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A Briefing on Health Technology Assessment

By Lucien Wulsin, Jr. and Adam Dougherty

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I. INTRODUCTION

The United States spends nearly double the percentage of Gross Domestic Product on healthcare than any other country in the world. Much of this spending has been attributed to the ever-increasing development, use and pricing of new medical technologies, estimated to account for half of increasing costs.[1] Though the United States is a recognized leader in biotechnology and medical research, it has not translated into improved population health outcomes. The United States performs poorly when compared with other nations.[2] As the rate of healthcare spending continues to rise, combined with a growing variation in medical practice patterns, and poor quality outcomes, there is a demand for better information to improve healthcare decision making.

New healthcare products and services are being introduced at an increasing rate. Questions about the quality, effectiveness, and overall value are being raised. As noted by the Institute of Medicine, "what is newest is not always the best."[3] According to the Congressional Budget Office (CBO), "A variety of evidence suggests that opportunities exist to constrain health care costs both in the public programs and in the rest of the health system without adverse health consequences."[4]

Health technology assessments, such as comparative effectiveness measures, are tools that provide stakeholders with information to make informed, scientific evidence-based decisions. If used effectively, these efforts can improve the quality of care and contain healthcare costs. The central aim of these efforts is to get the greatest value (health outcome) for the invested healthcare spending**.** However, the CBO has found that "…hard evidence is often unavailable about which treatments work best for which patients and whether the added benefits of more-effective but more-expensive services are sufficient to warrant their added costs…"[5]

This report will outline and describe the process of health technology assessment, including comparative clinical effectiveness. Both positive and negative effects will be explored. The report will describe stakeholders and the agencies and organizations that engage in technology assessment activities. It also will summarize current legislation and current state/national activities and will outline a proposal for a new centralized body dedicated to the formal scrutiny of innovative (and existing) technology and services.

II. WHAT IS HEALTH TECHNOLOGY ASSESSMENT?

Health technology assessment (HTA) is "the systematic evaluation of properties, effects or other impacts of health technology[6]" in order to inform policymaking and improve the practice of healthcare. Technology in this sense is a broad term, including medical devices, pharmaceuticals, procedures, therapies, or systems. In clinical terms, HTA can serve to assess a product's efficacy, effectiveness, and cost benefits.

This information can be assessed both prior to a product's release (such as phase trials for FDA approval) and well after its diffusion. Examples of HTA can be seen in Table 1. Note that HTA can be applied to new or old technologies as well as to new or old treatments. This information is important to patients, clinicians, health plans, hospitals, lawmakers and technology manufactures as well as many others involved in the field. The relative value to different stakeholders is seen in Table 2.

Table 1: Examples of HTA Applications[7,8]

Ineffective Treatments Determined Through Technology Assessments
• Hormone replacement therapy for healthy menopausal women • Prescription Vioxx for pain • Radiation therapy for acne • Gastric freezing for peptic ulcer disease
Effective Treatments Determined Through Technology Assessments
• Invasive prenatal diagnostic testing for all women • CT angiographic source images replacing non-enhanced CT scans to detect stroke
Other Research Findings From Technology Assessments
• Rural emergency departments have higher rates of medication errors in children • Physician residents use specialized personal digital assistants most for drug references and medical calculations

Table 2: HTA Value to Different Stakeholders

Patients	Clinicians	Hospitals	Biotechnology Companies	Health Plans	Lawmakers
Identify best medical approach for individuals	Information to maximize health outcomes	Informed decisions on device acquisitions and healthcare treatments	Product development and marketing	Coverage determination, compensation and disease management	Policy regarding healthcare innovation and regulation

III. HOW IS IT BENEFICIAL?

There is a desire for more and improved data for healthcare decision making. Interest has turned to comparative clinical effectiveness, a component of HTA, and its ability to develop comparative information on new and old treatments and technologies. Stuart Altman, Professor of National Health Policy at Brandeis University, argues, "The nation cannot afford healthcare that is not supported by evidence of sufficient benefit." It also must facilitate "the need to move aggressively forward to develop the capacity of this country to do effective comparative research.[9]"

The evident increase of healthcare expenditures with no or limited improvement in health outcomes indicates a need for evidence-based information on the benefits, costs, and risks associated with different treatment options. Efficiency is central to improving value as David Cutler explains, "without explicit rationing, evidence based practice is the only hope we have of saving money in medicine."[10] To improve the value of healthcare, providers and patients must utilize lower-cost, higher-quality care that is founded on scientific evidence.

