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IMPROVED AVAILABILITY OF COMPARATIVE EFFECTIVENESS INFORMATION: AN ESSENTIAL FEATURE FOR A HIGH-QUALITY AND EFFICIENT UNITED STATES HEALTH CARE SYSTEM

American College of Physicians
A Policy Paper
2008

Improved Availability of Comparative Effectiveness Information: An Essential Feature for a High-Quality and Efficient United States Health Care System

Summary of Position Paper Approved by the ACP Board of Regents, January 2008

What is Comparative Effectiveness?

Comparative effectiveness analysis evaluates the relative (clinical) effectiveness, safety, and cost of two or more medical services, drugs, devices, therapies, or procedures used to treat the same condition. Although the use of the term comparative effectiveness broadly refers to the evaluation of both the relative clinical and cost differences among different medical interventions, it is notable that most comparative effectiveness research engaged in and used by stakeholders in this country focuses solely on evaluated relative clinical differences to the exclusion of cost factors.

Why is it Important to Make Comparative Effectiveness Research Available?

Information about the comparative effectiveness of currently available health care interventions should be readily available to physicians, health care payers, and patients to help them make informed decisions about the relative value of different medical services. Currently, the United States expends insufficient funds to develop comparative effectiveness data, and there is no coordination or prioritization of current efforts in either the public or private sector to help produce comparative effectiveness information that would provide the greatest health care impact.

The absence of readily available, essential comparative effectiveness information interferes with the ability of physicians and their patients to make effective, informed treatment choices that meet the unique needs and preferences of the patient and the ability of payers to optimize the value received for their health care expenditures. Consequently, ACP calls for an adequately funded, trusted national entity to prioritize, sponsor and/or produce this comparative information.*

Key Findings and Recommendations from the Paper

ACP takes the following policy positions:

- ACP strongly supports efforts to improve access to information comparing clinical management strategies.
- Specifically, ACP strongly supports the establishment of an adequately-funded, independent entity to sponsor and/or produce trusted research on the comparative effectiveness of health care services.
 - The federal government should have a significant role in the funding, implementing, and maintaining of this comparative effectiveness entity.

- The newly proposed comparative effectiveness entity should:
 - Have a structure and adopt operating procedures that encourage trust in its impartiality and adherence to the strictest scientific standards;
 - Be responsible for the development of evidence concerning comparative effectiveness necessary for clinical practice; conduct all proceedings and present results in a transparent manner;
 - Involve all relevant stakeholders;
 - Implement a prioritization process that ensures that the evidence developed will have the greatest positive impact on improving the quality and efficiency of health care;
 - Support the development of evidence at all levels, include relevant clinical information available from federal agencies as well as private and academic settings in its analyses; and
 - Ensure that the comparative effectiveness findings developed are accessible in a timely manner and in a comprehensible form to all stakeholders.
- The proposed comparative effectiveness entity should be charged with systematically developing both comparative clinical and cost-effectiveness evidence for competing clinical management strategies.
- A panel of stakeholders and additional scientific experts should be formed and charged with updating cost effectiveness procedures, developing a framework to reconcile disparate estimates, and developing recommendations both for the general public and for stakeholders who plan to use the cost effectiveness research for clinical and coverage decisions.
- All health care payers should employ both comparative clinical and cost-effective information as factors to be explicitly considered in their evaluation of a clinical intervention. However, cost should never be used as the sole criterion for evaluating a clinical intervention.

* The Patient Centered Outcomes Research Institute (PCORI) was instituted as a part of the Affordable Care Act of 2010 and serves this purpose. However, it is notable that PCORI is prohibited from conducting cost-effective evaluations.

For More Information

This issue brief is a summary of *Improved Availability of Comparative Effectiveness Information: An Essential Feature for a High-Quality and Efficient United States Health Care System*. The full paper is available at http://www.acponline.org/advocacy/where_we_stand/policy/healthcare_system.pdf.

