

# Comparative Effectiveness Research and Evidence-Based Health Policy: Experience from Four Countries

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**Context:** The discussion about improving the efficiency, quality, and long-term sustainability of the U.S. health care system is increasingly focusing on the need to provide better evidence for decision making through comparative effectiveness research (CER). In recent years, several other countries have established agencies to evaluate health technologies and broader management strategies to inform health care policy decisions. This article reviews experiences from Britain, France, Australia, and Germany.

**Methods:** This article draws on the experience of senior technical and administrative staff in setting up and running the CER entities studied. Besides reviewing the agencies' websites, legal framework documents, and informal interviews with key stakeholders, this analysis was informed by a workshop bringing together U.S. and international experts.

**Findings:** This article builds a matrix of features identified from the international models studied that offer insights into near-term decisions about the location, design, and function of a U.S.-based CER entity. While each country has developed a CER capacity unique to its health system, elements such as the inclusiveness of relevant stakeholders, transparency in operation, independence

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of the central government and other interests, and adaptability to a changing environment are prerequisites for these entities' successful operation.

**Conclusions:** While the CER entities evolved separately and have different responsibilities, they have adopted a set of core structural, technical, and procedural principles, including mechanisms for engaging with stakeholders, governance and oversight arrangements, and explicit methodologies for analyzing evidence, to ensure a high-quality product that is relevant to their system.

**Keywords:** Health reform, comparative effectiveness research.

**I**N 2003, SENIOR OFFICIALS FROM THE AGENCY FOR HEALTHCARE Research and Quality (AHRQ) and the Center for Medicare and Medicaid Services (CMS) described serious gaps in the generation of information needed by decision makers in health care in the United States: "Neither of the major sources of funding for clinical research in the United States—the National Institutes for Health and the medical products industry—has as a primary mission the goal of ensuring that studies are performed to address clinical questions important to decision-makers" (Tunis, Stryer, and Clancy 2003, pp.1627–28). Four years later, the head of the Congressional Budget Office testified before the House Ways and Means Subcommittee on Health on the potential impact of comparative effectiveness research (CER) on health outcomes and expenditure:

Better information about the costs and benefits of different treatment options, combined with new incentive structures reflecting the information, could eventually yield lower health care spending without having adverse effects on health . . . even if it did not bring about significant reductions in spending, more information about comparative effectiveness could yield better health outcomes from the resources devoted to health care. (Congressional Budget Office Testimony 2007, p. 2)

*Comparative effectiveness research* is a relatively new and distinctly American term. Other countries still use terms such as *health technology assessment* or *evidence-informed policymaking* to describe essentially the same activity. Different U.S. organizations have suggested different definitions of CER. Throughout this article, we use the definition from a recent Institute of Medicine (IOM) report:

{Comparative evidence research is} the comparison of one diagnostic or treatment option to one or more others. In this respect, primary comparative effectiveness research involves the direct generation of clinical information on the relative merits or outcomes of one intervention in comparison to one or more others, and secondary comparative effectiveness research involves the synthesis of primary studies to allow conclusions to be drawn. (IOM 2007, pp. 7–8)

In order to include comparative costs, we also qualify the IOM definition with that of the American College of Physicians: “the evaluation of the relative (clinical) effectiveness, safety, and cost of 2 or more medical services, drugs, devices, therapies, or procedures used to treat the same condition” (American College of Physicians 2008, p. 1). CER is an analytic activity that is explicitly guided by the information needs of decision makers. A final qualification: by “CER entities,” we are referring to formal structures that use CER to make or inform decisions about health services and technologies covered by payers. The relationship between decision making and CER is of central importance: CER entities set (mostly secondary) CER priorities and use (primary and secondary) CER findings to inform their (mandatory or advisory) decisions about specific aspects of health policy and practice. There is currently no such “CER entity” (or group of entities) in the United States. Instead, most of the current discussion pertains to research organizations established to generate primary or secondary CER rather than to a CER decision-making or decision-informing entity.

Both comparative effectiveness research and the challenge of using evidence of what works to inform health policy and clinical decisions have some important precedents in health care policy discussions in the United States (Reinhardt 2004). In the opening pages of its 1994 report *Identifying Health Technologies That Work: Searching for the Evidence*, the Office of Technology Assessment (OTA) characterized the work of the Agency for Healthcare Policy and Research (AHCPR) and other organizations as follows:

The basic rationale for the current federal effort to identify which existing health care technologies work best has been the hope that the results of this effort can increase not only the benefits of health care but also the value. As a number of advocates have argued, if a particular

use of a technology is ineffective or unnecessary, eliminating that use should benefit patients and payers alike. (Office of Technology Assessment 1994, p. 12)

For several years, a number of U.S. agencies have been created to undertake similar tasks in order to inform decision makers: the OTA's health program in 1975, the National Center for Health Care Technologies in 1978, the Institute of Medicine's Council on Health Care Technology Assessment in 1984, and the AHCPR in 1989. Most of these agencies are no longer operational whilst "policy" was removed from AHCPR's title and the organization was reborn as the Agency for Healthcare Research and Quality (AHRQ).