Summary of Benefits

- **Optimize** health outcomes
- **Increase** quality of care
- **Reduce** adverse reactions
- **Limit** unnecessary/outdated procedures
- **Decrease** care spending
- **Improve** overall value of investment

Comparative clinical effectiveness (CCE) research compares two or more healthcare services or treatments. CCE relies on data from clinical outcomes and provides information on each service's effectiveness.[11] Comparisons on effectiveness can be between similar competing drugs (products in a common drug class, often called "me too" drugs), different treatment approaches (surgery vs. drug therapy vs. combination), or assessing a new technology against a standard mode of diagnosis and treatment. These assessments can be based on the population as a whole or for demographic-centered subpopulations, which are important as outcomes can vary based on age, gender, or ethnicity. CCE can be used to decide whether insurance should cover a new technology, in what circumstances and how much to pay for it.

Comparative tools have the potential to control costs by limiting the use of unnecessary, expensive, or outdated procedures while improving health outcomes.[12] If the data is widely disseminated, it may shift the sentiment of "more is better" to "new may not necessarily be best." The following section describes the process of how technology is assessed and compared.

IV. HTA TOOLS AND COMPARATIVE MEASURES

Efficacy and Effectiveness

Efficacy is not effectiveness. Efficacy research generates narrowly focused data that does not address clinical practice conditions, patients with co-morbidities, or other variables. "Efficacy" can be ascertained through Randomized Controlled Trials (RCT). In pharmaceutical research RCTs compare a new drug to a placebo under controlled conditions to test a drug's efficacy. These studies remove, to the extent possible, any variance between subject groups, and quantify outcomes based on intermediate measures such as blood pressure or cholesterol level (as opposed to clinical outcomes such as cardiovascular mortality).[13]

A treatment's effectiveness, on the other hand, measures the health outcome in routine clinical practice across different settings. It compares a drug, device or treatment, not to a placebo, but rather to alternative forms of treatment. Because this evidence is commonly based on epidemiological and observational data, it can be seen as less certain, relatively weaker evidence. The value of certainty is important in evidence-based decision making, and is discussed in the following section.

Strength of Evidence

At what point can a service be deemed safe and effective enough for introduction into clinical use? The tension between scientific rigor and timely reporting of results is a subject of debate. Teutsch et. al. argues, "the full range of potential benefits and risks associated with therapeutic decisions across the range of potential clinical applications is not known until long after the technologies have been widely adopted."[14] A continuous feedback of information based on clinical effectiveness may be necessary to achieve maximum effectiveness.

Satisfactory evidence varies with the characteristics of the treatment. RCTs, for example, are more appropriate when high levels of certainty are needed, where the burden of illness, risks, and costs for an intervention are high. Other interventions may need less rigorous studies to reach a proper level of certainty. Most medical and clinical decisions are made using available evidence, using a combination of RCT findings and literature meta-analyses.[15]

Aggregating clinical data across providers and payers is gaining significant attention as a way to strengthen scientific evidence. Rowe points out that the development of electronic health records (EHR) can greatly improve the content and usefulness of aggregated databases.[16] Through EHRs, it will be possible to include clinical experiences from millions of patients in real time. Lynn Etheredge predicts that EHRs and CCEs will not replace RCTs, but will effectively create a "Rapid-Learning System" to fill "major knowledge gaps" in healthcare costs, risks and benefits, and geographical variations.[17] EHRs will be able to readily report data from millions of patients, including variables such as genetic markers and environmental factors, and thereby facilitate evidence-based

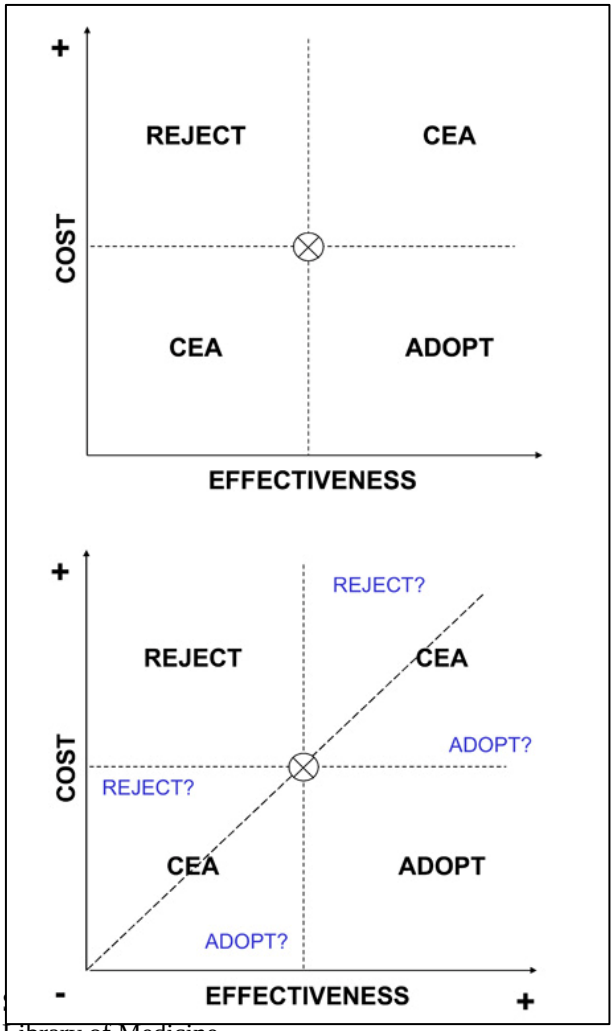
decision making by clinicians and policymakers to make improved, evidence-based decisions.

