.** Health plans identify patients with specific clinical conditions, e.g., diabetes or hypertension, who are eligible for reduced or waived co-payments or co-insurance for medications or services. The University of Michigan Focus on Diabetes Program, for example, reduced co-payments for selected "evidence-based" medications and services for employees with diabetes.

- **Design by condition severity.** High-risk patients eligible for disease management programs qualify for lower (or zero) co-payments or co-insurance A program introduced by Caterpiller, Inc., for example, identified people at highest risk for coronary heart attack, stroke, or diabetes. The program waived the co-payment for drugs for diabetes and related co-morbidities and provided free colorectal screening for at-risk employees as well as other disease prevention and monitoring services.

- **Design by disease management participation.** Reduced or waived co-payments or co-insurance is tied to (1) participation in a disease management program provided by a preferred network, and (2) participation in specific health promotion activities or the attainment of specific clinical benchmarks. A pilot program developed by the Service Employees International Union (SEIU) for workers in Minneapolis and Milwaukee reimbursed employees with chronic conditions for their doctor visit co-payments if they enrolled in a disease management program and reimbursed employees without chronic conditions for their doctor visit co-payments if they participated in telephonic coaching for weight loss or smoking cessation.

Implementing evidence-based design depends in part on data systems that can identify target populations, assess the use of particular diagnoses and use of services, and calculate and track payments and cost-sharing requirements. As health information systems become more accurate, usable, and widely adopted, health plans will be able to make sophisticated use of evidence. They will identify populations that might benefit from specialized benefits or provide customized information that could help individuals obtain appropriate, evidence-based care. Figure 2 shows how WellPoint uses its medical and laboratory claims database to inform physician-patient dialogue by identifying possible gaps in recommended care and potential safety issues associated with drug interactions across a patient's entire experience.

Challenges to Evidence-Based Insurance Design

Reliance on evidence-based health care is growing in both the public and private sectors in the United States and internationally, but only limited guidance is available to policymakers or plan administrators who want to make the best use of this evidence base. In the United States, the complexity of the public and private health delivery and health insurance systems creates both opportunities and challenges for translating research findings into practice. In a competitive multipayer system, insurance plans survive by offering different sets of health insurance benefits to different populations. A multiplicity of plan incentives that differ in detail or requirements, even if intended to encourage providers and consumers to use health care more effectively, could prove frustrating to providers and patients.[29] At the same time, from an actuarial perspective, benefit designs that include lower cost-sharing for plan participants with certain conditions could attract enrollees with those conditions.[30] In addition, public payers

need to consider the health care needs of different, often vulnerable populations in the context of public policy and the political environment. The details of how benefits are structured—what type of health care is covered, the conditions of coverage, and the allocation of reimbursement for the costs of covered services between providers and consumers—all vary tremendously across types of public and private insurance.

Currently, the evidence is insufficient to support general conclusions about the effects of evidence-based approaches on the quality or cost-effectiveness of health care.[31] Similarly, the dearth of information limits decisions on how to structure aspects of benefit design, including financial incentives, to optimize the integration of effectiveness findings into practice. Efforts to move ahead with evidence-based insurance designs face several important issues.

- One underlying issue relates to the need to establish consistent expectations or standards for evaluating new treatments or technologies and making determinations about what health insurance does/does not cover and under what circumstances. The goal should be to set out clear expectations about (1) health outcomes (2) comparative effectiveness data that drug and device manufacturers need to generate, and (3) how outcomes and effectiveness will be evaluated and monitored over time. For example, policymakers may establish rules for what is termed "managed entry" of new products, which would include programs for coverage with evidence development, where coverage is approved only if care is provided as part of a clinical trial. Evidence from that trial would help inform a final coverage decision.[32] The coverage determination process needs to reflect the continually changing environment of health care technology and health care delivery. A stable, accountable system is essential for assuring the legitimacy of evidence-based insurance design.