IMPROVED AVAILABILITY OF COMPARATIVE EFFECTIVENESS INFORMATION: AN ESSENTIAL FEATURE FOR A HIGH-QUALITY AND EFFICIENT UNITED STATES HEALTH CARE SYSTEM

A Policy Paper of the
American College of Physicians

This paper, written by Neil Kirschner, was developed for the Medical Services Committee of the American College of Physicians (ACP); Joseph W. Stubbs, MD, (Chair), Mary M. Newman, MD (Vice Chair), William R. Hersh, MD, Michael D. Lahey, MD, Peter Basch, MD, Yul D. Ejnes, MD, Jeannine Z. Engel, MD, Stephen D. Fihn, MD, MPH, Susan H. Gunn, MD, J. Leonard Lichtenfeld, MD, Eric M. Mazur, MD, Stephen G. Pauker, MD, and Michael C. Sha, MD. It was approved by the ACP Board of Regents on 13 January 2008.

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For questions about the content of this Position Paper, please contact ACP, Division of Governmental Affairs and Public Policy, Suite 700, 25 Massachusetts Avenue NW, Washington, DC 20001-7401; telephone 202-261-4500. To order copies of this Position Paper, contact ACP Customer Service at 800-523-1546, extension 2600, or 215-351-2600.

Executive Summary

This policy paper highlights the need for increased efforts to develop and distribute information to physicians, health care payers, and patients regarding the comparative effectiveness of currently available health care interventions. Comparative effectiveness refers to the evaluation of the relative (clinical) effectiveness, safety, and cost of two or more medical services, drugs, devices, therapies, or procedures used to treat the same condition. Following a review of comparative effectiveness efforts in this country and internationally, the paper calls for the establishment of an adequately funded, trusted national entity to prioritize, sponsor, and/or produce this comparative information. It defines several recommended attributes for this entity that include protection from undue government and private sector influence, transparent proceedings and reports, extensive stakeholder involvement, and implementation of processes to ensure the general distribution of findings to all interested parties. This policy paper further recommends that the entity produce both comparative clinical and cost-effectiveness data. It examines the current arguments against the use of cost-effectiveness data in health care decision-making processes and concludes that the availability of these data in an explicit and transparent form is vital to the obtaining of value for health care expenditures by all payers, including the individual consumer.

This policy paper contains the following position statements:

Position 1: The American College of Physicians (ACP) strongly supports efforts to improve access to information comparing clinical management strategies.

Position 2: The College strongly supports the establishment of an adequately funded, independent entity to sponsor and/or produce trusted research on the comparative effectiveness of health care services.

Position 3: The College believes that the federal government should have a significant role in the funding, implementing, and maintaining of this comparative effectiveness entity, but takes no formal position on its organizational structure (e.g., government or joint public-private)

Position 4: The College recommends that the newly proposed comparative effectiveness entity should:

- Have a structure and adopt operating procedures that encourage trust in its impartiality and adherence to the strictest scientific standards, by ensuring its independence from undue governmental and private sector influence.
- Be responsible for the development of evidence concerning comparative effectiveness necessary for clinical practice, coverage, or pricing decisions, but have no direct involvement in the making of these health care decisions.
- Conduct proceedings and present results in a transparent manner.
- Involve all relevant stakeholders, including beneficiaries, payers, scientists, providers, and industry representatives, at all levels of the evidence development process.
- Implement a prioritization process, informed by input from the stakeholder groups, that ensures that the comparative effectiveness evidence developed will have the greatest positive effect on improving the quality and efficiency of the overall health care provided in the country.

- Support the development of evidence at all levels from review and synthesis of existing evidence to initiation of new research in priority areas in which essential evidence does not already exist.
- Include relevant clinical information available from federal agencies as well as private and academic settings in its analyses.
- Ensure that the comparative effectiveness findings developed are accessible in a timely manner and in a comprehensible form to all stakeholders.

Position 5: The College recommends that the proposed comparative effectiveness entity be charged with systematically developing both comparative clinical and cost-effectiveness evidence for competing clinical management strategies.

