

Toward More Rational Management of Medical Technology in the United States

A Review of Barriers to Wider Use of Evidence in Medical Technology Assessment and Coverage Policy

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I. Executive Summary

The Kaiser Permanente Institute for Health Policy (hereafter, the Institute) is in the preliminary stages of defining policy initiatives that might improve the management of medical technology in the United States. As a first step, the Institute commissioned this survey to learn more about technology management problems that have been identified by experts in the field.

A. Assumptions and Methods

As used in this report, the term “medical technology” includes all drugs, devices, biologics and surgical and medical procedures used in medical care. The author also assumes that the tools of evidence-based medicine (EBM)—the systematic review and application of scientific and economic evidence to technology assessment, coverage policy and clinical decision-making—will be the primary mechanisms to improve technology management. The problems and proposed solutions contained in this report were culled from published health policy literature as well as through interviews with technology assessment practitioners, consumer experts, journalists and others.

B. Findings

The report focuses on four sets of problems that impede the continued expansion of an evidence-based approach to technology management. The categories and most significant issues are:

1) The quantity and quality of available evidence. Significant gaps in the evidence base continue despite international efforts to address them. No research has been conducted on many technologies; for other technologies, existing research may not be of sufficient quality to guide reliable decision making, or may not have been designed to answer the questions of those who must make coverage or treatment decisions.

Factors contributing to these evidence gaps include:

- Lower public funding for clinical research than for basic science;
- The lack of priority-setting mechanisms that would allocate scarce research dollars towards filling the most pressing evidence concerns;
- Evidence requirements that support FDA approval processes but not the needs of health care purchasers, particularly the use of surrogate endpoints versus health outcomes and the lack of studies that measure effectiveness in typical clinical settings;
- The lack of regulatory oversight (or other requirement) that would motivate effectiveness research on medical and surgical procedures and the off-label use of drugs and devices; and
- Unresolved methodological issues and questions.

Policy experts have proposed additional funding for clinical and health services research, public/private priority-setting initiatives, mandates for post-market surveillance and a new entity to establish research requirements for technology not subject to FDA review.

2) The processes to evaluate scientific evidence of effectiveness. Many technologies remain unevaluated. Others fail formal evaluations based on insufficient evidence, but these failures do not inform future research priorities. Consumers may not understand or accept the outcome of the evaluation processes. Contributing factors include:

- Conflicting objectives inherent in the evaluation process, particularly with respect to the desires of the individual patient versus the most effective use of resources to improve population health.
- Largely decentralized and market-driven technology assessment processes that lead to redundant evaluations of high-cost technology, while other technologies go unevaluated. Public goods—for example evaluations of technology to treat rare disease, methodological standards, and public payer competency in assessment—may also be under-supplied.
- Inconsistent levels of transparency that leave consumers unaware of the existence of evidence reviews. Consumers may also distrust results they consider tainted by conflict of interest.

Initiatives and proposals to address these problems include wider consumer participation and greater transparency in many review panels. The Center for Evidence-based Policy seeks to elevate state-payer competency by providing systematic reviews of comparative drug effectiveness.

3) Disconnects between coverage policy and effectiveness evaluations. Payers and purchasers want evidence to guide coverage decisions so that reimbursement can be used as a tool to improve system-wide value. They additionally want to use coverage—or the lack thereof—to force the development of better evidence that would protect the quality of health care provided to all patients. It is difficult however to design coverage policy that can address fine gradations of clinical indication. The courts have not consistently supported coverage decisions based on scientific evidence and ethically, many believe the courts should not grant coverage unless there is clear evidence that the treatment is not effective. Finally, legislative mandates to provide coverage are often political responses rather than evidence-based decisions. To address this last issue, some states have legislated that benefit mandates be backed by high-quality evidence of effectiveness.

4) Low consumer support for evidence-based controls on technology diffusion. Consumers do not widely agree that technology development and diffusion are problems that U.S. health care policy makers need to address. Many evince negative attitudes toward incorporating cost-effectiveness analysis into technology assessment. At time of use, consumers may not have access to the best clinical evidence or receive information about the potential benefits and harms of the proposed and alternative treatments in a form that is meaningful to them.

Media coverage contributes to these problems by over-promoting the benefits and underplaying the potential harms of technology. The market has lacked clear incentives to develop and promote evidence-based information for consumers, such as freely-available Internet resources and patient decision-aids. Initiatives to address these problems include: efforts by the Association of Health Care Journalists to improve health care reporting from within; new resources for consumers seeking the results of systematic evidence reviews, including websites sponsored by Consumers

Union and the AARP; and new research into consumer attitudes about technology and cost-effectiveness.

C. Next steps

As planned, the Institute should select a limited number of the issues identified by this survey for further development. A small group of Institute staff and other internal stakeholders could then identify key policy questions to be addressed in one or more expert roundtable discussions. Additional interviews and other “peer review” addressing the selected topics should inform the development of short briefing papers to provide background for the roundtables. The Institute should particularly try to obtain feedback on the issues and briefing content from sources who were under-represented in this first paper, including physicians in private practice, drug and device manufacturers and other interests, such as venture capital.

II. Introduction

The Kaiser Permanente Institute for Health Policy (the Institute) is in the early stages of defining one or more policy initiatives to improve medical technology management in the United States. As a preliminary step, the Institute commissioned this report summarizing the key current problems—and proposed solutions if any—that have been identified by various experts on technology issues.

No one paper can fully capture the many scientific, economic and political issues that must be addressed to effect any significant change in the nation's approach to medical technology. The scope of this report is confined to four sets of related issues, all of which obstruct the expanded application of evidence-based tools to technology assessment and coverage policy. The issue categories were selected based on early discussions with the Institute, which defined the following perspective on current technology management:

The United States' decentralized health care system absorbs technology in a haphazard, non-evidence-based way. Our reimbursement systems do not discriminate well between a technology with high clinical value and one with low clinical value, thus encouraging treatment expansion to populations that may receive few benefits from the technology. Consumers are largely unaware of the policy debates around technology and evidence, and demonstrate little support for controls on the diffusion of low-value technology.

By contrast, in a world of "ideal" technology management, researchers would systematically measure the clinical and economic effectiveness of all medical technology, and unimpeachable evaluations of the research would inform coverage and reimbursement decisions. Consumers would demand to know the evidence before deciding on any significant course of treatment and would understand how technology expenditures reduce resources available to provide other needed health care services.

What policy changes might move the nation closer to this ideal state? The report looks at four categories of issues that correspond to various facets of the "ideal" scenario outlined above. The categories comprise problems with:

- Measuring clinical and economic effectiveness i.e., the need to expand the existing evidence base. *See Section IV: Expanding the Evidence Base;*
- Unimpeachable evaluations of the research, i.e. problems with current evidence evaluation processes. *See Section V: Evaluating the Evidence;*
- Evidence-informed coverage and reimbursement decisions. *See Section VI: Linking Coverage Policy to the Evidence;* and
- Evidence-informed consumer acceptance and support. *See Section VII: Linking Consumers to the Evidence.*

III. Approach and Limitations

As used in this report, the term “medical technology” includes all drugs, devices, biologics and surgical and medical procedures used in medical care.

The problems and proposed solutions documented in this report were culled from published health policy literature and obtained through semi-structured interviews with technology assessment practitioners, academic observers, consumer experts, health care journalists, and others. Early interviews with Jill Yegian of the California Health Care Foundation, and Robin Cisneros, Director of Technology Assessment for the Permanente Federation identified some key interview sources, including:

- Consumer experts Marge Ginsburg, and Ellen Severoni, and
- Richard Rettig of the Rand Corporation—author of a 1997 study on technology assessment commissioned by the Department of Health and Human Services.