Cost Analysis

The relative costs of alternative treatments and services are one aspect of HTA. Cost analyses can become controversial when they become part of health policy decisions (coverage, reimbursement) or medical decision making.[18] A policy decision made at the health plan or government level that limits a particular treatment or expensive drug based on cost may be perceived as rationing care from an individual patient's point of view.

Cost analyses include a number of approaches, including Cost-benefit analysis (CBA) and Cost-effectiveness analysis (CEA). CBA measures costs and outcomes in monetary units, though it is difficult (and contentious) to assign monetary values to health outcomes such as length and quality of life.[19] CEA, on the other hand, uses direct health outcomes such as quality-adjusted life years (QALYs), when assessing a service's cost. Services are not solely judged on cost-effectiveness; their effectiveness also is judged in comparison to another service.

Figure 1: Quadrants of Cost-Effectiveness



Library of Medicine

Goodman portrays this decision-making scale as quadrants in Figure 1. Those technologies with low cost and high effectiveness would be adopted while those that have high cost and little efficacy could be rejected without concern. Most fall into gray areas; low costs and lower effectiveness or higher costs and higher effectiveness. While some comparisons using cost-effectiveness can be easily determined and be either adopted or rejected, most comparisons are not clear cut and are, therefore, subject to further research, analysis and discussion.

John C. Lewin, CEO of the American College of Cardiology; Gail Wilensky, Senior Fellow, Project Hope; and others recognize the importance of comparative cost analyses but argue that the comparative clinical effectiveness measurements should be separate from comparative cost analyses.[20,21] Inclusion of cost analyses has been contentious as may be seen in Section VI (page 9).

V. CONCERNS AND CRITICISMS OF ASSESSMENT TOOLS

Transparency and Bias

CCE and other forms of technology assessment raise important concerns regarding who actually performs the research, and how that may affect research findings. All decision making introduces some degree of subjectivity, even when based on scientific evidence.[22] Levels of bias and conflict of interest confound the validity and clinical application of technology assessments, and create the need for complete transparency in the assessment process with appropriate input from all relevant stakeholders.

Political influence and special interest groups (pharmaceutical companies, paid physician researchers, device patent holders and others) are examples of potential for bias. Though multidisciplinary stakeholder input is important, Gail Wilensky contends that the three crucial concepts of "credibility, objectivity, and transparency" must be maintained throughout the assessment process.[23]

Innovation

Requirements to adhere to scientific evidence create a fear that innovation may be stifled. Decision makers must be able to accept a certain degree of uncertainty, as Teutsch believe adoption of a new technology "only when there is unambiguous evidence that would delay the adoption of new technologies by many years."[24] Sean Tunis, Director of the Center for Medical Technology Policy, argues against waiting, as the use of technology in the field is precisely how evidence is gained.[25] Pre-market evidence requirements should be balanced with post-market results so as not to discourage smaller device companies who have limited resources.

Common Apprehensions in HTA Use

- Concern of adverse/unknown health outcomes following an evidence-limited analysis (e.g. pharmaceutical recalls)
- Worry that assessments can be influenced by special interests
- Creating "cookie-cutter" or "cookbook" medicine
- Fear that health plans will restrict coverage or compensation based on findings
- Concern that population-based decisions may be detrimental to individual patient circumstances

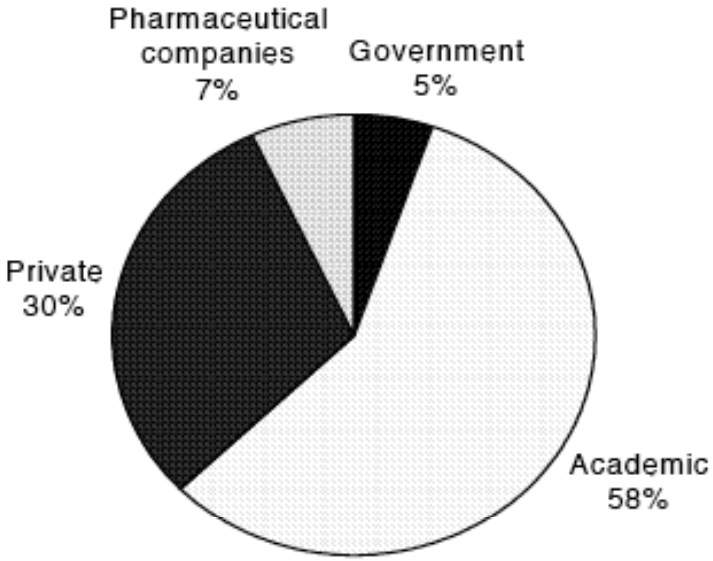
Though rapid diffusion of beneficial technology is ideal, unknown long-term effects leave opportunity for risks. High profile failures such as Vioxx reveal an underinvestment in assessing longer-term evidence of clinical effectiveness. The development of post-market surveillance (such as those possible with EHRs, see Section IV) may be able to identify complications earlier, allowing novel procedures and treatments to be allowed into the marketplace while removing unforeseen harmful ones in a timely manner.