Position 6: The College recommends that as part of the implementation of the proposed comparative effectiveness entity, a panel of stakeholders and additional scientific experts, including specifically experts in the area of cost-effectiveness analyses, be formed and charged with:

- Updating and expanding upon the recommendations of the 1993 Panel on Cost-Effectiveness and Health¹ and developing related procedures to ensure that the proposed entity produces high-quality cost-effectiveness information.
- Developing a framework and related procedures to reconcile apparently disparate estimates of cost effectiveness regarding specific clinical management comparisons.
- Developing recommendations, including suggested model procedures for potential use by stakeholders who plan to consider this cost-effectiveness information in clinical, coverage, purchasing, and pricing decisions. These recommendations should:
 - Recognize that cost-effectiveness analysis is only a tool to be used in coverage and pricing decisions and cannot be the sole basis for making resource allocation decisions.
 - Help to ensure that the use of cost-effectiveness information as part of the decision-making process within the doctor-patient relationship takes into account the unique needs and values of each patient (is patient-centered) and the clinical opinion of the treating physician, while also recognizing the limited nature of health care resources available to society in general (the Medical Commons²).
- Developing recommendations to establish a mechanism to educate the general public and promote discussion on the use of comparative clinical and cost-effectiveness information to both meet the needs of the individual and help ensure the equitable distribution of finite health care resources throughout society.

Position 7a: The College recommends that all health care payers, including Medicare, other government programs, private sector entities, and the individual health care consumer, employ both comparative clinical and cost-effectiveness information as factors to be explicitly considered in their evaluation of a clinical intervention.

Position 7b: The College recommends that cost should never be used as the sole criterion for evaluating a clinical intervention. Cost should only be considered along with the explicit, transparent consideration of the comparative effectiveness of the intervention.

The Institute of Medicine (IOM) recently released a paper describing an evidence gap in the U.S. health care system—the system has failed to produce an adequate supply of reliable and practical information regarding what health care works best for whom in a given clinical situation³. This evidence gap directly contributes to the following problems within the health care system:

- The unsustainable growth in health care costs that adversely affects both payers and beneficiaries⁴
- The presence of significant quality gaps, particularly when compared with other industrialized nations that spend much less on health care⁵
- The presence of significant variation in health care practices and costs throughout this country, without any evidence that increased costs result in improved care⁶.

It is in the best interest of those who pay for, deliver, and receive health care that our system provide the services that are most effective and affordable. The members of the American College of Physicians (ACP), the nation's largest medical specialty organization representing 124,000 physicians and medical students in internal medicine, are dedicated to providing the best possible medical care to their patients, and this goal is not possible without good comparative clinical effectiveness and cost information. From the perspective of practicing physicians and their patients, the insufficient availability of data about what works best for whom creates critically important limitations for the clinical decision-making process. Each day, in the privacy of the examination room, patients are treated for conditions for which there are numerous treatment options. This includes treatment for common conditions, such as intermittent heartburn, more serious chronic conditions, such as high blood pressure or diabetes, and immediate life-and-death issues, such as choosing the best approach for the treatment of acute coronary syndrome or an aortic dissection. The limited availability of valid data to supplement the physician's clinical experience and professional knowledge, data that compare the clinical effectiveness and cost of different treatments for the same condition, makes it difficult to ensure that an effective treatment choice is made—one that meets the unique needs and preferences of the patient.

The lack of available information on the relative clinical effectiveness and costs of different treatments for the same condition limits the ability of primary health care payers, including the federal and state governments through Medicare and Medicaid, private employers or insurers, and the individual consumer, to ensure that the highest value is obtained for health care dollars spent and that their health care expenditures are being used effectively to provide high-quality care and achieve the best possible patient outcomes. The harmful effects of this evidence deficiency increase each year, as new advances in medical procedures, medical devices, biologics, and pharmaceuticals are introduced into the health care system. Absent increased investment to develop this important evidence about comparative effectiveness, the nation is at serious risk of producing more and more innovations without an effective and efficient means of incorporating them into a health care system with limited resources.

Position 1: The American College of Physicians strongly supports efforts to improve access to information comparing clinical management strategies.

Definition of Concepts

Clinical effectiveness analysis evaluates the extent to which a health care intervention provides an outcome consistent with its intent. Data for these analyses are typically obtained through one of two basic approaches:

Trial-based approach, in which clinical trials are conducted to assess the effectiveness of an intervention for a given condition.

Data synthesis approach, in which evidence from already existing clinical trials, studies published in the medical literature, and data from a variety of secondary sources (e.g., administrative claims data, registries, or observational studies) are integrated.

Comparative effectiveness analysis evaluates the relative (clinical) effectiveness, safety, and cost of two or more medical services, drugs, devices, therapies, or procedures used to treat the same condition. Although the use of the term *comparative effectiveness* broadly refers to the evaluation of both the relative clinical and cost differences among different medical interventions, it is notable that most comparative effectiveness research engaged in and used by stakeholders in this country focuses solely on evaluating relative clinical differences to the exclusion of cost factors. This issue will be addressed in more detail later in this policy paper.