The author was previously acquainted with Dr. Wade Aubry and selected him for an interview based on his past tenure with the technology assessment boards for Blue Shield, the Blue Cross Blue Shield Association's Technology Evaluation Center, and the Medicare Coverage Advisory Committee.

Mark Gibson, Deputy Director of the Center for Evidence-based Policy, was also interviewed early in the project, based on the unique work being conducted at his organization and his previous connections with the Institute.

Each interviewee was asked for referrals to additional subject matter experts. Remaining information gaps were filled by contacting the authors of published papers on the topic and experts associated with particular initiatives and proposals. A complete list of interview subjects is provided in Section IX of this report.

The report does not discuss certain issues that should be considered once the Institute selects a set of policy questions for further development. These include intellectual property rights, physician acceptance, and the economic drivers of physician, hospital and manufacturer behavior. Additionally, because payer and purchaser perspectives tend to dominate the source materials used in developing this paper, the Institute should solicit additional feedback—validation, modification or restatement of the selected issues—from technology experts before finalizing the problem set to be addressed. Specifically, the Institute should solicit the views of physicians in private practice, technology manufacturers, consumers, and other interests such as venture capital.

IV. Expanding the Evidence Base

Whether one approaches the clinical evidence base as a physician looking to recommend the right treatment, a legislator proposing health policy, or a payer defining coverage rules, one finds the same result. Significant gaps in the evidence base remain, despite international efforts over a number of years to address them (Tunis et al., 2003). There are two types of evidence gaps: missing or poorly designed clinical research; and research that—however rigorous—does not provide the type of information needed by clinicians and coverage decision-makers.

Many technologies in wide use have never been evaluated. New technology may be evaluated and approved for a specific indication, but then used for other indications once in the market. As Wennberg (2004) notes, “what is done with a new technology once it’s in the market depends on the inventiveness of physicians, and they are terribly inventive” (p.78). No regulatory authority oversees surgical procedures or other treatments that do not involve the use of a drug or device, thus reducing market incentives to conduct expensive, rigorous clinical studies on their effectiveness (Rettig interview).

Research conducted to gain regulatory approval may fail to provide the information health care decision-makers need. For example, clinical trials on drugs and devices are often conducted by highly skilled practitioners, working in academic medical centers, treating narrowly-defined patient populations. These trials leave unanswered many questions about the effectiveness of the technology for broad patient populations receiving treatment under normal clinical conditions (Tunis et al., 2003). Additionally, health care decision-makers want to base treatment protocols and coverage on actual health outcomes—such as long-term survival rates—and these data may take many more years to develop than is practical for a typical clinical trial.

The literature identify a number of factors that contribute to current gaps in the evidence base, including issues in research funding; a lack of formal research priority-setting mechanisms; regulatory deficiencies; and methodological problems.

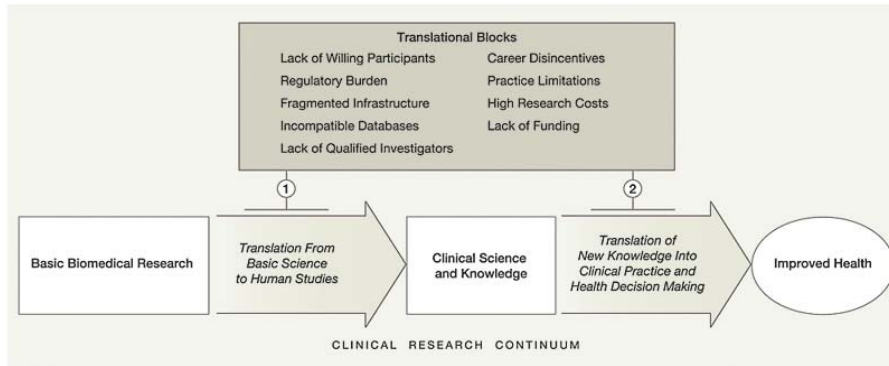
A. Research Funding

In aggregate, the U.S. invests significantly more public funds on the discovery and development of new technology than in evaluating technology effectiveness or relative value. AcademyHealth (2004) has estimated that federal funds support about \$33 billion of health research annually, including the research budgets of the National Institutes of Health (about \$28 billion), the Centers for Disease Control (CDC), the Department of Defense and other agencies. Of these funds, about 75% is spent on basic science, 20% on clinical research and 5% on health services research.¹

¹ Clinical research is research conducted with human subjects, designed to answer a question about disease etiology, concomitants, diagnosis, prevention, outcome or treatment (Source: www.mrc.ac.uk, accessed April, 2005). Health services research examines how people get access to health care, how much care costs, and what happens to patients as a result of this care (Agency for Healthcare Research and Quality, 2002, quoted on www.academyhealth.org). For purposes of funding, the NIH includes health services research within clinical research.

The Institute of Medicine’s Clinical Research Roundtable identified two “translational blocks” or obstacles between basic scientific discovery and human benefit. The first set of obstacles keeps basic science discoveries from moving into clinical research studies, the second obstructs the translation from clinical studies into standard medical practice (Sung et al., 2003). This second translational block is the source of many perceived gaps in the evidence—missing data on technology effectiveness in broad patient populations.

Figure 1: Two Translational Blocks



(Source: Sung et al., 2003)

Observers believe that while the NIH has increased its commitment to clinical research in recent years, its funding tends to focus on the first translational block rather than the second (Rettig interview, Crowley et al., 2004).

Distribution by role of agency. Federal budget appropriations over the past several years also demonstrate funding priorities. Between 1998 and 2003, Congress doubled the budget for the National Institutes of Health (NIH) from \$13 billion to over \$27 billion. During this same time period, the budget for the Agency for Healthcare Research and Quality (AHRQ)—the agency with primary responsibility for promoting evidence evaluation—has also increased, but continues to represent only about 1% of the NIH appropriation.

Congress also declined to increase funding for the Food and Drug Administration (FDA) in tandem with the increase in the NIH budget, and the FDA’s FY2005 budget appropriation was just over \$1.45 billion. The agency also receives about \$300 million in industry user fees that must be used for new drug and device approvals. However, because about \$500 million in funds were added and earmarked for protection of the food supply following the attacks of September 11 (Slater, 2005), non-earmarked appropriations are at about the same level as in 1998. This funding pattern suggests the FDA has little capacity to expand its current programs in ways that could improve or expand information about drug and device effectiveness.

Exhibit 1: Federal Budget Appropriations by Agency (in billions)

	1998	1999	2000	2001	2002	2003	2004	2005
FDA*	\$0.97	\$1.1	\$1.2	\$1.24	\$1.8	\$1.4	\$1.4	\$1.5
NIH	\$13.6	\$15.6	\$17.8	\$20.5	\$23.3	\$27.1	\$27.9	\$28.6
AHRQ	\$0.146	\$0.171	\$0.205	\$0.27	\$0.299	\$0.309	\$0.304	\$0.319

Sources: www.fda.gov; www.nih.gov; www.ahrq.gov

* Totals exclude “user fees” paid by manufacturers applying for a drug or device approval.