Over the last few years, since the publication of a proposal to create a new national center for comparative effectiveness, written by Gail Wilensky, the former administrator of the Health Care Financing Agency that oversaw Medicare and Medicaid, a number of policy analyses and recommendations have supported the need for a major expansion in CER (focused on research, as opposed to decision making) capacity, including the proposals by America's Health Insurance Plans, the Commonwealth Fund's *Bending the Curve* report, a position statement by the American College of Physicians, an IOM report on CER, analyses by Academy Health, and a series of meetings organized by the Medicare Coverage Advisory Committee on identifying high-priority topics by CER (American College of Physicians 2008; America's Health Insurance Plans 2007; Congressional Budget Office Testimony 2007; Congressional Research Service 2007; IOM 2007; Medicare Payment Advisory Commission 2007; Schoen et al. 2007; Wilensky 2006). Furthermore, legislation was introduced several times in 2007 and 2008 in both the House and the Senate, to establish an entity that would deliver CER information to decision makers, including the Conrad–Baucus Senate bill to create a Health Care Comparative Effectiveness Research Institute. Most important, the American Recovery and Reinvestment Act (ARRA), the economic stimulus bill signed into law by President Barack Obama in early 2009, provides \$1.1 billion to "accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies." (U.S. Congress 2009). The funds will be divided among AHRQ, the National Institutes for Health (NIH), and the Department of Health and Human Services (HHS). About \$1 million will be allocated to the Institute of Medicine for helping determine the

priority of topics for CER, which the bill defines as research comparing “clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions” and would “encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health care data that can be used to generate or obtain outcomes data.”

Despite the interest in comparative effectiveness information by policymakers, academics, payers, consumers, and manufacturers, and the federal government’s recent commitment as shown in the ARRA, questions remain about the mechanisms for generating CER, including funding and governance arrangements and the framework (legislative and other) within which the information could then be used to support population-level coverage determinations, general reimbursement policies, and individual-level clinical management decisions. Furthermore, whether comparative *cost*-effectiveness should help inform resource allocation and treatment decisions in the United States, and whether a national CER center, with or without decision-making responsibilities, should produce this information, are still being hotly disputed (Garber 2008; Wilensky 2008).

In this article, we describe four national-level models created to evaluate health technologies and broader management strategies to inform health care policy decisions in the United Kingdom (National Institute for Health and Clinical Excellence, or NICE), France (Haute Autorité de Santé, or HAS), Australia (Pharmaceutical Benefits Scheme, or PBS), and Germany (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, or IQWiG), in order to contribute to the U.S. debate on CER.<sup>1</sup> The purpose of this analysis is to derive lessons that may be useful to U.S. policymakers in expanding the resources for and application of CER in the United States. These countries were selected as examples of different Western health care systems that use CER in their decision making. Several other countries and states use CER to determine aspects of health care policy, including the Common Drug Review and the Ontario Health Technology Advisory Committee in Canada and the Pharmaceutical Management Agency (PHARMAC) in New Zealand. Although this article is not intended to be a comprehensive review of international models, the countries we selected do represent the CER capacity of a variety of health care systems, ranging

from the British nationalized single-payer system to the French and German social insurance models.

Our analysis is based on a review of published, peer-reviewed literature as well as gray literature, references to agency databases and websites, and discussions with stakeholders from each country, including senior officials and/or executives of the overseas agencies, as well as U.S. experts. In addition to our own experience from currently serving or having in the past served at various technical and policy posts in these entities, this article also draws on a workshop sponsored by the Commonwealth Fund, which was held in December 2008 in London and brought together senior policymakers from the countries studied and the United States.

In the first part of this article, we identify ten core structural, political, methodological, and procedural attributes that capture the establishment, evolution, and current format and function of CER entities across the four countries studied. We describe the important country-specific characteristics for each attribute and discuss areas of relevance to the United States. In the second part, we cite the main lessons learned from these international experiences. Our aim is to help U.S. policymakers and academics and to contribute to the current discussion about using comparative effectiveness research to improve efficiency and outcomes, by studying the successes and failures of similar entities in other countries.

### A Common Theme: CER as a Demand-Driven Activity

Perhaps the characteristic found most often in all four international models is that CER was developed, albeit using somewhat different structures, methods, and processes, as a demand-driven activity aimed at meeting the needs of public and private payers, patients, clinical professionals, and policymakers. This approach was first used by Australia in the early 1990s, followed by more countries, including the UK, in 1999, and then Germany and France more recently. Each approach contains mechanisms to ensure that the activities are not diverted to pursuits of only academic interest. Rather, the focus is on producing the specific information needed to act on the highest-priority topics currently being discussed. As a result, all the entities choose topics for review through a prioritization process closely linked to the decision makers' needs.

## Ten Core Attributes of CER Entities in Britain, France, Australia, and Germany

Table 1 lists the core attributes, applicable to the four agencies, that capture the main aspects of the CER entities' current function. U.S. policymakers will have to define these basic characteristics in order to establish a functional CER structure suitable for the United States.

1. *Stated purpose and objective:* Although each entity's purpose, objective, and evolution vary depending on the structure of the country's health care system and the broader political environment, they all share certain principles, subject to the breadth of their remit, such as setting quality standards based on evidence of what works and ensuring that health care resources are invested efficiently. Determining the value for money of the health care investment (from general tax revenue or insurance funds), by explicitly weighing costs against net health benefits, was introduced relatively recently in the history of all CER entities, with the exception of the UK's NICE, which has considered costs since its inception in 1999.

2. *Scope of assessment:* The scope of each CER entity's remit also varies, from a focus solely on pharmaceuticals, in the case of the PBS in Australia, to the French HAS's very broad scope, which includes, in addition to the assessment of health care technologies for pricing and reimbursement, clinical and public health guidelines, hospital accreditation, labeling of patient information websites, disease management models, and continuous professional development. The scope of the German IQWiG includes the benefit and cost-benefit evaluations of medical services, recommendations for disease management programs, evaluations of clinical guidelines and the quality of health services, and the development of information for patients and the general public. The UK's NICE recently added health promotion and disease prevention interventions to its responsibilities, which include clinical guidelines and coverage recommendations for drugs and devices.