- A second, even more difficult issue involves how to move beyond the narrow scope of current efforts in evidence-based insurance design, which largely focus on (1) evaluating medical innovations—drugs, devices, treatment protocols, and other technologies—to determine if they should be covered by insurance and (2) providing incentives that encourage consumers to use high-value, effective services. Much of every-day medical care has not been subject to rigorous comparative effectiveness research. Even with evidence that the effectiveness of every-day practice could be improved, it is hard to implement incentives that target high-cost, low-value services that are already part of community practice.[33] Electronic medical records and advances in health information technology should significantly increase the quality and usability of data on the process and outcomes of health care. Greater use of large-scale observational data sets to track use and outcomes can help fill some of the gaps in information, but even keeping abreast of new technologies is a daunting task

- A third issue pertains to an improved understanding of how different forms of incentives work, thereby accelerating the effective use of evidence-based benefit designs. A thorough understanding of incentives could be particularly useful in building negative incentives into value-based insurance design in order to discourage the use of low-value services.[34] In fact, behavioral economists have posited that the achievement of better outcomes, including reduced morbidity and mortality, may depend as much or more on learning how to motivate behavior change as on developing more effective treatments.[35] Research on how individuals respond to incentives associated with health behavior, care seeking, and using different types of providers and services can, for example, build on behavioral economics and related disciplines to address questions about how positive incentives versus negative incentives—carrots versus sticks[36]—influence consumer behavior such as taking recommended medications or participating in smoking cessation programs.[37] Research could also help answer questions about what thresholds, in terms of dollars or time frames, work for different people with different health needs or how different approaches to structuring benefits and cost sharing do/do not result in the desired response in different patient populations.[38]

- A fourth issue relates to questions about the implications of insurance coverage for health and economic equity as well as perceptions of equity. For example, singling out patients at risk for hypertension and diabetes by reducing out-of-pocket costs of office visits for those participating in exercise classes may appear discriminatory if patients unable to participate in such programs pay higher premiums. Evidence-based benefit designs may appropriately limit coverage for technologies or treatments that benefit small subgroups of patients, but the process of making exceptions can involve significant time and effort for both plan administrators and consumers. Designs intended to promote the use of beneficial services by particular patients or to provide for highly specialized services for certain patients can also lead to increases in the costs of care for all enrollees because the appropriate use of medically effective services may or may not result in savings.

Designing benefits linked to evidence may involve trade-offs between the specificity of benefit designs and administrative efficiency. "Getting it right" can be technically difficult and expensive, not to mention politically problematic. Yet, a more generalized approach would be less likely to apply specialized evidence-based incentives to the most effective care either service by service or case by case, limiting the direct integration of CER into insurance design. "Moving in the right direction" could, however, link evidence to benefits, guiding consumers in making

better choices about important aspects of health behavior and use of services.[39]

As the effectiveness evidence base grows, the need for sound research to support policy decisions about how to use evidenced-based findings will become even more crucial. Insurance design offers a potentially powerful tool for integrating research into practice. Whether better information can drive better use of health care will, however, require both better systems and processes for determining the range of insurance coverage and a clearer understanding of how consumers respond to insurance incentives.

About the Author

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Endnotes

1 As defined by the Institute of Medicine, for example, CER compares the benefits and harms of alternative treatments to prevent, diagnose, treat, or monitor clinical conditions or improve quality of care (IOM June 2009).

2 This concept of the research goal draws on the discussion of the purpose of comparative effectiveness research set out by the Institute of Medicine (IOM June 2009).

3 Volpp K. and A. Das. "Comparative Effectiveness–Thinking beyond Medication A versus Medication B," *New England Journal of Medicine*, Vol. 361, No. 4, July 23, 2009, pp. 331-3.

4 The term "value-based" is commonly used to refer to systems that employ effectiveness and outcomes research to craft cost-sharing strategies in the design of drug or other health benefits. However, approaches that are labeled "value-based" are not necessarily evidence-based. They may also incorporate dimensions of "value" such as offering benefits that could improve quality of care but have not been thoroughly evaluated and/or proven to be effective or cost-effective, or performance on various indicators of consumer satisfaction. The term "evidence-based insurance design" used here refers more specifically to benefits, including coverage and financial incentives, based on the systematic analysis of the clinical effectiveness, or comparative clinical effectiveness, of specific health care technologies, treatments, or services

5 Fendrick, A. "Value-Based Insurance Design Landscape Digest." Center for Value-based Insurance Design and National Pharmaceutical Council, July 2009, available at http://www.sph.umich.edu/vbidcenter/pdfs/NPC_VBIDreport_7-22-09.pdf.