Cost or Economic Analysis—Various terms and procedures are used when cost factors are a significant aspect in the comparison of the effectiveness of different medical interventions⁷. These include:

- **Cost analysis** or **Cost-identification analysis**, which estimates and compares the net costs of different strategies.
- **Cost consequence analysis**, which computes and lists the component costs of different interventions for the same condition without aggregation of the results into a single measure.
- **Cost benefit analysis**, which measures and compares the costs and benefits of different interventions for the same condition solely in monetary terms. This analysis requires estimates of the monetary value of health care benefits; deriving and agreeing on these estimates is often problematic.
- **Cost-effectiveness analysis (CEA)**, which compares the incremental or marginal economic cost per unit of health care gain observed among the different interventions for the same condition without attempting to monetarize the health care gain. More specifically, this approach provides a single ratio, a cost-effectiveness (C/E) ratio, which reflects the difference in the comparison interventions' costs (in dollars) divided by the difference in their health effectiveness or outcomes:

$$\text{Cost Effective Ratio} = \frac{\text{Cost}_{\text{intervention A}} - \text{Cost}_{\text{intervention B}}}{\text{Health Outcome}_{\text{intervention A}} - \text{Health Outcome}_{\text{intervention B}}}$$

Health outcomes are defined in various ways, including life years gained, cases of a particular disease prevented, and improvements in functional status. The current, most frequently used measure of health outcome, recommended by the respected Panel on Cost-Effectiveness in Health and Medicine⁸, is health-related quality-adjusted life years (QALYs). A QALY is a measure of health outcome that assigns a weight to each period of a patient's expected remaining years of life, ranging from 0 (death) to 1 (perfect health), that corresponds to the quality of life during that period. Thus, the value of a QALY can be less than the actual life year of expected survival. QALYs provide a common currency to assess the benefits that patients gain in terms of health-related quality of life and survival.

Previous College Policies Related to Comparative Effectiveness and Related Concepts

The College has a long history of supporting the production of clinical effectiveness data and encouraging use of these data by its members. Since 1981, ACP has been developing evidenced-based clinical treatment guidelines through its Clinical Efficacy Assessment Program. The College also publishes a continually updated, evidence-based reference of internal medicine practices, *ACP Medicine*, and offers the Physicians' Information and Education Resource (PIER), a Web-based decision-support tool designed for rapid point-of-care delivery of up-to-date, evidence-based guidance for clinicians, free to its members.

A 1996 ACP policy paper on reforming Medicare emphasized the need for increased production of outcome research reflecting the relative effectiveness of different treatments for the same condition and specifically called for the use of cost-effectiveness as criteria for the coverage of new technology. The College's ambivalence regarding the use of cost-effectiveness information in coverage decisions is reflected in their decision to join a coalition of health care groups in expressing opposition to this use, primarily due to methodological concerns, in a letter to the Medicare Administrator that same year⁹.

The College, in collaboration with the American Board of Internal Medicine and the European Federation of Internal Medicine, developed a physician's "Professionalism Charter"¹⁰ in 2002 that states, "While meeting the needs of individual patients, physicians are required to provide health care that is based on the wise and cost-effective management of limited clinical resources."

The current *ACP Ethics Manual*¹¹, published in 2005, states "Physicians have a responsibility to practice effective and efficient health care and to use health care resources responsibly. Parsimonious care that utilizes the most efficient means to effectively diagnose a condition and treat a patient respects the need to use resources wisely and to help ensure that resources are equitably available. In making recommendations to patients, designing practice guidelines and formularies, and making decisions on medical benefits review boards, physicians' considered judgments should reflect the best clinical literature, including data on the cost-effectiveness of different clinical approaches. When patients ask, they should be informed of the rationale that underlies the physician's recommendation."

A 2006 resolution passed by the College's Board of Regents promoted serious consideration of how cost-effectiveness methodology could be incorporated into Medicare and other health plan coverage decisions.