3. *Prioritization process:* These countries have different systems for selecting topics to be considered. In no system is a CER entity completely free to prioritize its work program; external stakeholders, most frequently those decision makers financially supporting the entity, like ministers in the case of the tax-funded NICE, are actively involved in selecting the topics to be considered. With the exception of the Australian PBS, whose work program is determined by the timing of the drug

TABLE 1  
Key Attributes across CER Entities

Attributes	NICE	HAS	IQWiG	PBS
1. Stated objective and purpose	Reduce variation in practice; accelerate uptake of new technologies; set quality standards and improve efficiency.	Improve the quality of health care services through hospital accreditation, best care standards, and continuous professional development; evaluation of medical effectiveness, public health impact, and health technology assessments (new and within the existing formulary).	(1) Search for, assessment, and presentation of current scientific evidence on diagnostic and therapeutic procedures for specific diseases; (2) Preparation of scientific reports and expert opinions on quality and efficiency issues of Statutory Health Insurance fund, taking age, gender, and personal circumstances into account; (3) Appraisal of evidence-based clinical practice guidelines on epidemiologically most important diseases; (4) Development of recommendations on disease management programs; (5) Provision of understandable evidence-based information for patients and public.	(To support) timely access to the medicines that Australians need, at a cost that individuals and the community can afford.



<p>2. Subject and scope of assessment (e.g., drugs, technologies, management strategies)</p>	<p>Medical technologies including drugs, devices, and diagnostic tests; clinical guidelines for disease management; public health guidance on disease prevention; information for patients and the public.</p>	<p>Medical technologies including drugs, devices, procedures, and diagnostic tests; clinical guidelines for disease management; public health guidance on disease prevention and health care system organization.</p>	<p>Pharmaceuticals (drugs), medical devices, quality control interventions, surgical procedures, diagnostic tests, clinical practice guidelines and aspects of disease management programs, and evidence-based information for patients.</p>	<p>Limited to assessment of prescription medicines for subsidy; the Pharmaceutical Benefits Advisory Committee (PBAC) also evaluates vaccines for inclusion on the National Immunization Program.</p>
<p>3. Topic selection and prioritization process</p>	<p>Run by NICE based on explicit criteria: final approval for new technologies to be reviewed remains a ministerial responsibility.</p>	<p>* For single HTA, initiated by companies seeking listing on formulary. * For multiple HTA, annual consultation with Ministry of Health and insurers. * Suggestions from other stakeholders (medical societies, patients' associations) also considered by HAS.</p>	<p>Commission from Federal Joint Committee, Ministry of Health, or IQWiG's own initiative.</p>	<p>N/A. No prioritization required. The PBAC's work program is determined by the timing of submissions made (usually) by pharmaceutical companies seeking listing of medicines on PBS formulary. All submissions received before a specified lodgment date are considered.</p>

*Continued*

Table 1—Continued

Attributes	NICE	HAS	IQWiG	PBS
4. Type of research evidence used (prospective trials, claims data analysis, systematic reviews, and decision analysis)	Mostly evidence synthesis of existing experimental and observational studies; economic modeling; small number of prospective trials funded by public sources.	Synthesis of existing experimental and observational studies; increasing use of economic modeling and public health analyses; analysis of postmarketing and postlisting studies data when available.	Mostly evidence synthesis of existing experimental studies, economic modeling, guidelines, and, occasionally, method studies. For patient information, high-quality systematic reviews.	Applicant identifies, synthesizes, and presents evidence. PBAC prefers evidence from meta-analyses of well-conducted head-to-head RCTs of proposed drug and main comparator but has no minimum standard. Economic modeling is generally required.
5. Relationship with research infrastructure (e.g., links with academic institutions and research groups; responsive research arrangements)	Responsive arrangements with National Institute for Health Research—funded academic centers and with NICE-funded professional organizations (royal colleges) to undertake systematic reviews, evidence syntheses, and economic modeling to inform decisions.	Progressive shift toward contracting with external experts for modeling and original data analyses and for preparing evidence syntheses.	Working with network of external experts and external organizations on preparing evidence synthesis.	Contractual arrangements with academic institutions to undertake clinical and economic evaluation of submissions and prepare evaluation commentaries for Department of Health and Ageing.

<p>6. Structure and relationship to health care system</p>	<p>Part of NHS; independent of central government, issues guidance directly to health service and broader public sector (local authorities, transport, and education boards).</p>	<p>Independent of central government, health ministry, or insurance funds. Accountable to the French parliament.</p>	<p>Established by the Federal Joint Committee, independent from government, private foundation, receives commissions from Federal Joint Committee and Ministry of Health and advises FJC who issue their directives to Statutory Health Insurance funds.</p>	<p>Policy and program management is responsibility of the Pharmaceutical Evaluation Branch (PEB) of Pharmaceutical Benefits Division of Department of Health and Ageing; the PEB supports the PBAC and its subcommittees and manages evaluation process, pricing negotiations and arrangements, public dissemination of decisions, and liaison with pharmaceutical industry.</p>
<p>7. Budget and source of funding</p>	<p>£35 million per year: funded by Department of Health.</p>	<p>In 2006, € 70 million funded by the following sources: 34% through earmarked taxes levied on drug companies spending on advertising, 15% from hospitals' accreditation fees, 7% from fees from manufacturers, 3.2% by NHI, 10% by government, 2% by investment income.</p>	<p>€ 15 million; 50% from a levy on every hospital case to be invoiced and 50% from an increase in reimbursement rate of medical and dental outpatient services paid by the health insurance funds. Details determined by the Federal Joint Committee.</p>	<p>The PBS is a demand-driven program with an uncapped appropriation. Management of the PBS listing process is part of Department of Health and Ageing portfolio funding and is approximately AUD \$14 million per year.</p>