6 See, for example, Docteur E. and R. Berenson. "How Will Comparative Effectiveness Research Affect the Quality of Health Care?" Washington, D.C.: The Urban Institute and The Robert Wood Johnson Foundation, February 2010; Garber A. and S. Tunis. "Does Comparative-Effectiveness Research Threaten Personalized Medicine? *New England Journal of Medicine*, Vol. 360, No. 19, May 7, 2009, pp. 1925-7;and Avorn J. "Debate about Funding Comparative-Effectiveness Research," *New England Journal of Medicine*, Vol. 360, No. 19, May 7, 2009, pp. 1927-8.

7 Federal agencies within the U.S. Department of Health and Human Services sponsoring comparative effectiveness research include the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare & Medicaid Services (CMS), and the National Institutes of Health (NIH), with AHRQ and NIH playing lead roles in a major CER initiative created under the American Recovery and Reinvestment Act of 2009. The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) also support some CER work. The U.S. Department of Veterans Affairs (VA) conducts and supports a large program of comparative effectiveness research, and the U.S. Department of Defense conducts some CER work as well. State governments fund CER through programs such as the Drug Effectiveness Review Project and the Medicaid Evidence-Based Decisions Project organized by Oregon, and the Washington State Health Technology Assessment Program. Private sector programs and consortia include technology and outcomes assessment organizations, units, and committees organized by insurance companies and health plans, e.g., HealthCore, a subsidiary of WellPoint (www.healthcore.com), the Blue Cross Blue Shield Technology Assessment Center; other groups include the Institute for Clinical and Economic Review at Massachusetts General Hospital's Institute for Clinical and Economic Review, the Tufts Center for the Evaluation of Value and Risk in Health, the Center for Medical Technology Policy, the ERCI Institute, and Hayes, Inc. Descriptions of many of these and other programs focused on pharmaceutical and clinical effectiveness may be found in Hussey P., E. Gillen, and E. McGlynn. "Feasibility and Design Options for a Potential Entity to Research the Comparative Effectiveness of Medical Treatments," a report sponsored by the Commonwealth of Massachusetts (Rand Health 2010), available at http://www.rand.org/pubs/technical_reports/2010/RAND_TR803.pdf. See also Congressional Budget Office. Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role, Washington, D.C., December 2007, available at http://www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf, and Federal Coordinating Council for Comparative Effectiveness Research. Report to the President and the Congress, June 30, 2009, available at http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf.

8 With respect to clinical care, efficacy refers to whether a technology or service has the intended effect under ideal conditions; safety refers to whether a technology or service causes or has the potential to cause harm to patients. The FDA review of new drugs and technologies focuses on safety and efficacy.

9 Cost-effectiveness is an economic concept usually measured in terms of a technology's or service's cost in achieving a unit of a health benefit, usually an extra year of life or quality-adjusted year of life. See Gluck M.E. "Incorporating Costs into Comparative Effectiveness Research," AcademyHealth Research Insights, http://www.academyhealth.org/files/publications/ResearchInsightsCER.pdf.

10 Blue Cross Blue Shield Association, http://www.bcbs.com/blueresources/tec/.

11 The fours tiers established by WellPoint are (1) superior: deserving of our nation's investment; (2) comparable: value-based decisions should be based on equally effective treatment options; (3) personalized: treatments need to be managed as they may be appropriate or effective for only some subset of the population (e.g., individuals with a particular genetic make-up); and (4) ineffective: treatments that need to be removed from the system because research proved them ineffective and/or potentially harmful. S. Nussbaum, Wellpoint, Inc., presentation slide from session on "Using Evidence to Design Benefits," AcademyHealth National Health Policy Conference, Washington, D.C., February 9, 2010.

12 Hussey P., E. Gillen, and E. McGlynn. "Feasibility and Design Options for a Potential Entity to Research the Comparative Effectiveness of Medical Treatments," a report sponsored by the Commonwealth of Massachusetts (Rand Health 2010), available at http://www.rand.org/pubs/technical_reports/2010/RAND_TR803.pdf.

13 Chalkidou K. et al. "Comparative-Effectiveness Research and Evidence-Based Health Policy: Experience from Four Countries," *The Milbank Quarterly*, Vol. 87, No. 2, June 2009, pp. 339-67.

14 The American Recovery and Reinvestment Act of 2009 (PL 111-5) provided $1.1 billion to federal agencies for comparative effective research.