Finally, in recent testimony provided to the House Ways and Means Committee¹², the College reaffirmed its support for the increased development and provision of comparative clinical effectiveness information for all stakeholders. ACP supported the creation of an independent, trusted entity to facilitate the development of this information, and provided cautious support for the development of cost-effectiveness information by this entity. This current policy paper is an expansion and advancement of this recent testimony.

Current State of Comparative Effectiveness Research in the U.S. and Internationally

The United States currently does not have a systematic means of producing comparative information on the relative effectiveness of drugs, durable equipment, therapies, or procedures. The limited amount of comparative effectiveness data that is produced is done piecemeal, with little or no rational prioritization on the basis of the benefits it would provide to individual patients and the general population, little coordination or harmonization of evaluative efforts, and uneven methodological standards for evaluating and reporting the results to clinicians and patients. Furthermore, the United States currently spends less than 0.1% of its approximately \$2 trillion annual health care expenditures, including both public and private sources, on effectiveness research—exclusive of pharmaceutical industry-funded clinical trials—with a much smaller portion of this amount specifically related to comparative effectiveness research^{13,14}. Current comparative effectiveness research and data use efforts in this country are outlined below.

Federal Government

The federal government currently engages in a limited amount of comparative effectiveness research and analysis. The Center for Medicare and Medicaid Services (CMS), which is the single largest health care payer in the nation, is limited by statute¹⁵ to making national coverage determinations based upon whether a service is “reasonable and necessary.” Traditionally, this has meant that the determination of whether to cover a service is based on evidence that the medication or medical equipment is “safe and effective” and evidence that the procedure “improves health outcomes.”¹⁶ The Medicare Coverage Advisory Committee (MedCAC) reviews available technical and effectiveness data and advises CMS on whether to cover the specific service. CMS’s use of comparative effectiveness data for these coverage determinations is limited to providing evidence for the effectiveness of the procedure (as opposed to its relative effectiveness), and cost-effectiveness data by historical precedent, and possibly statute, is not considered in these determinations. Medicare has precedence for using comparative effectiveness data in the rate setting process¹⁷. For example, Medicare and its contractors have on occasion set the payment for a new service (e.g., an alternative erythropoiesis-stimulating agent) at the same rate as an already existing service if the new service demonstrated equivalent clinical effectiveness.

Other agencies within the federal government involved in comparative effectiveness activity include:

- **National Institutes of Health (NIH):** The NIH is this country’s largest sponsor of clinical research. A small percentage of this funding, estimated to be less than 0.3%, has been focused on the comparative effectiveness of health interventions¹⁸. Recent comparative effectiveness studies funded by NIH addressed antipsychotic drugs, antihypertensive and lipid-lowering agents, and approaches to heart failure.
- **Federal Drug Administration (FDA):** The FDA assesses the safety and effectiveness of drugs, and to a lesser extent medical equipment, but the research it considers generally compares performance to no treatment conditions, rather than to competing drugs already in the market place. A drug company is required to provide to the FDA comparative effectiveness data if they explicitly desire to advertise that their drug is more effective than a competing drug.

- **Veterans Administration (VA):** The VA engages in a substantial amount of clinical research and focuses some of these efforts on comparative effectiveness and cost-effectiveness analyses. The VA also requires cost-effectiveness analyses from drug manufacturers desiring to place drugs on the VA formulary that are significantly more costly than similar medications already on the formulary.
- **Agency for Healthcare Research and Quality (AHRQ):** The AHRQ conducts and supports research with a focus on outcomes, comparative clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services. This mandate was authorized through Section 1031 of the 2003 Medicare Modernization Act (MMA). Congress has provided a small yearly appropriation of \$15 million toward these efforts, despite the fact that \$50 million was authorized. Through its Effective Health Initiative, this agency has established itself as a trusted source of comparative effectiveness data with significant transparency and stakeholder involvement. Since its implementation, it has produced eight comparative effectiveness research reviews and is in the process of developing at least eight others. The AHRQ accomplishes this research through contracts with 13 nongovernment Evidence-Based Practice Centers throughout the country. The AHRQ has also made a substantial effort to ensure that the findings from these studies are accessible to consumers, providers, and policy makers in a meaningful form.