*Continued*

Table 1—Continued

Attributes	NICE	HAS	IQWiG	PBS
8. Consideration of costs (e.g., budget impact analysis, CEA, other)	Comparative cost-effectiveness analysis part of its remit since establishment in 1999. Budget impact analysis to inform implementation but not as a decision input.	Since January 2008, consideration of economic and other dimensions as part of remit to inform decisions about sustainability and feasibility.	Since 2007, description of relationships between costs and benefits along with an efficiency frontier and a budget impact analysis to provide a decision basis for ceiling prices of drugs (currently under development).	Comparative cost-effectiveness analysis since 1988 (mandatory since 1993); budget impact analysis (mandatory and considered as part of recommendation, and by government for final decision).
9. Status of guidance (e.g., mandatory, advisory) and relationship with coverage and reimbursement decisions	Guidance on use of medical technologies mandatory (funds must be made available to cover recommended technologies). Public health and clinical guideline recommendations have advisory status.	Guidance on drugs and devices mandatory since 1999. Recommendations on use of procedures and other public health and clinical guideline recommendations have advisory status.	Advisory to the Federal Joint Committee. After approval by the Ministry of Health, the directives by Federal Joint Committee based on IQWiG reports are mandatory.	As part of listing recommendations, PBAC may recommend specific circumstances in which medicines should be subsidized; positive advice is subject to ministerial/parliamentary approval. Negative advice is mandatory.

<p>10. Dissemination and implementation/enforcement strategies (e.g., audit, educational tools, academic detailing, financial incentives – P4P)</p>	<p>Responsibility for supporting implementation since 2004: audit and educational tools, field consultants, budget impact analysis, continuous medical education. Financial and regulatory performance schemes to encourage uptake.</p>	<p>Implementation is fostered by integration of recommendation within various dimensions of HAS's remit, from hospitals' accreditation to continuous professional development and patient information.</p>	<p>Implemented through directives of the Federal Joint Committee, which considers equipment and training needed for implementation by the insurance funds. Insurance funds can use different health plan strategies within directives' frame.</p>	<p>National Prescribing Service (NPS), established in 1998, is an independent organization funded by government that promotes quality use of medicines (QUM) through professional education, academic detailing, training in rational prescribing, clinical audits, conferences, the national Therapeutic Advisory and Information Service, and a range of publications for prescribers. Prescriber audit is the responsibility of Medicare Australia.</p>
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sponsors' listing applications, each system selects topics for its work based on what payers, health care providers, policymakers, clinicians, and patients decide are most important.

4. *Types of research used:* Evidence synthesis, in some cases accompanied by economic modeling, rather than prospective trials or primary research using routinely collected data, is the main type of research used by the CER entities to inform their decisions. All entities that rely on evidence synthesis have struggled with the challenges associated with the limited availability or quality of the studies available for review. Partly to address the problem of limited primary evidence, CER entities are experimenting with conditional coverage or "coverage with evidence development." In addition, some of these entities, such as IQWiG and HAS, have a statutory right to recommend prospective trials. HAS increasingly requires companies to produce additional evidence that will be used to reassess drugs (within five years following the initial advice), medical devices, or procedures. Although IQWiG has the same statutory right, it has not yet used it, mostly because of budgetary and time considerations.

In addition to criteria of clinical effectiveness and value, CER entities often take into account value judgments and legal considerations when making their decisions. Different entities are more or less flexible about how these values are elicited and applied to decision making (Rawlins and Culyer 2004).

5. *Relationship to academic research infrastructure:* In all cases, CER entities contract with external academic and professional groups to help them with the assessment (evidence synthesis); the ratio of in-house to outsourced work varies in different organizations. In-house capacity is very limited for NICE and PBS, whereas IQWiG and HAS have larger in-house capacities. In all cases, however, CER entities maintain relationships with academic groups that are used to completing work suited to the decision makers' time frames and information needs. All four international models commission the research from academics familiar with the organizations' policy and decision-making context.

6. *Relationship to health care system:* The relationship of each CER entity to the health care system in which it operates ranges from an integrated model in the case of NICE, which forms part of and issues its advice directly to the NHS, to an arm's-length relationship in the case of IQWiG, which advises the Federal Joint Committee (FJC). The responsibility for developing and implementing health policy in light of IQWiG's advice

lies with FJC, which includes representatives from the providers (hospitals and professional associations) and the payers (insurance funds). France's HAS also is at arm's length from insurers and government and other stakeholders, even though these stakeholders help determine its annual work program. In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations to the minister for health and ageing, who must have a positive recommendation in order to list a drug on the PBS formulary. Any decisions whose net cost to the program is expected to exceed AUS\$10 million per year must be endorsed by the cabinet.

7. *Budget and funding source*: Although the funding for CER entities varies from country to country, in no case does their overall budget exceed the equivalent of USD 100 million per year, which is relatively small compared with those countries' expenditures on health care or pharmaceutical products (less than 0.1 percent of their overall health expenditures). In the case of NICE and PBS, funding comes from the central government (although the Australian government has announced, but not yet implemented, plans to introduce a cost-per-cost recovery mechanism for PBAC processes). IQWiG's funding comes from a levy based on a percentage of each reimbursed case in the Statutory Health Insurance fund, which ensures that the agency remains independent of any stakeholders, including the government. HAS uses a novel funding model in which, in addition to the government's and insurers' subsidies, hospital accreditation fees, and fees from medical devices and drug manufacturers, about a third of its total budget comes from (10 percent of) a government tax on the pharmaceutical industry's promotional expenditures.