Public vs. private investment. Neumann and Sandberg (1998) document the increasing share of total research spending represented by private investment. These researchers note that while there is no inherently correct distribution of private and public research investment, the changing distribution of funds does suggest various areas of concern. First, private research funding contributes to the increasingly close relationships between private industry and academia. These relationships in turn contribute to difficulties finding researchers and reviewers who are free from conflict of interest (Gibson interview). Second, since the return on private investment follows from discoveries that can be patented, private research skews toward the investigation of drugs, devices and biologics over procedures (Kuszler, 2000), alternative therapies or the option of no treatment at all. Finally, the objective of private research is often to increase market share—in ways that may advance our knowledge of effectiveness, but may alternatively just generate consumer demand (Gibson interview).

Initiatives and Proposals

Some policy experts have proposed substantial additional funding for clinical research to expand the available evidence on treatment effectiveness. The IOM's Clinical Research Roundtable recommended that funding for agencies such as AHRQ, the CDC, and the Department of Veterans' Affairs should increase to a level comparable with the national investment in basic science (Sung et al., 2003). That recommendation would represent about \$25 billion in total clinical research funding.

A sub-group of Clinical Research Roundtable participants has gone a step further and suggested creating a public-private partnership, the National Clinical Research Enterprise, to increase public understanding, confidence and participation in clinical research, improve the clinical research workforce, improve the biomedical informatics base, and fund innovative clinical research. They propose funding equal to .25% of the national health budget for all public and private payers (Crowley et al., 2004).

B. Priority-Setting

At the national level, there are no established mechanisms to determine what critical gaps exist in effectiveness evidence, balance the information priorities of public and private decision-makers and distribute clinical research funds with an eye toward strategically filling the evidence gaps (Tunis, 2005).

Private payers could certainly influence research priorities if they were to become a major funding source. Clinical trials are extremely expensive however, and the information obtained is available to all. No single payer or purchaser therefore has an incentive to independently produce more of this public good. Public payers, such as The Centers for Medicare and Medicaid Services (CMS) and the states, also have evidence priorities, but generally lack statutory authority to fund the research that might address them.

Initiatives and Proposals

The IOM's Clinical Research Roundtable recommended that Congress create incentives such as tax breaks to promote investment in clinical research by health care purchasers and payers, and "develop, articulate, and enhance a health services research agenda." They additionally recommend that the nation "promote and support

research and systematic reviews that compare new and existing treatments and positively impact human health." (Sung et al., 2003, p. 1285).

Finally, Section 1013 of the Medicare Modernization Act of 2003 mandates that the Secretary of Health and Human Services (with broad consultation from relevant stakeholders) establish a list of priority research items, and that the Director of AHRQ conduct and support research to meet those priorities. No additional funding was allocated to AHRQ to fulfill this mandate.

C. Regulatory Requirements

Regulatory requirements drive a significant portion of the clinical research that is conducted in the U.S. Gaps in the evidence base therefore correlate to the structure of our regulatory processes as well as to the differing objectives of regulators versus health policy decision-makers. For example, the FDA is chartered to ensure a product is safe and effective—regardless of the price, or what other treatments exist in the market. In contrast, policy makers and purchasers would ideally consider resource constraints, relative effectiveness, and whether there is a clinical need to offer multiple treatment options. As discussed below, the literature describe a variety of ways in FDA oversight affects the research that is conducted and thereby the quality of the evidence base. Additionally, a significant portion of medical technology—including surgical procedures and physician's off-label use of drugs and devices—falls outside the scope of any federal regulation, making these types of technology less likely to be the subject of rigorous scientific evaluation.

FDA approval and monitoring processes.

- Efficacy vs. effectiveness: Randomized controlled studies of technology provided in highly-specialized settings, by highly skilled practitioners, have the best chance of picking up a biologic effect of a new treatment (Tunis, 2003). These types of trials (measuring biologic efficacy) therefore present the most promising route to FDA approval. But these studies often fail to produce the information needed by decision-makers about clinical effectiveness—answers to "practical questions about the risks, benefits and costs of an intervention as they would occur in routine clinical practice" (Tunis et al., 2003, p.1626).
- Surrogate endpoints² vs. health outcomes. There is a growing schism between payers and manufacturers on the validity of surrogate endpoints as evidence of effectiveness. Payers want to tie coverage to evidence based on clinical outcomes, while technology manufacturers are increasingly attempting to gain approval based on surrogate endpoints (Rettig interview). Manufacturers want to use surrogate endpoints because very long trials may be required to demonstrate an impact on health outcomes, and long trials use up valuable periods of patent protection. The device industry in particular is opposed to long trials, arguing that next generation devices may be on the market before a rigorous study of outcomes can be completed (Weissberg interview).

However, it can be equally time-consuming to validate some surrogate endpoints, that is to establish a causal chain rather than just correlation between an intermediate outcome and the health outcome. As a result, the approval process

² Surrogate endpoints are biologic markers (e.g., tumor shrinkage) that have been correlated with health outcomes (e.g., cancer survival rates).

may rely on surrogates that have not been adequately validated, and this approach has led to the FDA approving treatments that ultimately were shown to cause significant harm to patients (Fleming, 2005).

- Surrogate endpoints and the accelerated approval processes: The FDA specifically allows the use of surrogate endpoints to evaluate promising treatments for life-threatening illnesses under its accelerated approval process. Under accelerated approval guidelines, manufacturers may market treatments prior to formal demonstration of patient benefit (Source: www.fda.gov, accessed 4/12/05). Once marketing authorization has been granted under accelerated approval however, the missing evidence may be a long time coming. FDA internal reviews have documented significant delays in completing (or even beginning) validation trials (Mathews, 2005). In other cases, completed validation trials showed minimal treatment benefit, but marketing for the treatment continued (Fleming, 2005).
- Problems specific to devices: Medical devices do not fit well within the FDA's traditional emphasis on limited-term, randomized controlled trials. Real world, long-term studies are needed to evaluate the durability of a heart valve or complications that may eventually occur with certain devices (Foote interview). While the FDA often requests such studies as a condition of regulatory approval, flawed tracking and enforcement mechanisms have allowed many of these studies to remain uncompleted. The agency has announced changes to improve oversight, but may still struggle to force completion when practical considerations limit their ability to remove the devices from the market (Mathews, 2005).
- Weak post-marketing surveillance protocols: The FDA's post-market surveillance programs are designed to capture safety problems in product use, not low clinical efficacy in new treatment populations. Currently they rely almost exclusively on physician, facility or manufacturer reporting of adverse effects, and their processes are "fraught with opportunities for human error" (Slater, 2005, p. 295). Additionally, physicians and facilities using technologies for indications outside the scope of FDA approval have disincentives to report adverse outcomes that could lead to greater FDA scrutiny or increased liability exposure (Mehran, et al., 2004).

Unregulated technology. No agency regulates medical procedures or limits the right of licensed physicians to use drugs or devices for indications beyond those approved by the FDA. As a result, relatively few randomized controlled studies on procedures are conducted (Rettig interview).

Some of the most contentious debates over the need for better evidence to support coverage have been conducted over medical and surgical procedures. Researchers who have studied the politics and court decisions surrounding the use of high dosage chemotherapy with autologous bone marrow transplant (HDC/ABMT) to treat breast cancer, suggest the absence of FDA-like review over medical procedures creates an institutional deficit. When new, potentially life-saving, medical procedures are the subject of dispute, this deficit allows a "default system of patients, physicians, patient advocates, lawyers, entrepreneurs, federal administrators, state legislators, and the media" to overwhelm efforts to appropriately control technology diffusion (Edwards, 2005, p.2, citing Rettig et al., 2005)

Initiatives and Proposals

U.S. Senators Grassley and Dodd have recently introduced Senate Bill 930—the Food and Drug Administration Safety Act of 2005. This legislation would create an Independent Center for Post-market Drug Evaluation Research that reports directly to the FDA Commissioner.