15 Descriptions of MEDCAC's structure, process, and reports and recommendation issues are available at http://www.cms.hhs.gov/FACA/02_MEDCAC.asp.

16 One example of CER research supported by WellCore, a subsidiary of WellPoint, contributed to clinical policy reflecting differences in real-world outcomes. The research focused on inhaled steroids versus oral medications for managing asthma. It found that combination therapy was more effective but that the higher-cost oral medication was more effective as a consequence of higher compliance

rates. See Tan H., C. Sarawate, J. Singer et al. "Impact of Asthma Controller Medications on Clinical, Economic, and Patient-Reported Outcomes," *Mayo Clinical Proceedings*, Vol. 84, No. 8, August 2009, pp. 675-84.

17 Tunis S., D. Stryer, and C. Clancy, "Practical Clinical Trials: Increasing the Value of Clinical Research for Clinical and Health Policy," *Journal of the American Medical Association*, Vol. 290, September 24, 2003, pp. 1624-32.

18 Gerrity M. "Using Evidence in Health." Oregon Health & Science University, Center for Evidence-based Policy, slide presentation, May 17, 2009, available at http://www.csg.org/knowledgecenter/docs/health/CSGTalkMGerrity.pdf.; updated information available at http://www.ohsu.edu/ohsuedu/research/policycenter/med/index.cfm.

19 Hussey P., E. Gillen, and E. McGlynn. "Feasibility and Design Options for a Potential Entity to Research the Comparative Effectiveness of Medical Treatments," a report sponsored by the Commonwealth of Massachusetts (Rand Health 2010), available at http://www.rand.org/pubs/technical_reports/2010/RAND_TR803.pdf.

20 Berenson R. and B. Dowd. "Medicare Advantage Plans at a Crossroads–Yet Again," *Health Affairs* Web exclusive, November 24, 2008, w29-40, available at http://content.healthaffairs.org/cgi/content/abstract/28/1/w29.

21 In March, 2010, the states participating in DERP were Arkansas, Colorado, Idaho, Maryland, Missouri, Montana, New York, Oregon, Washington, Wisconsin, and Wyoming; see http://www.ohsu.edu/ohsuedu/research/policycenter/DERP/index.cfm.

22 The Oregon Health Services Commission determines the rank order of services and assignment to tiers based on its review of the available evidence and other considerations, including public input regarding values and preferences and legal considerations such as mental health parity requirements. Saha S., D. Coffman, and A. Smits. "Giving Teeth to Comparative Effectiveness Research--The Oregon Experience," *New England Journal of Medicine*, February 4, 2010: Vol 362, No. 7 pp. e18(1)-e18(3); available at http://content.nejm.org/cgi/content/extract/NEJMp0912938v1.

23 Washington approves services for coverage under Medicaid when randomized controlled trials or consistent observational sites demonstrate effectiveness. Without such evidence, other services are approved on a case-specific basis. Mathematica Policy Research, Inc., Benefit Design Strategies for Containment, Transparency and Efficiency, 2009.

24 Silow and Altera, 2007; Mathematica, 2009.

25 Centers gain the Blue Distinction designation when they attain better outcomes, fewer complications and infections versus other centers offering specialty care, and thus better value and cost saving per event. Criteria are developed in collaboration with physician and medical organizations and include measures of structure, processes of care, and outcomes based on clinical data from hospitals and registries. The six areas of specialty care covered by the Blue Distinction Centers are bariatric surgery, cardiac care, complex and rare cancers, knee and hip replacement, spine surgery, and transplants. Blue Cross Blue Shield Association. Blue Distinction Fact Sheet, http://www.bcbs.com/innovations/bluedistinction/blue-distinction-fact-sheet.pdf, updated February 9, 2010.

26 Fendrick A. and M. Chernew. "Value-based Insurance Design: Aligning Incentives to Bridge the Divide between Quality Improvement and Coast Containment," *The American Journal of Managed Care*, Vol. 12 Special Issue, December 2006, pp. SP5-SP10.

27 See, for example, De Brantes F. and J. Camillus. "Evidence-Informed Case Rates: A New Health Care Payment Model." The Commonwealth Fund Publication No. 1022, April 2007.