The AHRQ has strong ties to two other public-supported entities:

- **Drug Effectiveness Review Project (DERP):** DERP operates out of the University of Oregon and provides comparative effectiveness reviews for the consideration of drugs to be included within 13 state Medicaid programs. The Oregon Evidence-Based Practice Center, which actually conducts the research, is partially supported by AHRQ.
- **Centers for Education and Research on Therapeutics (CERTs):** CERTs conduct research and provide education that advances the optimal use of therapeutics (i.e., drugs, medical devices, and biological products). The program consists of 11 research centers and a Coordinating Center and is administered under a cooperative agreement by the AHRQ, in consultation with the U.S. Food and Drug Administration (FDA). The CERTs, as an entity, receive funds from both public and private sources, with AHRQ providing core financial support.

Private Sector Entities

Private sector entities, including pharmaceutical and durable medical equipment companies, pharmaceutical benefit managers, health plans, large provider groups, and private consulting firms (e.g., ECRI or Hayes, Inc.), also produce comparative clinical and cost-effectiveness data; however, the details of these studies are often not transparent, access to the data is limited due to their proprietary nature, and there is evidence questioning the objectivity of some of these findings¹⁹. These data are used for many reasons, including demonstrating the value of a company's products within the market place, determining pricing, developing pharmaceutical formularies, and establishing utilization management strategies. The Technology Evaluation Center established by the Blue Cross Blue Shield Association (BCBSA) in 1985 is one of the early private sector efforts to develop comparative clinical effectiveness data for use in developing coverage decisions and treatment guidelines for its affiliates²⁰. Note that except for the pharmaceutical area (e.g., establishing formularies that include pricing and utilization management protocols), efforts to develop and employ formal cost-effectiveness data in these private activities have been minimal.

International Comparative Effectiveness Activities

The heterogeneity of comparative effectiveness efforts in this country is in marked contrast to the coordinated activities conducted in a number of other countries, including Canada, Great Britain, Germany, France, Sweden, and Australia, and multinational collaborations, such as the European Medicines Agency and the European Network for Health Technology Assessment. These international efforts all demonstrate significantly greater coordination, central prioritization, and use of cost-effectiveness data than the United States^{21,22,23}.

The most recognized of these international comparative effectiveness efforts is the National Institute for Health and Clinical Excellence (NICE) program in Great Britain²⁴, which serves as a model of a coordinated, prioritized comparative effectiveness program. NICE reviews all types of medical technologies and is designed to promote trust in its findings through establishing transparency in its proceedings and promoting strong stakeholder involvement at all levels of the assessment process. This information is used by the National Health Service (NHS) to help inform coverage decisions and guide providers on the appropriateness of various interventions for the management of target conditions within specific patient populations. The ultimate goals of the program are to improve the standard of care and the effective use of resources by the NHS. A recent review of the program indicates that it is having a substantial positive impact toward these goals²⁵.

The Cochrane Collaborative is another highly respected multinational non-profit organization that produces, through its structure of 51 research groups, systematic reviews on the clinical effectiveness of various interventions from the available worldwide literature. A portion of these reviews addresses the issue of comparative effectiveness. The collaborative has no centralized prioritization process, nor does it have the capability to actually fund necessary research to fill noted evidence gaps^{26,27}.

The Need to Develop a Center for Comparative Effectiveness Information in the United States

The preceding review of comparative effectiveness activities in this country and comparison with international efforts leads to the following conclusions:

- The United States expends insufficient funds to develop comparative effectiveness data
- There is no coordination or prioritization of current efforts in either the public or private sector to help produce comparative effectiveness information that would provide the greatest health care impact
- The absence of readily available, essential comparative effectiveness information interferes with the ability of physicians and their patients to make effective, informed treatment choices that meet the unique needs and preferences of the patient and the ability of payers to optimize the value received for their health care expenditures.

These and similar observations have led to a call from a number of health care leaders for the development of a substantially increased capacity to produce comparative effectiveness data. Most recently, the Institute of Medicine²⁸, former CMS Administrator Gail Wilensky²⁹, the Medicare Payment Advisory Commission (MedPAC)³⁰, the Congressional Budget Office³¹, and a study by Emanuel et. al.³² have all specifically called for establishing an independent entity to sponsor and/or produce trusted research on the comparative effectiveness of health care services. Furthermore, recent legislation has been introduced—the Enhanced Health Care Value Act of 2007 (HR 2184) and Section 904 of the Children’s Health and Medicare Protection Act of 2007 (HR 3162)—that provides federal funding and a suggested structure for the expansion of comparative effectiveness research.