8. *Consideration of costs*: All four entities explicitly consider costs and cost-effectiveness when making decisions or recommendations. PBS was the first to include costs in the 1990s, followed by NICE, when it was established in 1999. HAS and IQWiG added or enhanced cost considerations as part of their remit by law, in 2008 and 2007, respectively. With the exception of NICE, the original focus of CER entities was to conduct comparative clinical effectiveness reviews without considering costs, but in each case the lack of economic assessment was found to limit these organizations' ability to complete their assessments.

This has been an incremental process: for example, HAS's new economic remit does not cover initial listing decisions of technologies

(single technology appraisal), in which HAS offers advice on price and copay levels set by government and insurers. Such advice is given within a short time period and only on the basis of comparative clinical effectiveness. Conversely, when reassessing classes of drugs or categories of medical devices/equipment or organizational aspects of health delivery, cost-effectiveness and other nonclinical considerations (e.g., ethical) now supplement the clinical effectiveness data in its multiple technology assessments.

9. *Status of guidance*: Different entities have adopted various models regarding the status of their guidance. For example, positive NICE guidance for health technologies is both mandatory and a patient's legally enforceable right. This means that if a clinician and his or her patient decide to access the technology, funding needs to be made available, at the point of delivery, by the local payers, to ensure access free of charge to the patient. At the same time, guidance on service configuration, broader disease management strategies, or health promotion programs is advisory and may form part of providers' performance management schemes. In the case of entities using CER evidence for listing, pricing, and reimbursement decisions, such as HAS or PBAC, their recommendations effectively determine which drugs will be made available through the public system. IQWiG's recommendations have an advisory character, and the Federal Joint Committee that receives IQWiG's advice decides whether the individual insurance funds should take action. In France, HAS must assess all individual new technologies before the Ministry of Health and the National Insurance Fund (single technology appraisal) makes any pricing and reimbursement decisions. HAS's multiple technology appraisals, however, include whole therapeutic classes of drugs or categories of medical devices/equipment as well as the health system's organization and so serve an advisory role for French decision makers.

Several different tools are used to implement CER-based findings in the case of drugs: risk-sharing schemes or coverage decisions at a national level (NICE), ceiling price (IQWiG), or level of copay (HAS). For HAS, although CER that informs the copay and price decision for a new technology is based solely on evidence of clinical effectiveness, best-practice guidance, based on multiple technology assessments (which now include costs), is another means of promoting both quality and efficiency. Even when it is only advisory, the relevant actors (payers, professionals, and providers) are encouraged to follow CER-based guidance.



10. *Dissemination and implementation*: Disseminating the outcomes to all relevant stakeholders, including patients, is a priority for those agencies responsible for using CER to inform decisions. All NICE guidance is also produced in a lay-friendly format (“Understanding NICE Guidance”). IQWiG has a dedicated program of work producing up-to-date evidence-based, understandable health information for patients and the general public ([www.informedhealthonline.org](http://www.informedhealthonline.org)) (Bastian 2008). The objective of this program is to support patients’ decisions by addressing questions they may have, but not to communicate government advice or to serve as a national health promotion campaign. Information about newly listed PBS medicines in Australia is distributed by the National Prescribing Service (NPS), an independent organization established in 1998 and funded by the government, which provides professional education, academic detailing, and training in rational prescribing; the national Therapeutic Advisory and Information Service; and a range of publications for prescribers. HAS also produces disease-specific and/or product-specific information, for example, documents advising professionals on the best use of pharmaceuticals, diagnostic protocols, and disease management guides, as well as disease guides designed specifically for patients, particularly those diagnosed with long-term, chronic conditions.

Interestingly, the implementation of CER decisions in the health care system originally was outside the remit of all the four CER entities reviewed. Traditionally, separate bodies were responsible for ensuring that providers and payers adhered to CER-based guidance through monitoring, regulation, and pay-for-performance schemes. NICE and HAS are the two examples of agencies for which implementation is now becoming an important priority. Since 2004, NICE has included “supporting implementation” in its remit and its implementation team is the fastest growing in the institute. This may be the result of the realization that merely making information available is insufficient for its effective and timely adoption, especially advisory standards for nonpharmacological interventions. Financial and regulatory incentives are increasingly used to promote the adoption of NICE guidance and reduce inappropriate variation and wasteful practice through (1) a stronger system of incentives, directly linking NICE guidance to monetary rewards for primary care physicians (Quality and Outcomes Framework) and secondary care providers (through regular adjustments of DRG prices to reflect NICE guidance and a move to normative CER-based DRGs, whose “price tag”

reflects the cost of best practices, like not paying for an extended stay or high rates of caesarean sections); (2) a new accreditation scheme for providers linking their accreditation with, among other things, adherence to NICE standards; and (3) an NHS constitution, making access to NICE-recommended treatment regimes a right for every NHS patient. For HAS, implementation is facilitated by the fact that its purview is very wide, thereby allowing its guidance to be translated into various HAS functions, from hospital accreditation to professional guidelines and continuous professional development programs. No direct incentives or sanctions are associated with guidance follow-up, however. In Germany, implementation is part of the responsibilities of FJC, not IQWiG. FJC takes into consideration the benefit of the medical services along with the applicability and feasibility of implementing these services through mandatory directives issued by the health insurance funds, which cover health care expenses for 90 percent of the population.