28 Fendrick A. *Value-Based Insurance Design Landscape Digest.* University of Michigan Center for Value-based Insurance Design and National Pharmaceutical Council, July 2009, available at http://www.sph.umich.edu/vbidcenter/pdfs/NPC_VBIDreport_7-22-09.pdf. The report includes brief case studies of value-based insurance designs implemented by WellPoint, Inc.; Caterpiller, Inc.; Service Employees International Union Health Care Access Trust; Mid-America Coalition on Health Care; Health Alliance Medical Plans, Inc.; Hannaford Brothers Company; City of Springfield, Oregon; Midwest Business Group on Health; and United Healthcare.

29 Arguing for the need to "harmonize" approaches to reform for Medicare and the private sector, Lee, Berenson, and Tooker stressed that incentives targeting improved outcomes, high value, and coordinated care must be consistent across payers; without sufficient alignment, reforms "run the risk of creating a confusing hodgepodge of requirements, incentives, penalties, and rewards for providers and patients alike." Lee P., R. Berenson, and J. Tooker. "Payment Reform– The Need to Harmonize Approaches in Medicare and the Private Sector," *New England Journal of Medicine*, vol. 363, no. 1, January 7, 2010, pp. 3-5.

30 When benefit design increases the use of resources by some patients, costs are spread across the enrollee population and covered by insurance. If, however, benefit designs differ significantly across plans and people move from plan to plan, adverse selection resulting from evidence-based design options could undermine plan stability. An analysis by the American Academy of Actuaries noted that, among the challenges to value-based insurance design, was the potential for adverse selection. "This potential for adverse selection" according to the actuaries, "can be a particular concern when employees are offered multiple plan choices." "Value-Based Insurance Design," American Academy of Actuaries Issue Brief, June 2009, available at http://www.actuary.org/pdf/health/vbid_june09.pdf.

31 Chernew M. et al. "Evidence That Value-Based Insurance Can Be Effective," *Health Affairs*, Vol. 29, No. 3, February 2010, pp. 530-536; Mathematica Policy Research, Inc. *Transparency, and Efficiency: Evidence-Based Purchasing and Tiered Provider Networks* prepared for the Commonwealth of Massachusetts, February 2009, available at http://www.mass.gov/Eeohhs2/docs/dhcfp/pc/2009_02_13_Benefit_Design_Strategies_final-C6.pdf.

32 Difference in the standards set by the Food and Drug Administration for the marketing of new highly specialized devices or technologies used in diagnostic testing ("test kits") and the standards for tests for office-based clinical laboratories provide an example of inconsistent standards that can undermine efforts to incorporate effectiveness research into coverage policy.

33 Neumann P. et al. "Challenges in Identifying 'Low-Value' Services for Value-Based Insurance Design," *American Journal of Managed Care*, Vol. 16. No. 4, 2010, pp. 280-6.

34 *Ibid.*

35 See, for example, Lowenstein G., T. Brennan, and K. Volpp. "Asymmetric Paternalism to Improve Health Behaviors," *Journal of the American Medical Association*. Vol. 98, No. 20, November 27, 2007, pp. 2415-7.

36 Volpp K., M. Pauly, G. Lowenstein et al. "P4P4 (An Agenda for Research on Pay-for-Performance-for Patients," *Health Affairs Market Watch*, Vol. 28, No. 1, January/February 2009, pp. 206-14.

37 See, for example, Volpp K., A. Troxel, M. Pauly et al. "A Randomized Trial of Financial Incentives for Smoking Cessation," *New England Journal of Medicine*, Vol. 360, No. 7, February 12, 2009,,pp. 699-709.

38 See, for example, Volpp K., L. John , A. Troxel et al. "Financial Incentive Based Approached for Weight Loss: A Randomized Trial, *Journal of the American Medical Society*, Vol. 300, No. 22, December 10, 2008, pp. 2631-7.

39 Prominent examples of a more generalized approach to helping people make better choices by using "default options" include auto-enrollment (e.g., Medicaid managed care enrollment), or performing routine testing, vaccinations, and automatically refilling of prescriptions rather than relying on individuals to take the initiative to seek appropriate services (see Halpern S., P. Ubel, and D. Asch. "Harnessing the Power of Default Options to Improve Health Care," *New England Journal of Medicine*, Vol. 357, No. 13, September 27, 2007, pp. 1340-4).