VI. WHERE HAS IT BEEN DONE? FEDERAL LEVEL

Public agencies, private entities, and other organizations conduct a range of HTA and CCE research. There is diversity in how the data are viewed and utilized. Many organizations conduct comparative research, however the results are not coordinated and the diffusion is not widespread.

Figure 1 describes the relative share of studies published in PubMed by different entities from 2004-2007, as found in a Congressional Research Service report. The search focuses on clinical comparative effectiveness research, and does not include clinical trials against a placebo. Private institutes include for-profit and nonprofit entities not based at a university or pharmaceutical company. Research is conducted primarily in academia and the funding comes from public agencies and other organizations.

Figure 2: Share of Comparative Clinical Effectiveness Studies Published in the Medical Literature, by Each Type of Entity, January 2004-August 2007



Source: Congressional Research Service analysis from search of PubMed at the National Library of Medicine.

National Center for Health Care Technology

One of the first federal programs to assess medical technology was the National Center for Health Care Technology. This short-lived program was established in 1978 as a division of the Department of Health, Education, and Welfare and given a broad mandate to conduct and promote technology research. The Center sponsored and co-sponsored

evaluations and made 75 recommendations to Medicare regarding coverage of new technologies. The program ceased operations in 1981 due to a combination of changing national priorities and strong provider/industry opposition.

The Office of Technology Assessment (OTA)

The OTA was established in 1972 Congress as a bipartisan effort to study a variety of technologies, many of which were healthcare focused. The Technology Assessment Board composed of six Senators and six Representatives, accepted proposals to conduct assessments; over a two year period the Office would create a report, which included the diverse views of stakeholders. The Office proved controversial for its inclusion of costs and cost-effectiveness in its technology assessments. The work was also often criticized as not timely, duplicative, and not applicable to public programs. The OTA was disbanded in 1995, as a result of increasing controversy and the budget reductions of the 104th Congress. [26]

The Agency for Health Research and Quality (AHRQ)

The AHRQ is the most prominent federal agency that supports HTA and comparative effectiveness research, though only a portion of its $300 million budget goes towards technology assessments. The agency experienced criticism in the 1990s (as the formerly-known Agency for Healthcare Policy and Research) when it incorporated cost-effectiveness into its Medical Treatment Effectiveness Program (MEDTEP). Opposition to the inclusion cost data in the analysis was expressed by the Institute of Medicine, the Government Accountability Office, and the Physician Payment Review Commission. Congress responded by reducing the Agency's 1997 budget by 20 percent and eliminating the MEDTEP program. In 1999, the agency was reauthorized, and now research is conducted through four programs with centers primarily based at academic institutions:

- The Centers for Education and Research on Therapeutics (CERTs) is a program conducted jointly by the AHRQ and the U.S. Food and Drug Administration. The research attempts to realize the most beneficial use of drugs, biological interventions, and devices by comparing the risks, benefits, interactions, and economic implications of treatment.

- AHRQ created the Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) program to conduct and support research specifically on treatment appropriateness, health outcomes, and comparative effectiveness. Unlike other programs, DEcIDE centers do not look at the cost-effectiveness of technologies. The agency had funded 15 projects through this program as of August 2007.

- The Evidence-based Practice Centers (EPC) Program was established to improve the quality and effectiveness of healthcare through technology assessments. Reports from the 13 centers are used to inform public and private insurers' coverage determinations, as well as to generate quality measures, guidelines, and educational

materials. Cost-effectiveness has also been used as a research tool. Over 150 reports had been published by the centers through 2007.

- In 2001, The Research Initiative on Clinical Economics (RICE) was created to fund research on healthcare intervention cost effectiveness, cost benefit, and value estimation. As the research has not been used to generate either clinical guidelines or coverage decisions, it has not generated any controversy.

The Department of Veteran's Affairs (VA)

The VA works with the Department of Defense (DoD) to review evidence of treatment efficacy through an extensive review of patient records. The program relies on comparative clinical effectiveness to generate clinical guidelines and establish its drug formulary. Of note is the program's ability to quickly and reliably gather patient data through the use of the VistA electronic medical record system. VistA allows for national data to be aggregated for analysis to discern trends and significant outcomes.