The FDA is also collaborating with CMS on the use of Medicare claims data for post-market surveillance. Participants in a Dartmouth Symposium suggested that the organizational integration of pre and post-market approval staffs would improve post-marketing surveillance. This idea contrasts to the Grassley/Dodd bill, which further separates pre-and post-market accountability. Symposium participants also suggested device-specific registries, and FDA-authored guidelines that establish standards for post-market surveillance studies (Mehran et al., 2004).

Rettig and colleagues propose a public-private partnership to fill the gap on technology not currently subject to FDA oversight. The proposed partnership would be endowed with the authority to set a path toward dispute resolution when the evidence is in doubt (Edwards, 2005, Rettig interview).

D. Research Content and Methodology

Decision-makers and consumer advocates criticize the preponderance of clinical trials that focus narrowly on easily measured statistics such as mortality and morbidity. They call for studies that measure a much wider range of health outcomes, including long-term effects and quality of life post-treatment (Bastian, 2000; Tunis et al., 2003). Head-to-head comparisons of alternative therapies, particularly comparisons of adverse effects and clinical efficacy between older, inexpensive agents and newer (more expensive) agents are also few and far between (Tunis et al., 2003).

As a means to assess whether trial results will generalize to a wide population, some health care decision-makers have called for a greater emphasis on "large, simple trials." These are defined as trials that "use large numbers of patients, more flexible patient entry criteria, and fewer data entry requirements...and provide health outcomes data for wider groups of patients in a variety of settings thought to be more representative of general practice" (Goodman 1997, p.5).

Others argue against large, simple trials on the basis that opening the door to something other than the randomized control trial design means never getting the study that definitively answers the effectiveness questions (Aubry and Weissberg interviews). In support of this argument, opponents point to the effect that coverage mandates, based on small observational studies, had on clinical trials for HDC/ABMT in breast cancer. Because the treatment was available without participation in a trial, it took years to recruit enough trial participants. The trials ultimately showed the treatment to be harmful rather than beneficial, but between 1990 and 1999, approximately 42,700 women received the treatment at an estimated \$3.4 billion cost to society (Mello & Brennan, 2001).

The counter-argument does not suggest the randomized controlled study (RCT) should be displaced as the gold standard of clinical research, but observes that with finite clinical research dollars, traditional RCTs will never supply all the evidence we need.

RCTs are an uneasy fit for evaluating many devices and procedures because it is difficult to create the placebo scenario (Foote interview). Additionally, RCTs are often inappropriate for vulnerable populations such as children, seniors or those with multiple chronic conditions. The lack of RCT evidence for these populations is particularly problematic for decision-makers trying to generalize to a Medicaid population, where seniors with multiple chronic conditions generate the majority of expense and children comprise the majority of plan participants (Bella, 2005).

A related problem is that policy makers may assume that diversity in the trial population is synonymous with generalizability and demand that publicly-funded research meet a diversity standard. For example, federal law requires inclusion of women, minorities and children (Baird, 1999, cited in Kravitz et al., 2004). Perversely, this approach can create demographic subgroups that are under-powered for statistical analysis. A better approach might be to require that all groups be studied over time, rather than in the context of one clinical trial (Kravitz et al., 2004). Kravitz and colleagues additionally suggest that a combination of more sophisticated trial design for the RCT and complementary cohort studies would better suit the objective of generalizability. For example, advance cohort studies could target the population group most likely to benefit from a new therapy, and post-marketing studies could look for enhanced responsiveness in particular patient subgroups.

Initiatives and Proposals

Recently, CMS has been at the forefront of efforts to force development of additional evidence by linking payment to the development of post-marketing designs other than randomized controlled studies, such as new patient or device registries, or other evidence requirements (Hlatky et al., 2005; Kolata, 2004; McClellan & Tunis, 2005; Pear, 2005; Stanton, 2005; Weiss, 2005). CMS considers its new "Coverage with Evidence Development" approach a positive step to ensure: 1) that covered treatment is reasonable and necessary (a statutory requirement for Medicare payment); and 2) that the technology improves overall patient outcomes (CMS, 2005). A number of implementation and methodological questions require resolution however, before these objectives can be met—such as coding accuracy and other quality issues that arise when complex data are collected in a non-controlled environment (Weissberg interview).

V. Evaluating the Evidence

Health technology assessment (HTA) refers to the evaluation of evidence documenting the clinical effectiveness of medical technology. Technically, HTA also includes an evaluation of economic data, though U.S. evaluators seldom include cost-effectiveness in their assessment criteria. Health technology assessment occurs after the technology receives FDA approval (if it is required) and before private and public payers make the reimbursement decision³ (Rettig, 1997).

HTA is a two-step process. The first step comprises a systematic review of the scientific literature on the effectiveness of the technology for a pre-specified clinical indication. These reviews may be conducted by academic researchers, by private enterprise, by physician-specialty organizations or other entities. In the second step, medical consultants and others trained in scientific evaluation methods assess the quality of evidence obtained by the review against pre-established criteria to make recommendations for treatment protocols or coverage decisions. Criteria such as those used by the Technology Evaluation Center (TEC), shown in Exhibit 2, have become standard for both private and public-payer technology assessment panels.

Exhibit 2: TEC Evaluation Criteria

1. The technology must have final approval from the appropriate governmental regulatory bodies.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
3. The technology must improve the net health outcome.
4. The technology must be as beneficial as any established alternative.
5. The improvement must be attainable outside the investigational settings.

Source: Blue Cross Blue Shield Association.

TEC, the Technology Evaluation Center, is jointly sponsored by the Blue Cross Blue Shield Association and Kaiser Permanente.

A primary problem with HTA is that the majority of technology goes unevaluated. Systematic reviews are time-consuming and costly to conduct. The estimated cost for a Cochrane Collaboration⁴ review is about US\$50,000. Evaluations conducted by AHRQ's Evidence-based Practice Centers address broader questions and are therefore more expensive, costing \$250,000 or more (Fox, 2005). Additionally, many technologies fail the evaluation process because the research is missing or not of adequate quality to draw conclusions—but there is no resolution process that links HTA results back to research priorities (Aubry interview). Consumers may not be

³ Reimbursement decisions (a component of coverage policy) are closely intertwined with technology assessment, and the outsider may view the terms as synonymous. They are technically separate however, for example, payers may confer on the quality of evidence, but discussing reimbursement might constitute an anti-trust violation (Interview with Cisneros, 2005). Additionally, technology assessment is a key component of numerous non-payment-related activities, e.g. the development of clinical guidelines and other efforts to improve quality of care.

⁴ The Cochrane Collaboration is an international, independent, non-profit organization of researchers who produce and publish systematic reviews of healthcare interventions (Source: www.cochrane.org, accessed 4/19/05).

aware of health technology assessment activity or may distrust the objectivity of the results (Lerner, 1998).

Finally, because HTA has followed a primarily private-sector development path in the U.S. in recent years, some public goods may be undersupplied, such as assessments of technologies that treat rare diseases, leadership in developing priority-setting mechanisms, and national methodological standards (Mendelson et al., 1998).

These problems and contributing factors are discussed below within the categories of process and methodology limitations, decentralization and market incentives and the lack of transparency and consumer participation in HTA processes.