### Emerging Themes and Lessons for the United States

As noted earlier, a number of organizations were established in the United States to review the existing evidence in order to inform health policy and practice. Each conducted and supported work that would fit within the current understanding of CER, but has historically been referred to as *health technology assessment*. For a variety of reasons, each of these organizations was discontinued or significantly reorganized, reflecting the significant political challenges of linking the objective analysis of evidence with decision making in health care. One important lesson from the United States' and the international CER entities' experience is that intense controversy, negative press, and rapid transformation are intrinsic to the enterprise. An organization that manages to avoid controversy and criticism is probably not fulfilling its role of being useful to decision makers.

Next we describe the policy "insights" of those involved in the establishment and/or day-to-day running of CER entities. We found common themes, or "lessons learned," that are likely to be relevant to U.S. policymakers.

### *A Core Set of Desirable Procedural Principles*

Usually through a trial-and-error process, a number of core principles emerged as necessary, and often conflicting, requirements for the operation of CER entities in the countries we studied. Even though the various countries are at different stages, they all are moving toward realizing these principles:

- *Independence* from central government, insurance agencies, and industries, by recognizing any conflict of interest in policies and processes for engaging with different stakeholders.
- *Transparency* in the way the topics are selected, the evidence is synthesized and assessed, and the final decision is made, by opening meetings to the public, publicizing all relevant analyses, and minimizing the extent to which information is protected.
- *Inclusiveness*, achieved through broad and repeated consultation and dialogue with all relevant parties.
- *Scientific rigor*, achieved by applying peer review and maintaining methodological currency in evidence generation and analysis.
- *Contestability*, made possible through a mechanism for reconsidering or appealing a decision.
- *Timeliness*, gained by issuing advice while the technology or practice is still at an early stage of diffusion. The German system is an exception, as the health insurance funds initially reimburse most drugs and services, which only later are submitted for evaluation to IQWiG. As a result, stakeholders tend to delay the evaluation process by IQWiG, fearing a negative result, instead of striving for timeliness.

### *Learning Organizations*

CER entities evolved considerably and rapidly over time in their attempt to tackle new challenges and increase their relevance and impact within their respective, also evolving, health care settings. We identified the following two components of this evolution:

*Consideration of Costs.* Costs were not included in the original remit of any of the CER entities studied here, with the exception of NICE. Even in NICE's case, the introduction of economic evaluation as one input in the decision-making process gained traction only relatively recently for clinical guidelines assessing whole pathways of care. But it seems that all CER entities have gradually come to appreciate the need

to consider “value” when judging the relative worthiness of clinical interventions. This is true not only for NICE, which operates within the NHS’s set budget, but also for HAS, IQWiG, and PBS, which have “open” (demand-driven) budgets, prospectively adjusted to meet the needs of the covered population. The concept of “purchasing outcomes,” which underpins the Australian PBS listing process, and the introduction of “value-based pricing” for drugs in the UK, with the full support of industry, reflect this maturing process in the thinking of stakeholders operating in a CER context. In France, however, the consideration of costs is kept separate from the clinical effectiveness assessment for single technology assessments and influences reimbursement and pricing decisions only indirectly. For multiple technology assessments, its impact rests mainly on the development of best-practice guidance.

*Prospective Evidence Generation.* In no CER entity studied here was prospective evidence generation initially included in its remit. All these CER entities rely primarily on a synthesis of existing scientific studies (usually undertaken by separate research organizations) as their main analytic methodology, mostly because of timeliness and resource constraints. That is, prospective trials tend to be expensive and take longer to complete, and these organizations were established to support health systems’ decisions regarding the adoption of medical technologies. Concerns about the entity’s independence are another reason. In the original proposals to establish IQWiG in 2004, a “trial coordination” function, to help bridge evidence gaps important to decision makers, was included in its remit. This idea was later abandoned because of concerns about maintaining the institute’s independence of industry: the original idea was for IQWiG to influence the design of industry-sponsored trials, which led to concerns about industry’s influencing IQWiG’s evaluation of the results of trials it helped design. If funding from industry was not an option, the issue of whether public bodies should/could bear the entire financial burden of clinical research involving commercial products remained. And even though the importance of linking evidence synthesis to primary research was recognized, the risk of compromising IQWiG’s independence or inappropriately burdening the public budget meant that the idea had to be abandoned.

More attention is now being paid to all entities’ developing evidence as part of their essential functions, in most cases including the use of some form of “coverage with evidence development” to financially support studies of emerging technologies. NICE has developed

responsive arrangements for commissioning primary research with the publicly funded National Institute for Health Research (NIHR) through patients' organizations, such as the Arthritis Research Campaign and Cancer Research UK (Chalkidou et al. 2008b). Some research projects, such as a randomized trial of the nonpharmacological management of children with depression and a registry of bariatric surgery, have already been advertised and/or commissioned. Another way for NICE to influence primary research is through the implementation of its "only in research" option of conditional reimbursement (Chalkidou et al. 2008a; Tunis and Chalkidou 2007). Finally, risk sharing and patients' access schemes for new technologies of unproven value are key components of Britain's recent pharmaceutical pricing reform. Data of effectiveness and cost are collected in the real world, and the NHS receives a rebate if the technology does not perform according to the manufacturer's claims; an increase in price also is allowed if greater effectiveness is demonstrated (Department of Health 2008). In Germany, IQWiG can recommend to FJC that a technology be used only for research. FJC can then decide to undertake "coverage with evidence development" or allow the academic research groups to ask, through FJC, that insurance funds reimburse the medical technology (but not the research costs) for their study.