Center for Medicare and Medicaid Services (CMS)

As the public provider for over 80 million Americans, CMS has a daunting task of addressing what constitutes medically reasonable and necessary care. The determination of coverage takes place on two levels: as national coverage determinations (NCDs) and local coverage determinations (LCDs). The NCDs apply across the nation, whereas regional contractors make the LCDs that apply only in their own region. The determinations are evidence-based, and include information from expert opinion, experimental and informal studies, and other sources. CMS now explicitly excludes treatment costs from the NCDs after opposition throughout the 1990s. Local contractors have the authority to include cost and cost-effectiveness for LCDs; these are most often termed "least costly alternative" policies.[27]

In 2006, the Medicare Payment Advisory Committee (MedPAC) noted that clinical and cost effectiveness could vary across study methods, and thereby produce varying results. As is the case with clinical trials, the Committee urges that studies be methodologically comparable. (For more information, see the MedPAC *Report to the Congress: Increasing the Value of Medicare*, June 2006, "Chapter 10: Medicare's Use of Clinical and Cost-effectiveness Information.")

Federal Legislation

There have been a number of bills introduced in Congress that focus on technology assessment and clinical effectiveness. While most examples include expansion of funding and research as a portion of the bill, more recent proposals such as S.3408 explicitly call for the formation of a new body dedicated to effectiveness research.

The Comparative Effectiveness Research Act of 2008, S. 3408, Baucus (D-MT)

The bill would amend Title XI of the Social Security Act to provide opportunity for better comparative effectiveness research. The Act would establish a Health Care Comparative Effectiveness Research Institute as well as a Comparative Effectiveness Research Trust Fund.

Enhanced Health Care Value for All Act, H.R. 2184, Allen (D-ME)

The bill would amend the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, to expand and fund comparative effectiveness research in order to improve the value of healthcare. The Act would include expanded research authority and increased funding, and establish a Comparative Effectiveness Advisory Board.

Healthy Americans Act, S. 334, Wyden (D-OR), H.R. 3163, Baird (D-WA)

Would encourage clinical effectiveness research through incentives to device and pharmaceutical manufacturers. The Act also includes disincentives for products without clinical comparative evidence, including a mandatory disclosure statement on promotional material and tax deduction exemptions.

Food and Drug Safety Act of 2007, Tierney (D-MA)

Would amend the Food, Drug, and Cosmetic Act to improve drug safety. The bill includes a measure to establish a Center for Postmarket Evaluation and Research for Drugs and Biologics. The center would instruct companies to conduct comparative clinical effectiveness studies on products already in the marketplace.

VII. WHERE HAS IT BEEN DONE? – STATE LEVEL

Several state governments have experimented with technology assessments, such as simple data collection and dissemination to establishing clinical practice guidelines.[28] HTA also has been important to some state-subsidized insurance benefit designs.

Minnesota Health Technology Advisory Committee (HTAC)

The HTAC was created in 1993, to be an "objective, state-specific source of technology evaluation information" for both public and private sector decision makers.[29] HTAC was made up of nineteen representatives from physician groups, technology industry representatives, health plans, and ethicists. The group conducted public forums, received testimony from multiple stakeholders, and made recommendations on emerging technologies. Though the Committee was terminated in 2002; due to state budget cuts, its reports can still be viewed on the Minnesota Department of Health website.[30]

Oregon Medical Technology Assessment Program (MedTAP), Oregon Health Plan

In an effort to expand public insurance coverage to the poor and cut costs in the early 1990s, the Oregon Health Plan (OHP) generated some controversy for its "infamous prioritized list of medical conditions and treatments."[31] This was the first large-scale public attempt to apply cost-effectiveness analyses to compile and prioritize a list of public health services. MedTAP was commissioned to establish this list, though the cost-effective ratios were highly criticized for having major flaws. For example, capping teeth would have had a higher priority than life-saving appendicitis surgery.[32] The plan was revised with somewhat subjective re-rankings, and implemented in 1994. Where most other cost-benefit and clinical effectiveness analyses compared like treatments, the OHP explicitly compared treatments of entirely different diseases. Ultimately, the program achieved success in expanding insurance coverage to the uninsured, though in the wake of the state's economic crisis, OHP has experienced setbacks.[33]

Health Technology Assessment Program (HTA), Washington State Health Care Authority

The Washington program began in 2007, with a goal of achieving 14 technology assessments in two years. The assessments will gauge the safety, clinical effectiveness, and cost-effectiveness of selected technologies. Beginning with a period of public input, the HTA Clinical Committee of 11 independent practicing healthcare professionals will then review the evidence and make their recommendation to state agencies. Five assessments have been completed thus far and can be found at the website; which includes information on future assessments as well as the assessment process.[34]

VIII. WHERE HAS IT BEEN DONE? – PRIVATE SECTOR

A number of for-profit and nonprofit entities are engaging in health technology assessment. They include health plans, device manufacturers, research organizations and others with grants from public sources.