A. Process and Methodology Limitations

Conflicting objectives and values. The objectives of technology assessment may conflict with those of individual patients who desire treatment even if the chance of benefit is slight, and with those of physicians trained to place the health of the individual patient before the health of the population. Other countries have attempted to explicitly incorporate these differing interests within their HTA organizational framework. Lehoux and Blume (2000) found that early U.S. definitions of HTA also placed the evaluation of social, political, and ethical ramifications within scope, but over time, the U.S. definition has narrowed to technical and clinical questions of safety and efficacy. HTA professionals are now expected to rise above politics, providing assessments that are "objective, uncompromised, and 'untainted' by political commitment" (p. 1101).

In truth, though assessors strive to remain impartial and focused on the science, evaluating the evidence still involves judgment, and judgment necessarily involves humans who bring certain values to the process. "The stakeholders—scientists, physicians, patients, policymakers, purchasers and insurance institutions—all seek evidence to guide adoption decisions. But all bring distinct readings of the evidence to decisions that may have heart-rending implications for quality, cost, and fairness" (Giljens et al., 2005, p.30). The continuing debates over PSA screening for prostate cancer, hearing tests for newborns and antibiotic use for ear infections—all issues for which the clinical evidence is quite clear—demonstrate that avoiding discussion of underlying values, preferences and community interests just cause them to masquerade as intractable disputes over the quality of the scientific evidence (Atkins et al., 2005).

Timing. Another issue is that HTA practitioners may scan extensively for technologies in the pipeline, but they can not begin the formal evaluation until clinical trial results have been published in peer-reviewed journals. In contrast, sophisticated device manufacturers and pharmaceutical companies begin product promotion well in advance of FDA approval. Media coverage of preliminary trial results or of physician pioneers using promising—though unproven—techniques also generates demand well in advance of availability. For example, U.S. News and World Report recently published a feature article on a heart repair surgery that may help migraine sufferers. Although clinical trials are still in progress, the article reports "demand for the procedure is already racing ahead of the evidence" and concludes with a quote from a migraine sufferer who says she already intends to "get the repair by hook or by crook"

(Harder, 2005). As a result of this timing difference, the assessors are always placed in reactive mode, lending strength to the perception that payers use HTA as an obstacle rather than as an objective, desirable process.

Narrow assessment scope. Several assessment experts commented in interview on the narrow focus of most assessments. Wade Aubry expressed this problem as a need to "evaluate all alternative treatments in comparison to each other, to look at the management of the disease, not the effectiveness of Drug X vs. Drug Y" (Aubry interview). Sandra Arthurs noted that a narrow focus on specific drugs, combined with our great national faith in drug treatment, limits the ability to incorporate the value of alternate treatments into published assessment results. "Some patients with pain, for example, may have better outcomes with multiple therapies and doctors. How can we use the evaluation of a specific treatment in a specific setting to form a credible message to the patient?" (Arthurs interview).

B. Decentralization and Market Incentives

Through the 1970s and 1980s, Congress made several attempts to establish a centralized technology assessment process. Political support for a strong federal government role in technology assessment waned over time, and today's technology assessment processes have evolved primarily as a decentralized market response to payer need. This decentralized, market-driven approach to HTA in the U.S. has helped develop robust analytic capacity and to the performance of more and broader assessments than a fully centralized system would generate (Rettig, 1997).

Today most major private payers have internal technology assessment capabilities, and are also able to purchase independently performed systematic evidence reviews. These reviews are developed, and sold as subscription services, by both not-for-profit groups such as the Cochrane Collaboration⁵, and by for-profit entities such as Hayes Inc. Public entities also play a variety of roles in HTA. For example, the Department of Veterans' Affairs and Department of Defense, both major health care providers, conduct assessments and cooperate with others engaged in technology assessment. The Agency for Health Research and Quality (AHRQ) sponsors twelve Evidence-based Practice Centers that perform systematic evidence reviews and provide technology assessments on request to the Medicare Coverage Advisory Committee. (Eisenberg & Zarin, 2002).

The market-driven approach also creates problems however, including redundancy of effort on some technologies and inadequate levels of public goods.

Redundancy. Because payer demand drives topic selection for private reviews, such reviews cluster redundantly around high-cost technologies, while a wide range of other technologies go unevaluated. Rettig (1997) argues that the redundancy is valuable and necessary, as a single review or study will not be definitive. Creating high-quality, systematic reviews of the medical evidence is an intensive, expensive and time-consuming process however, and existing reviews must be regularly updated to incorporate new evidence. Even significant players in the assessment industry can

⁵ Abstracts of all Cochrane Collaboration reviews are available free of charge. Access to the full reviews is by subscription, but several countries purchase national subscriptions, allowing free access to the reviews for all citizens. (Source: www.cochrane.org, accessed 4/19/05).

generate only a limited quantity of reviews. For example, TEC produces a total of 20-25 reviews per year (Source: www.bcbs.com/tec). In its first 18 months of existence, Britain's National Institute for Clinical Excellence (NICE) took on a total of 17 reviews (Taylor, 2002). With only about 500 reviews that meet international quality standards produced annually, an estimated 10,000 current health interventions to evaluate (Fox, 2005), and new technology constantly entering the market, redundancy may not be an entirely positive outcome.

Missing public goods. Market-driven systems can produce lower than optimal levels of public goods. In the case of the U.S. approach to HTA, these goods include: orchestrated feedback mechanisms to guide research priorities when a technology in high demand fails a technology assessment based on lack of evidence (Aubry interview); assessments of technology for rare diseases; identification of obsolete or inefficient technologies; and government leadership on the development of methodological standards (Mendelson, 1998).

Public-payer proficiency in HTA can also be viewed as a public good desirable to ensure these payers fulfill their fiduciary responsibilities to taxpayers. Under the current approach, payers such as state Medicaid programs have difficulty performing HTA effectively. They often have no internal staff qualified to evaluate the evidence, and neither the financial resources nor the statutory authority to purchase private assessments (Bella interview).

Initiatives and Proposals

Richard Rettig observed that the federal government should become no less competent than the private sector in using evidence-based technology assessment to guide its purchasing decisions (cited in Eisenberg & Zarin, 2002). CMS has seemingly taken this advice to heart in refining its processes for making national coverage decisions (Neumann et al., 2005), but the consistency and rigor of the HTA process is less clear for the reviews conducted by its local administrators.

To address state-specific needs for HTA, thirteen states and two non-profit organizations now jointly sponsor the Center for Evidence-based Policy. The Center's objectives are to increase state capacity to use evidence-based medicine, prioritize areas where more evidence is needed, and facilitate closer relationships between the research community and state policy decision-makers. The group's signature effort is its Drug Effectiveness Review Project (DERP), which performs systematic reviews of competing drugs within the same pharmaceutical class. At a minimum, DERP reviews can inform state Medicaid drug-purchase programs. Some states will also use the information to support other programs such as workers compensation (Gibson interview).

C. Lack of Transparency and Consumer Participation

A charge of "conflict of interest" can be levied against virtually any player in most technology assessment processes. The most commonly accused are payers who conduct technology assessment to inform coverage policy and the device manufacturers and pharmaceutical companies seeking approval for their particular technologies. But the motives of physicians whose reputation and income may be

affected by the outcome, and consumer advocacy groups—who may receive major funding from technology manufacturers—are equally suspect.