Similarly, in France, the "only in research" option is being discussed. HAS can now set conditions for temporary access for some new and innovative health products or procedures when their effects are uncertain. It can restrict their use to a limited number of qualified centers, define the conditions of use, and mandate the collection of data that will be considered when the technology is reassessed to help with the decision to extend coverage. These new legislative measures will allow funding a limited number of innovative technologies. HAS also includes post-listing study requests in its routine assessment regarding the listing of a new drug. These, usually observational, studies are funded by industry and inform future reassessments by HAS and, in some cases, pricing adjustments by the Economic Committee on Health Products of the French Ministry of Health. Furthermore, questions documenting cost-effectiveness issues will now be introduced for multiple technology reassessments.

Australia has not yet considered this option in regard to drugs, as this is not possible in its existing legislative framework, although this option can be used for procedures and devices.

By committing significant resources to CER, including prospective trials, the American Recovery and Reinvestment Act puts U.S. decision makers in a privileged position compared with their international counterparts. Trying to link decision makers' needs and a primary research agenda retrospectively or through conditional coverage policies has not succeeded in the international systems we studied. The challenge will be to make sure that CER priorities and the design of the studies used to answer these high-priority questions accurately reflect the evidence needed by patients, clinicians, payers, and policymakers.

### *"Selling CER"*

A common characteristic of all entities was the way in which they were "sold" to stakeholders. The purpose of CER was to improve quality, to reduce wasteful and often harmful variation, and to ensure the value of taxpayer-funded programs. Containing or rationing costs was never an objective of any CER entities. This was not necessarily a policy maneuver to win over stakeholders: "[Using CER to achieve] savings would be a promise we would not be able to keep!" the chairman of NICE asserted, reflecting his view that paying for cost-effective services would not have the overall effect of lowering total health care spending (Commonwealth Fund 2008). In fact, some empirical estimates show that NICE's recommendations for the adoption of new technologies and services have cost the NHS about £1.65 billion per year in additional investment.<sup>2</sup> Similarly, HAS's recent decision to include cost-effectiveness analyses included a promise that they would not be used to save money by restricting access to necessary services but, instead, to use available resources more efficiently and fairly.

Assessing the impact of a CER entity on overall spending has significant methodological challenges, particularly isolating it from the many other elements of the health care system. Disinvestment decisions (such as those made by HAS for certain drug classes) or guidance on the effective use of diagnostic procedures (e.g., HAS's professional guidance on the use of X-rays), both based only on the criterion of clinical effectiveness, can still save the system money, besides improving the quality and safety of care. Furthermore, the CER entity may be able to save money even when it decides to cover something. For example, NICE determined that Velcade was not cost-effective for multiple myeloma at

the price offered by the manufacturer, and the subsequent negotiated risk-sharing agreement led to access to the technology at a lower price for the NHS (Garber and McClellan 2007). As a result, overall expenditures were lower than they would have been if Velcade had been covered by conventional means, but presumably higher compared with the “pre-Velcade” NHS. Because of such limitations, a conventional time series on expenditures would not show the value gained by NICE or other CER entities. Efficiency savings could also result from avoiding duplicative activities, especially in a decentralized and fragmented system with multiple entities undertaking CER (focused on both research and decision making).

### *Oversight and Governance Boards*

The number, size, composition, and role of the different organizations’ boards vary as well. The structure of each organization, however, allows for a broad representation of stakeholders while also making sure that the process cannot be paralyzed by stakeholders whose interests may be threatened. A board’s involvement in decision making ranges from a direct influence in the case of PBS, for which the PBAC is equivalent to a board, to a less involved role in the case of NICE, whose nonexecutive board directors are responsible for overseeing the organization rather than running it (the role of NICE’s executive directors) or deciding on the guidance (the role of independent advisory committee members). The NICE board delegates responsibility for signing off on the guidance produced by the advisory committees to a small team of executive directors (guidance executive). IQWiG has several boards with different responsibilities. Its Foundation Council and Foundation Board of Directors were responsible for the initial establishment and structure of the institute and for the appointment of its director. The Scientific Advisory Board and board of trustees have an advisory role for IQWiG’s methods and actual guidance. But none of the IQWiG boards can directly influence IQWiG’s scientific process. HAS’s board, chaired by its president, is in charge of the overall strategy and has the final scientific responsibility for all products. The board works closely with the executive director (and the department directors) in charge of running HAS, and each member of the board chairs an independent, specialized committee. The HAS board members are experts

appointed for a full-time, six-year term by the parliament (Senate and National Assembly), the Economic and Social Council, and France's president.

Conflict-of-interest policies also are important for ensuring the organization's credibility. For example, NICE has a complex policy regarding the monetary and nonmonetary conflicts of interest which applies to all its employees and their families, the members of NICE's decision-making bodies, the board, and the academic and professional groups that NICE commissions to conduct analyses (NICE 2007). Similarly, HAS has enforced a policy for explicit conflict-of-interest declarations by all HAS workers and committee members, which is reviewed by an independent committee set up for this purpose. The way in which each entity decides to deal with the declared conflicts varies. For example, PBS does not allow the academic groups it commissions to review the evidence to engage in any industry-funded work. NICE's and HAS's policies are less restrictive and exclude only those individual academics carrying out industry-sponsored evaluations of the same technology being assessed by these organizations.

In addition to governance, the boards' compositions reflect how each entity has decided to involve various stakeholders. Board members generally have broad experience in health management, medicine, and economics and come from both the public and private sectors.