Drug Effectiveness Review Project (DERP), Oregon Health Science University

In the year 2000, the Medicaid program in Oregon experienced a 60 percent increase in the program's drug expenditure from the year before. The following year, the state legislature commissioned the Oregon Health Science University to assess comparative clinical effectiveness and drug safety in clinical practice. DERP reviews literature and evidence on the effectiveness of common-class drugs. If drugs are found to be equal in effectiveness, consideration is then given to cost. The project has rigorous research policies and data conflict of interest policy forbidding financial ties between researchers and pharmaceutical companies.

To obtain the best available information, the Project collaborates with the Oregon Evidence-Based Practice Center (EPC), and recently expanded to include resources from 14 states and the Canadian Agency for Drugs and Technologies in Health. Originally commissioned to help stem state Medicaid expenditures, DERP reports are publicly available and now used by other constituencies (see below). DERP I produced 28 new reports in addition to 45 updated reports. The second phase, DERP II, started in the fall of 2006, and is currently in progress.[35]

Consumer Reports' Best Buy Drugs Project

The Best Buy Drugs Project is a public education effort by the nonprofit Consumers Union, the publisher of *Consumer Reports*. The project utilizes DERP reviews in order to provide effectiveness information to consumers and providers. Its *Best Buys* are classified by drug class, and are updated periodically to include generic alternatives.[36]

California Healthcare Institute (CHI)

CHI was founded in 1993, as an independent organization that analyzes innovation in the biomedical community to advance the interests of the California biomedical community. The Institute provides analyses on state and national policy, as well as in-depth reports on research and development, and medical technology. CHI is a useful resource for news and perspectives with a database of over 2,500 companies, research institutes, and universities.[37]

Technology Evaluation Center (TEC), Blue Cross and Blue Shield Association

The TEC was established in 1985, as a pioneer in technology assessment. TEC reviewed clinical evidence, and was designated as one of the first EPCs by the AHRQ in 1997 (see Section VI). The Blue Cross and Blue Shield Association's website states that the TEC

averages 20 to 25 assessments per year, and that they are generated solely for public informational purposes. The center compares the effectiveness of pharmaceuticals, devices, and services while taking into account quality and length of life, as well as functionality. Cost-effectiveness analyses are designated as a Special Assessment, which also include sub-population analyses.[38]

Kaiser Permanente Technology Assessment

Kaiser Permanente Technology Assessment has worked closely with TEC since 1993, advising in topic selection, report drafts and providing expert clinical support on a wide range of topics. Jed Weissberg, MD, is the Associate Executive Director for Quality and Performance Improvement of The Permanente Federation and is a voting member of the TEC Medical Advisory Panel. This collaboration assists Kaiser in the development of clinical practice guidelines throughout the system.

Emergency Care Research Institute, ECRI

The ECRI Institute is a nonprofit organization dedicated to technology assessment and comparative effectiveness with over 5,000 member groups and clients including health systems, hospitals, public and private health plans, government agencies, and international health ministries. The Institute is both an AHRQ EPC and a Collaborating Center of the World Health Organization. ECRI also holds an annual conference on "Comparative Effectiveness of Health Interventions".[39]

For-profit Organizations

Many for-profit groups produce technology assessments, such as pharmaceutical and device manufacturers. Some of the data produced by the studies is confidential and is not available to the public.[40]

IX. INTERNATIONAL DEVELOPMENT

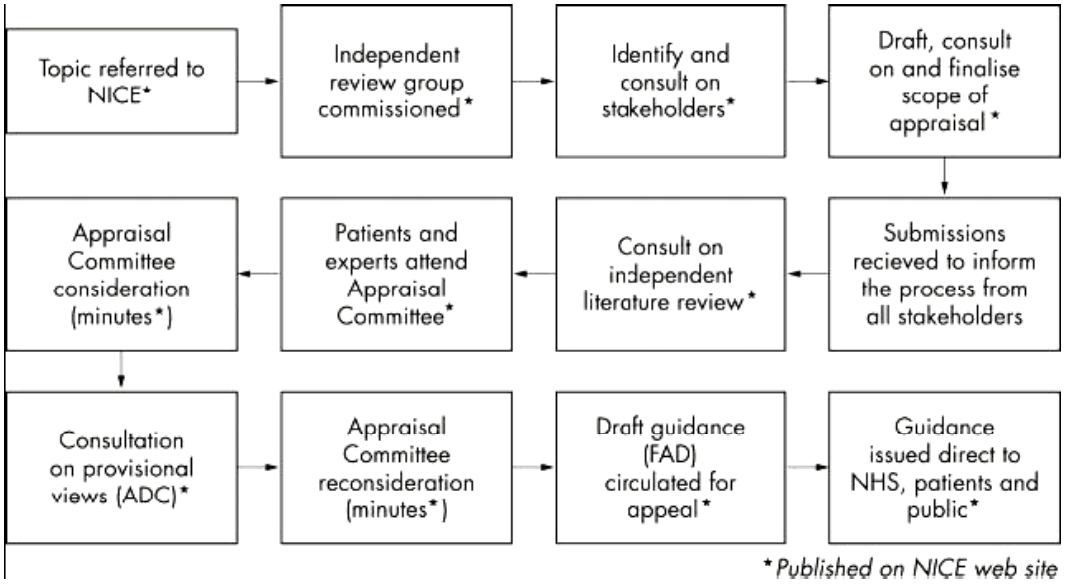
Internationally, technology assessments such as comparative clinical effectiveness and cost-analyses play a large role in national decision making on new technologies and reimbursement. Several variations follow.