Mark Gibson suggests that HTA needs to become much more open and transparent in disclosing both conflict of interest and process assumptions if it is to gain broad acceptance and cultural authority (Gibson interview). Progress has been made on this front; some review panels have expanded to include consumer representatives, some hold their meetings in open session, and many now make their decisions publicly available on the Internet. Hayes Inc., a major private source of technology assessments, provides a consumer version of their review data base that some payers purchase and provide as a service to their members. There are still practitioner holdouts on transparency, however, and the proprietary model of publishing assessments limits access for those without private insurance.

Consumers with the skills to interpret and evaluate scientific evidence can be hard to find, so review panels may tap patient advocacy group representatives to participate. But patient advocacy groups may accept significant funding from the pharmaceutical companies, leading to debate over whether these groups legitimately speak on behalf of the consumer (Gruman and Gibson interviews).

VI. Linking Coverage Policy to Evidence

"Coverage criteria sit aside the flow of money" (Eddy, 1996, p.651). That fact makes coverage policy⁶ the arena in which technology manufacturers, physicians employing novel procedures, and health care payers fight their battles. It is also the place where our judicial system, legislature, and the court of public opinion weigh in on the proper balance between limits to keep coverage affordable for the benefit of the group, and the rights of an individual to a particular treatment.

Payers view coverage criteria as the legal language of agreement between plans, physicians and health plan members over "how the members' money should be used to maximize the members' health" (Eddy, 1996, p.652). From that perspective, they want evidence to guide coverage. Additionally, payers want to use coverage—or the lack thereof—to force the development of better evidence. Payers face a number of practical, legal and political problems though, as they pursue tighter links between coverage policy and evidence of a technology's effectiveness.

A. Practical Issues

Few medical interventions are always effective or always ineffective. Coverage policy must therefore somehow address fine gradations of underlying disease states and risk factors that may define success or failure in treatment. To sidestep the impossibility of detailing medical indications in the benefits contract, managed care plans applied global pre-authorization requirements to the use of some technologies. These requirements became a focal point for managed care critics and fell from favor, but some plans are quietly reintroducing pre-authorization for lack of a better answer to the problem (Mays et al., 2004).

Additionally, payers do not have uniform capacity, desire or resources to evaluate the evidence in forming coverage policy. Manufacturers can use these variations to their advantage in a competitive payer market by using favorable coverage decisions from one payer to influence the coverage decision of another. When the target patient population is over-65, manufacturers can weigh the trade-offs between building national coverage region by region—through a succession of decisions by local Medicare administrators—and seeking a single national coverage decision from Medicare. When the latter approach is successful, access to the whole national market is assured, but the national coverage decision process may subject the technology to higher levels of scrutiny and demands for supporting evidence.

⁶ Coverage, benefit design and reimbursement are separate concepts, but the term coverage policy is often applied to the combination of the tools. A positive coverage decision reflects agreement that the service or technology meets an internal plan standard of medical appropriateness for a given condition, and that the group chooses to cover the underlying condition. For example, cosmetic surgery may be medically appropriate for a variety of problems, but is typically covered only to repair congenital abnormalities or for surgical reconstruction following an injury. A service may be covered, but subject to a low benefit payment that will discourage use, such as 50% coinsurance for out-patient mental health therapy. Payers (particularly public payers), can also use reimbursement as a control on technology diffusion. The service may seemingly be covered at a reasonable benefit level, but reimbursement levels may be set so low that no providers will offer the service.

Initiatives and Proposals

The National Business Group on Health is developing tools to help its member companies (self-insured employers) use benefit design to reward effective care and discourage ineffective care. They do not expect these tools will take the form of yes/no coverage decisions. Instead, they will reward process and informed patient decision-making around specific technologies. For example, the evidence on long-term outcomes for back surgery is very inconclusive, but some patients may be helped by the procedure. The NBGH guidelines would encourage, progressively: 1) the use of decision-support tools to communicate the evidence to the patient; 2) participation in back-care management programs; and 3) use of a center of excellence if surgery is ultimately performed (Goff interview).

B. Legal and Ethical Issues

Coverage decisions can create both legal and perceived ethical conflicts. Payers see basing coverage policy on evidence as a necessary and positive step toward maximizing value for the population of covered individuals. Opponents view the trend as the usurpation of physician autonomy and authority in clinical decision-making for the individual patient. Even if the members of society collectively accept that coverage should be tied to evidence, agreement is missing over the direction of proof required. Should payers be allowed to demand proof that treatment is safe and effective—as if they were the FDA—before granting coverage? Or, do we believe as Sara Rosenbaum and colleagues have suggested, that “an insurer should be able to set aside the decision of the treating physician only if the insurer can show that the proposed treatment conflicts with clinical standards of care, or that there is substantial scientific evidence...that the proposed care would be unsafe or ineffective” (Rosenbaum et al., 1999, p.232)

The judicial system is the final arbiter when these disputes become heated and there are indications the courts support the Rosenbaum position. Legal analysts looking at the trials over coverage for bone marrow transplants for breast cancer concluded that “the judicial forum tends to favor individual patients, not populations of patients and that judicial bias favors providing access to the experimental and discounting of no evidence of effectiveness” (Edwards, 2005, citing Rettig et al., 2005). In fact, the very nature of our judicial decision-making process—to weigh the testimony of competing experts and dueling statisticians—may work against proponents of evidence-based coverage policy. The clinical research used in payer coverage decisions often provides only probabilistic evidence, while civil cases turn on the preponderance of evidence, and criminal law seeks evidence that is without a reasonable doubt (Eisenberg, 2001).

C. Political Issues

Benefit mandates, or legislative requirements that plans cover a specific treatment or set parameters for how the treatment is covered, may or may not have a strong grounding in the evidence. Some mandates arise instead out of a perceived violation of social norms. Maternal length-of-stay coverage requirements—enacted by 41 states and the federal government to end “drive-through deliveries”—provide a good example. At the time of the mandates, scientific evidence for or against early discharge was inconclusive. Research conducted since the mandates have shown that neither the early discharge programs that generated the political backlash, nor the mandate for longer stays appear to have affected newborn health (Madden et al., 2002).

Another major political issue is the inability of either public or private payers in this country to incorporate cost-effectiveness into coverage determinations. Coverage criteria based on clinical effectiveness can help eliminate waste from the system but without complementary cost-effectiveness criteria, neither efficiency nor system-wide value can improve. As Alan Garber (2004) explains, efficiency improvement requires mechanisms to "guide utilization away from procedures that provide little benefit at high cost" (p.288) and to answer the question of "whether medical innovations that provide genuine but modest benefits at high cost should be adopted" (p.290).

Mobilized interest groups can also bar efforts to formalize technology adoption criteria. CMS attempted for years to develop coverage criteria that would define the meaning of their directive to pay only for technology or services that are "reasonable and necessary," but the medical device industry effectively blocked all attempts to promulgate this rule (Foote, 2002). In recent years, CMS has seemingly conceded the battle to forge stakeholder consensus on general coverage criteria, thus eliminating the opportunity to lead a national debate on how we value new technology and how we might incorporate cost-effectiveness into our evaluation protocols.

Initiatives and Proposals

Some states are giving greater weight to evidence reviews before passing new coverage mandates or regulations. For example, Washington State statutes require that coverage decisions be guided by systematic reviews of the best available scientific and medical evidence (Fox, 2005). California's Health Benefits Review Program was established by that state's legislature to "provide independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates" (Source: <http://www.chbrp.org>, accessed 4/18/05).