Finally, in addition to its board, NICE has a platform for engaging with all stakeholders at a strategic level: the Partners' Council. This is a forty-member group consisting of industry, managers, clinicians, and academics that meets twice a year to advise on specific challenges that NICE is facing. For example, NICE sought the Partners' Council advice in organizing its implementation program, and the council recommended against NICE's using the industry's detailing network to implement and evaluate its guidance.

### *Impact on Innovation*

Especially when costs are considered, some people see CER as a form of price control which, by reducing returns to industry, limits R&D expenditure, "stifles" future innovation, and compromises new products' access to markets. But no empirical evidence supports this concern in the countries reviewed here, especially since the pharmaceutical market is



international rather than local. Instead, when operating in a transparent, inclusive, and consistent fashion, CER entities create a more secure environment in which the naturally risk-averse medical technology industry can make its investment choices. The reason is that well-defined and consistent CER is a much more rational and predictable way for payers to make purchasing decisions than for administrators to impose price cuts arbitrarily, to shift costs to individual patients, or to ration needed technologies and services according to ability to pay. For manufacturers that believe in the value of their product, a predictable national process for evaluation should be better than haphazard local decisions, as is currently the case with Medicare's local contractors. Indeed, the lack of consistency in the way that payers make investment decisions may in fact discourage innovation, in addition to wasting valuable resources.

The evidence also suggests that systems that apply value-based pricing mechanisms to truly innovative medicines representing significant advances in therapy can command prices as high, and sometimes even higher, as "free" market mechanisms. This is particularly true of the prices of biologicals around the world (Danzon and Furukawa 2006; Roughead, Lopert, and Sansom 2007). Value-based pricing can be viewed as a means of indicating to the industry the type of innovation that is valued and will be rewarded (Hughes 2008).

The recent reform of the UK's pharmaceutical pricing scheme demonstrates how the discussion on value has evolved over the years as the NHS has used CER to inform its investment decisions. Nearly ten years after NICE was established, the Association of British Pharmaceutical Industries agreed to a variation of value-based pricing that adjusts the price of new technologies (up or down) to reflect outcomes for patients using the technologies, similar to a pay-for-performance scheme for drugs.

The political endorsement of CER signals to all stakeholders that industrial policies should not and need not be mixed with "buying health outcomes." For example, NICE's first decision not to provide an antiviral free of charge to NHS patients with flu-like symptoms who were otherwise healthy resulted in the British-owned manufacturer's lobbying the government. Political support for evidence-informed policymaking and for the process that NICE had followed, however, sent out a clear signal to all stakeholders that NICE's decisions would not be subject to political or other interference.

### *Three Ingredients for Success*

The first ingredient of success is strong political endorsement, especially at the early stages of the entity's life, as discussed earlier. The second ingredient is early engagement with the stakeholders, so as to anticipate and address controversial issues, as well as communication with stakeholders throughout the process, to explain negative decisions and offer the chance to dispute them through appeals and judicial challenge (rather than trying to avoid confrontation). The third ingredient is a demonstrable commitment to quality and evidence-based best practices in order to gain professional approval. Methodological rigor and the involvement of well-respected clinical and nonclinical researchers have helped legitimize each entity's role in its respective system.

### Conclusion

This article described the CER arrangements in four developed countries: Britain, France, Germany, and Australia. Even though the CER entities in these countries evolved separately and have different responsibilities and roles, they use (mostly secondary) CER evidence (usually commissioned by research-focused CER organizations) to make specific recommendations for best practices, from a clinical and (increasingly) cost-effectiveness perspective, within their health care systems. Despite the differences, all these models focus their priorities, design, generation, and implementation of CER evidence on the explicit objective of informing health care policy decisions on the use of and payment for clinical services. In none of these models is the organization's purpose described as centered on collecting knowledge to reduce uncertainty and address unanswered questions about what works in medicine. Rather, the explicit objective of producing knowledge that will affect clinical and health policy decisions is critical to these entities' structure, governance, and work and is clearly understood by the organization itself and its external stakeholders.

One of the most striking differences between the international models and the comparative effectiveness provisions of the American Recovery and Reinvestment Act is that by incorporating the provisions of section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, this legislation precludes conclusions from CER

(undertaken by AHRQ and NIH) from being used to determine coverage or reimbursement policies of private and public payers or to inform national clinical guidelines. The newly established Federal Coordinating Council for CER is the closest to a strategic function, charged with coordinating the activities of the different federal agencies, advising the secretary of health and human services on CER priorities (along with IOM), and, next year, reporting to the president and Congress on “the infrastructure needs, organizational expenditures and opportunities for better coordination of comparative effectiveness research by relevant Federal departments and agencies.” However, the Federal Coordinating Council is explicitly prohibited from deciding on coverage, reimbursement, or other policies of public and private payers. Furthermore, more detailed legislation institutionalizing CER in the longer run, currently being considered in Congress, similarly prohibits such a link between research findings and policy: “None of the reports made available or research findings disseminated by the Institute shall be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment . . . for any public or private payer” (Senators Max Baucus, D-MT, and Kent Conrad, D-ND, 2008).

Being less explicit and prescriptive may allow for a better-informed strategic decision to be made later and may help appease those strongly opposed to using evidence to change practice. But formalizing the links among research findings, their interpretation, and payers’ and providers’ policies, all while maintaining the CER entities’ independence, has been shown in all other international models to be a prerequisite if investment in CER is to improve health outcomes and overall spending.

## Endnotes

1. For a descriptive comparative analysis of the four entities, see the full report by the Commonwealth Fund to be launched on June 9, 2009.
2. Source: NICE net cost estimate, Implementation Programme, Costing Team, 2009.

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