The United Kingdom, National Institute for Health and Clinical Excellence (NICE)

NICE was established in 1999, to address under-utilization issues relative to geographic limitations of access to certain treatments and procedures. NICE now operates through three divisions to promote good healthcare, and advises the National Health Service in effective resource use combined with the highest quality care. The organization is funded by the Department of Health in the United Kingdom, but operates independently from government.[41]

Through a public and transparent appraisal process, NICE gives recommendations on new and existing technology and treatments. Although technically national 'advice,' these reports have been fundamental to NHS clinical guidelines and coverage. Central to these assessments are clinical and cost-effective measures, determined by a rigorous academic analysis. The cost-effective analyses are centered on subpopulation benefits, as well as overall affordability of a technology.[42] Committees consist of individuals from multidisciplinary backgrounds, who review all available information, and welcome public stakeholder opinion during the review process. Most importantly, NICE states that all determinations are based on the best available information and any new relevant findings can merit reevaluation.

Figure 3: NICE Recommendation Process



Source: Moon, *Creating a Center for Evidence-Based Medicine*, The American Institutes for Research, July 2007

Some NICE analyses have been criticized as based on limited or weak information, while other decisions have been perceived as not being in the best interest of an individual patient's case.[43] Researchers also disagree in the application of cost effectiveness; some believe analyses should include the overall impact on the NHS budget, while others question the use of cost comparisons altogether.[44]

Canada

The first Canadian HTA program was established in 1988, in Quebec, and today the country has similar programs at the national, provincial, and local levels in order to determine the use and insurance plan coverage of health technologies. The government-funded national program is now called the Canadian Agency for Drugs and Technologies in Health (CADTH). Clinical effectiveness studies and economic aspects are the areas most commonly addressed.[45]

Australia

Under Medicare, the public health insurance system in Australia, the Medicare Benefits Schedule and Pharmaceutical Benefits Schedule list the range of services offered and their corresponding fees. To determine if a service is covered, the Medical Service Advisory Committee and Pharmaceutical Benefits Advisory Committee assess new technologies on the basis of clinical and cost effectiveness and real benefit. The schedules are open to the public and are available in an online database.[46,47] Pharmaceutical companies must prove that their new products are cost effective before they can be reimbursed by the government, unlike the Canadian and British models, in which the analyses are "technically" advisory.[48]

International Organizations

The International Network of Agencies for Health Technology Assessment (INAHTA)[49]

- Includes 46 national/regional government agencies from 24 countries
- Provides a forum for the identification and pursuit of common interests in HTA

Health Technology Assessment International (HTAi)[50]

- International professional society focusing exclusively on the development and exchange of HTA information from multidisciplinary backgrounds
- Publishes quarterly journal, the *International Journal of Technology Assessment in Health Care*
- Conducts an annual international meeting of experts from around the globe (HTAi 2009: Singapore)

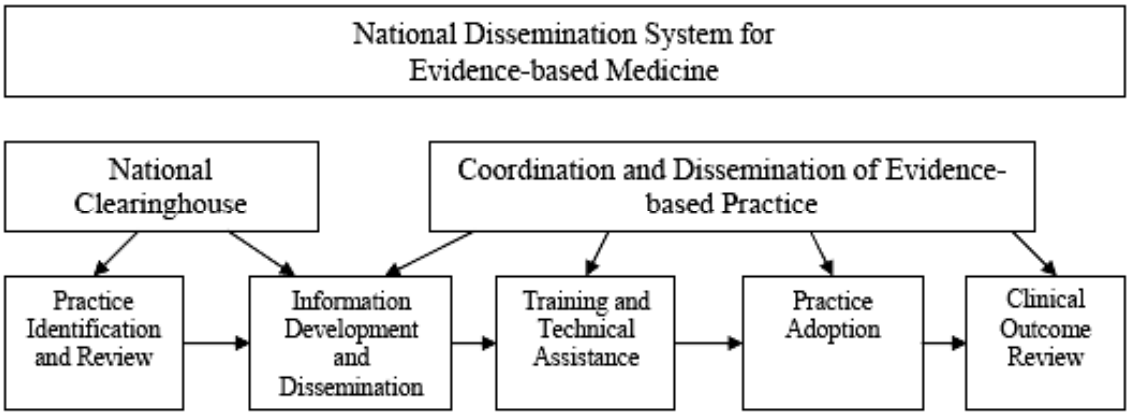
X. LOOKING AHEAD – THE FUTURE OF TECHNOLOGY ASSESSMENT