Susan Foote has suggested three potential strategies to break the interest group logjam on Medicare coverage criteria. First, Congress itself could develop detailed coverage criteria. Second, the stakeholders could use a process of negotiated rule-making, which allows direct negotiation between the diverse interests in contrast to the "notice and comment" rule-making approach. Her final suggestion is to abandon efforts to develop explicit policies and create a body of "common law" derived from actual coverage decisions (Foote, 2002). This last option is the path that CMS has seemingly elected, providing specific guidance on the process to obtain Medicare coverage rather than explicit coverage criteria, and an open, independent and transparent approval process rather than a forum for national debate (Tunis, 2004).

VII. Linking Consumers to the Evidence

Policy discussions about medical technology and evidence-based medicine continue to take place largely outside of the public forum. At the policy level therefore, consumers are largely unaware of the extent to which technology drives health care cost and premium increases, or what being "led by the technology horse" means in terms of tradeoffs for health care access and quality of care (Severoni interview).

The disconnect between the views of consumers and those of health care economists and policy experts was clearly displayed in results of a Kaiser Family Foundation (KFF) poll taken in 2003. While 81% of health economists believe that technology is the primary driver of rising care costs (Fuchs, 1996) only 8% of respondents to the KFF poll believed the use of technology is the most important factor.

Providing evidence-based information at the point of important treatment decisions would be beneficial in the moment to the patient, and might help build acceptance

and demand for the broader application of evidence in policy decisions. Today however, "the evidence is infrequently available in a form that can be acted upon at the time decisions must be made" (Clancy & Cronin, 2005).

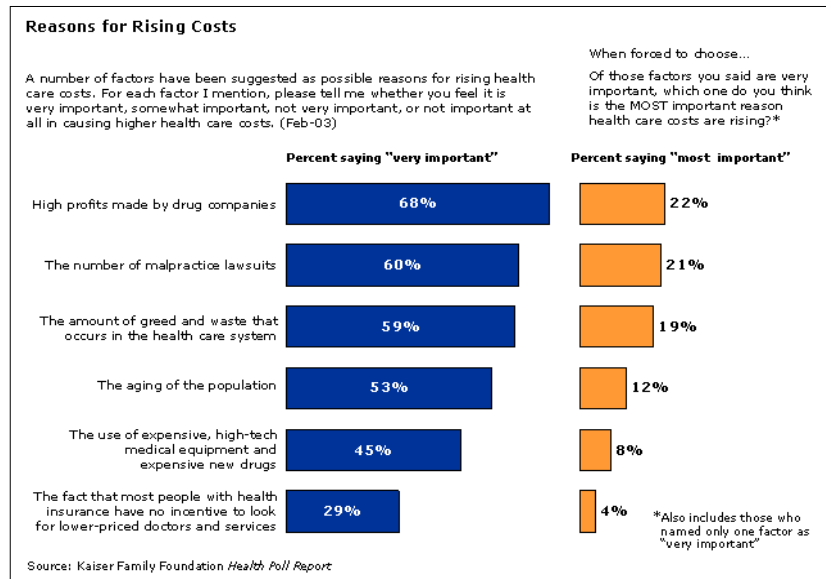
Finally, negative consumer attitudes about using cost-effectiveness as an input to clinical decision-making or coverage policy stand in the way of meaningful policy debates on how to increase system-wide health care value.

A. Role of the Media

The media contribute to consumer belief that technology is "all about miracles" rather than a problem to be addressed (Ginsburg interview) with stories that over-emphasize preliminary results, and highlight potential benefits while downplaying potential risks (Schwartz & Woloshin, 2004).

Lieberman (2001) identified seven deadly sins in media coverage of medical technology that contribute to consumer demand for untested, unproven and potentially harmful medical tests and treatments. For example, health news reporters may accentuate the positive while ignoring the negative; miss the weaknesses in scientific studies; fail to interpret the numbers; or confuse intermediate outcomes with health outcomes.

Researchers have found a number of problems with the way new drugs are covered in the media, such as reporting only relative and not absolute benefits, omitting any



discussion of harms and/or costs, and citing experts with undisclosed financial ties to industry (Moynihan et al., 2000, Cassells et al., 2003). Sensationalism is also an issue. Schwitzer (2003) analyzed 982 news stories on pleconaril—a treatment for the common cold that was ultimately rejected by the FDA—and reported descriptions of the drug as a "cure, miracle, wonder drug, super drug, [and a] medical first" (p. 1043) as well as comparisons to the Holy Grail and putting a man on the moon.

Broadcasting Video News Releases as medical "news," when these VNRs have been produced by public relations firms to promote physicians, hospitals, or pharmaceutical and medical device manufacturers, is of particular concern (Schwitzer, 1992, Lieberman 2001, Schwitzer interview). These marketing promotions can stimulate product demand and momentum that may be hard to reverse (Lieberman, 2001), particularly by dry and arcane systematic reviews of clinical research. The Federal Communications Commission has recently reminded broadcast licensees and cable operators of their obligation to disclose the origin of video news releases used in their television broadcasts (FCC Public Notice 05-84), but did not define disclosure requirements, or policing and enforcement mechanisms (Schwitzer, 2005).

Initiatives and Proposals

The Association of Health Care Journalists is working from within journalism "to improve the quality, accuracy and visibility of health care reporting, writing and editing" (Source: www.ahcj.umn.edu). The group holds an annual national conference, sponsoring in-depth, skill-building sessions on topics such as interpreting medical study results, and covering health policy debates.

The Council for the Advancement of Health, a Washington DC-based non-profit organization, provides issue briefs and expert referrals as a resource for journalists seeking readable and accurate information on evidence-based scientific research.

B. Building Consumer Demand for the Evidence

While there seems to be healthy public demand for health and medical information, many policy experts believe the public is unaware and unappreciative of systematic evidence reviews (Findlay interview). Part of the problem is that the language of clinical research and results (the evidence) is technical, complex and draws on measurements of probability and uncertainty that exceed the mathematical skills of many patients. Significant effort is needed to translate these data into a usable form for consumers.

Another aspect of the problem is the need for presentation by a trustworthy source. Lerner (1998) noted the "new coloration" of constraints on technology in the era of managed care and comments, "clearly the public is coming to feel that the motivation behind limitations on access to technology cannot be trusted. If scientific evidence says that a technology may not be useful, then the science itself is suspect" (p.83).

Finally, there is an issue of access. While some vendors have developed consumer translations of systematic evidence reviews, they are typically proprietary and available only when a paying sponsor, such as a health plan, makes them available to members.

Shared Decision Making and Patient Decision Aids. Shared decision-making protocols and validated patient decision aids introduce the consumer to the evidence

at the point a treatment is proposed. Shared decision making is the "process of interacting with patients in arriving at informed [patient] values-based choices...Patient-decision aids (PtDAs) are evidence-based tools designed to facilitate the process" (O'Connor et al., 2004, p.63).

Although medical schools today teach the principles of evidence-based medicine, individual physicians vary in the value they place on potential adverse outcomes versus potential positive outcomes (Weissberg interview). Physicians may also weight some outcomes or complications very differently from the value that patients might place upon them (Wennberg, 1988, cited by Billings, 2004). Even if physicians are committed to providing complete information "most clinicians are not trained or practiced at describing and explaining benefits and harms clearly to patients, and much of the time they also lack important information about these aspects" (Herxheimer, 2005, p.42). For example, many physicians do not understand the deficiencies in the FDA process and think that the evidence in support of an approved technology is much better than it really is (Weissberg interview).