This report has described potential benefits and drawbacks of HTA, as well as many of the organizations that perform such analyses. The purpose of the tools of HTA, comparative effectiveness and cost analyses is to improve clinical practice and get the best healthcare value for dollars spent. Translating this research into practice has proven the most complicated portion of this task. Gretchen Jacobson of the Congressional Research Service observes: "Overall, changing clinical practice is not a simple or inexpensive process, and requires far more than disseminating information and expecting individuals to comb through research studies and find ways to translate the findings into action."[51]

A New Center for Evidence-Based Medicine

The wide variations in clinical practice patterns and the large volume of research presents an opportunity for a new centralized and multidisciplinary body whose sole purpose would be to aggregate, evaluate, and disseminate evidence-based information. Moon, et. al. suggests that a new "national clearinghouse of evidence-based information" could systematically review evidence-based practices, conduct rigorous research reviews and disseminate objective information (somewhat similar to NICE in the UK).[52] The authors propose the process in Figure 4.

Figure 4: Proposed model for the new center



Source: Moon, et al, *Creating a Center for Evidence-Based Medicine*, The American Institutes for Research, July 2007

Gail Wilensky of Project Hope proposes for a new national Institute to serve an information function rather than a decision-making function. She advocates that the focus be on medical conditions rather than specific interventions, and include procedures in addition to pharmaceuticals and devices. It would work with the mindset "that technologies are rarely *always* effective or *never* effective;" and aim to help inform

decision makers about the probabilities of favorable outcomes, rather than setting coverage requirements. She also recommends that cost analyses should be housed separately, and that the Institute not be charged with responsibility for either coverage or reimbursement decisions. The entity would be freestanding, comparable to the Federal Reserve Board or a Federally Funded Research and Development Center (FFRDC) like the Lawrence Livermore Labs. The center would be most effective if it had both in-house research and contract research functions, similar to AHRQ and the NIH.

Funding for the new entity would be based on its structure. Wilensky puts the start-up cost around several billion dollars over several years to reach a readiness state. Without in-house research, though, that number could be far lower if the center drew on other sources for the expensive research activities, as proposed by Moon, et. al.[53] The Congressional Budget Office projects net nationwide savings of $6 billion over ten years. [54] More recently the Lewin Group projected net ten-year savings of nearly $12 billion. [55]

Whatever its structure, the proposed center would need to include experts from multiple disciplines, and include a public review process for all stakeholders. The outcomes would need to be based on strong, credible findings and be open to future revisions.

Background Resources for HTA

- *HTA 101: Introduction to Health Technology Assessment* by Clifford Goodman, United States National Library of Medicine, January 2004, http://www.nlm.nih.gov/nichsr/ta101/ta101.pdf
- *Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role*, Congressional Budget Office, http://www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf
- *Cost-Effectiveness and Evidence Evaluation as Criteria for Coverage Policy*, Alan M. Garber, *Health Affairs Web Exclusive*, May 19, 2004, http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.284v1
- *Medical Management after Managed Care*, James C. Robinson and Jill M. Yegian, *Health Affairs Web Exclusive,* May 19, 20004. http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.269v1
- Perspective: Integrating Disease Management into the Outpatient Delivery System During and After Managed Care, Victor, G. Villigara, *Health Affairs Web Exclusive*, May 19, 2004. http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.281v1
- *"Comparative Clinical Effectiveness and Cost-Effectiveness Research: Background and Overview* by Gretchen A. Jacobson, *CRS Report for Congress*, October 2007.
- Advanced Medical Technology Association (AdvaMed) Policy Position on Comparative Effectiveness Research, http://www.advamed.org/MemberPortal/.
- Technology Assessments in the Agency for Healthcare Research and Quality, http://www.ahrq.gov/.
- National Institute for Health and Clinical Excellence, UK, http://www.nice.org.uk/
- *ECRI Institute 15th Annual Conference Report: Key Questions and Issues* by Andrew Holtz, ECRI Institute 15th Annual Conference. https://www.ecri.org/comparativeeffectiveness/Pages/Holtz.aspx

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