PtDAs and the shared decision-making process attempt to address these problems, and research suggests they are successful on several fronts. "Patients who participate (1) are more knowledgeable about treatment options and their benefits/risks, (2) make decisions that are more consistent with their own attitudes toward these benefits/risks, (3) have more informed discourse with their physicians, (4) choose options that are consistent with available scientific evidence, and (5) generally make choices that are less costly (opting for less surgery than their more aggressive physicians would choose)" (O'Connor et al., 2004, cited in Billings, 2004).

For the reasons listed above, patient decision-aids and shared decision-making protocols are widely considered to be desirable. A number of obstacles however, hinder efforts to develop and disperse these tools more broadly. First, as with all tools that begin with a systematic evidence review, it costs "real money" to develop PtDAs and to keep them up to date, and there are no natural funding sources given our current market structures. Health plans have been major supporters, but association of the PtDA with a health plan or public payer can raise questions of conflict of interest (Billings, 2004). O'Connor and her colleagues (2004) identify four additional barriers to implementation: 1) awareness of their existence for a particular condition; the need for smooth, automatic and timely access; 3) practitioner acceptance, which is tied to low cost, ease of use and compatibility with the physician's practice style and personal beliefs; and 4) proven incentives for practitioners to adopt PtDAs, such as saved time and less repetition in patient interaction.

Initiatives and Proposals

ECRI, a not-for-profit organization that performs health technology assessments for private sector clients, has proposed the development of a National Patient Library. Similar to the National Medical Library, this new entity would identify, vet and organize health care information for consumers, but be operated as a public/private partnership (Lerner, 1998).

Consumers Union (CU) and the AARP are currently publishing electronic versions of the systematic reviews of drugs within class being produced by the Drug Evaluation

Review Project (developed by Oregon's Center for Evidence-based Policy). Both organizations have taken steps to make the information consumer friendly. With their "Best Buy Drugs" project, CU has gone a step further than the original DERP evaluations by comparing drugs on price as well as on effectiveness and safety issues.

CU sought grant funding both to help translate the evidence reviews and to create an outreach campaign in two trial sites: Atlanta and Sacramento. Their objective is promote the information to vulnerable populations and test whether 1) recipients understand the information and 2) information outreach can "create a grass-roots, word-of-mouth movement that will lead people to seek out this information on the web or in paper format" (Findlay interview).

To test whether there is a real, emerging consumer market for reviews of medical evidence, CU has also launched a sister project— Best Treatments—that will carry a separate subscription cost (Best Buy Drugs is free). Best Treatments will start with information and decision-support tools for about 60 diseases and treatments (Findlay interview).

C. Consumers and Cost-Effectiveness Analysis

In 1996, David Eddy wrote that "coverage criteria... must enable...health plans to weigh the benefits gained by an intervention against the costs and to allocate resources to interventions in a way that provides the greatest possible benefit...or there is little hope we will ever achieve the objectives of maximizing quality while controlling costs" (p.651). Research published in 2000 by Sacramento Health Decisions (SHD) on both physician and consumer attitudes about cost-effectiveness suggests that Eddy's objective will be extremely difficult, though perhaps not impossible, to achieve.

SHD found that consumers will not accept health plans using cost-effectiveness to deny treatment authorization for an individual patient. Many consumers however, will accept cost as a criterion used by their physicians, "when the patient trusts the physician, when it is clear that the patient is not forgoing a meaningful benefit and when the physician's opinion is not coerced or financially rewarded" (Sacramento Health Decisions, 2000, p.2). The same research found that physicians believe cost-effectiveness is an appropriate criterion in individual treatment decisions, but there is no consensus on how to use it in practice or consistency in physician response to patient demands for treatment that is not cost-effective.

Initiatives and Proposals

Sacramento Health Decisions has received a grant to supplement their previous research on cost-effectiveness with a broader analysis of consumer attitudes toward technology—including costs and the trade-offs consumers might find acceptable (Ginsburg interview).

Two researchers at City University of New York have received AHRQ funding to conduct consumer focus groups on the possible uses of cost-effectiveness in Medicare coverage decisions. They intend to test whether techniques the United Kingdom has used successfully to gain citizen acceptance of cost-effectiveness evaluation in technology assessment might be adaptable to U.S. populations (Gold interview).

VIII. Next Steps

This paper has described a variety of technology management issues, but at a high level of summary. Any one of these issues could easily be the topic of a full-length paper or extensive presentation. Additionally, defining solutions for many of these issues will require deliberation of factors that fall outside the scope of this paper, such as intellectual property laws and the economic determinants of drug and device manufacturer behavior.

With these factors in mind, the Institute might consider these steps to narrow initiative scope:

- 1) Facilitate a short discussion between internal stakeholders and potential partners—for example Institute and Federation staff—in order to pick three to five topics from this paper (or elsewhere) that warrant further exploration.
- 2) Identify key policy questions and develop short briefing papers specific to these questions by conducting additional interviews and obtaining “peer-review” of the material in this paper that pertains to the selected topics.
- 3) Identify potential partners and initiative co-sponsors for the selected topics.
- 4) Conduct one or two expert roundtables on the identified topics, with distinct but overlapping participation lists. For example, a panel of technically-oriented participants might best address topics on clinical research and technology assessment. Consumer acceptance of evidence-based reviews, media issues and developing support for evidence-based decisions in state legislatures might draw a very different set of panelists.
- 5) Articulate a one-two year plan for further policy effort on these topics based on the input of roundtable participants.

IX. Interview List

Name	Affiliation
1. Sandra Arthurs	Project Manager, Permanente Federation
2. Wade Aubry	Senior Advisor, HealthTech; Formerly, SVP and Chief Medical Officer, Blue Shield of CA, and Chairman, TEC Medical Advisory Board
3. Melanie Bella	Vice President for Policy, Center for Health Care Strategies, Inc.; Formerly, Medicaid Director, State of Indiana
4. Robin Cisneros	Director, Medical Technology Assessment, Permanente Federation
5. Agnes Cronin	Manager, New Medical Technology, The Permanente Medical Group
6. Steve Findlay	Managing Editor, Consumers Union (Best Buy Drug Project)
7. Susan Foote	Associate Professor and Division Health, Division of Health Services Research and Policy, UMN
8. Mark Gibson	Deputy Director, Center for Evidence-based Policy
9. Marjorie Ginsburg	Executive Director, Sacramento Health Care Decisions
10. Veronica Goff	Consultant to the National Business Group on Health, Committee on Evidence-based Benefit Design
11. Marthe Gold	Medical Professor and Chair, Community Health and Social Medicine, Sophie Davis School of Biomedical Education, City University of New York
12. Jessie Gruman	President, Council for Advancement of Health
13. Sharon Levine	Associate Executive Director, The Permanente Medical Group
14. Lisa Payne-Simon	Director (technology interest area), Blue Shield of California Foundation; Responsible for Blue Shield's Technology Assessment Committee
15. Richard Rettig	Rand Corporation; Formerly at Institute of Medicine, Participant in IOM Clinical Research Roundtable
16. Ellen Severoni	Executive Director, California Health Care Decisions
17. Gary Schwitzer	Faculty, UMN Program in Health Journalism; Also, Member of Board of Directors, Association of Health Care Journalists
18. Jed Weissberg	Associate Executive Director for Quality and Performance Improvement, Permanente Federation
19. Jill Yegian	Director, California Health Care Foundation

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