Position 2: The College strongly supports the establishment of an adequately funded, independent entity to sponsor and/or produce trusted research on the comparative effectiveness of health care services

Various structures for this entity have been proposed, including the establishment of a new agency within the federal government or the expansion of an existing federal agency’s role (e.g., the role of the AHRQ); the placement of the entity within a quasigovernment structure (such as the Institute of Medicine), federally funded research and development center, or public foundation; or placement within the private sector as a non-profit entity with mandated federal guidelines³³.

Position 3: The College believes that the federal government should have a significant role in the funding, implementing, and maintaining of this comparative effectiveness entity, but takes no formal position on its organizational structure (e.g., government or joint public/private)

Strong federal involvement would help ensure that the entity would have adequate funding to produce the costly comparative effectiveness research and that the data produced would be available to all stakeholders for the public good. Patients and providers obviously do not have the resources to produce these data. Private industry may have the resources to produce some, but the private-sector marketplace provides no incentive to share the findings with competitors and society in general or to ensure that such evidence is as unbiased as possible. Thus, the federal government, representing society in general, is the most appropriate candidate to take on this funding role. In addition, the federal government will derive substantial benefits from this activity, given that it currently funds approximately 45% of all medical care in the country.

It is envisioned that this comparative effectiveness entity would prioritize and coordinate national efforts and produce trusted and valid research that is easily available to all stakeholders and that this information would be used to:

- Establish information that could be used by clinical provider groups to establish evidence-based practices and clinical guidelines to help decrease the significant variability in practices and costs throughout the country.
- Provide critical information to physicians and their patients to allow them to engage in an informed shared clinical decision-making process. The involvement of the patient within this shared clinical decision-making process is a key feature of the Patient-Centered Medical Home model of care supported by the major primary care provider groups³⁴. Furthermore, research on active shared decision making indicates that it has the potential to reduce unwarranted variations in treatment among providers, increase patient accuracy in expected treatment outcomes, and provide patients with greater comfort in the treatment choice made³⁵.
- Provide important data to health care payers to help ensure increased value from their expenditures.

The College, after reviewing the comparative effectiveness activities of existing entities both in this country and abroad, has established a core set of characteristics for this new entity that it believes will facilitate its role as a trusted, effective source of comparative effectiveness information.

Position 4: The College recommends that the newly proposed comparative effectiveness entity should:

- **Have a structure and adopt operating procedures that encourage trust in its impartiality and adherence to the strictest scientific standards, by ensuring its independence from undue governmental and private sector influence.**
- **Be responsible for the development of evidence concerning comparative effectiveness necessary for clinical practice, coverage, or pricing decisions, but have no direct involvement in the making of these health care decisions.**
- **Conduct proceedings and present results in a transparent manner.**
- **Involve all relevant stakeholders, including beneficiaries, payers, scientists, providers, and industry representatives, at all levels of the evidence development process.**
- **Implement a prioritization process, informed by input from the stakeholder groups, that ensures that the comparative effectiveness evidence developed will have the greatest positive effect on improving the quality and efficiency of the overall health care provided in the country.**
- **Support the development of evidence at all levels from review and synthesis of existing evidence to initiation of new research in priority areas in which essential evidence does not already exist.**
- **Include relevant clinical information available from federal agencies as well as private and academic settings in its analyses.**
- **Ensure that the comparative effectiveness findings developed are accessible in a timely manner and in a comprehensible form to all stakeholders.**

The Reluctance to Use Cost-Effectiveness Information

A review of the literature indicates uniform support for the establishment of a center of information that provides evidence of the relative clinical effectiveness of health care services; however, support for the production and use of cost-effectiveness data is much more limited. This was most recently reflected in MedPAC's June 2007 Report to Congress, which states that the recommended entity's primary mission would be to sponsor studies that compare **the clinical effectiveness** of a service with competing treatment approaches. While the production of cost-effectiveness information wasn't ruled out, the MedPAC Commissioners evidenced significant ambivalence regarding this issue during the public hearing leading to the report, despite the recognition of its value³⁶. This ambivalence and limited support for the production and use of cost-effectiveness data are found in many sectors of the health care community.

Medicare has attempted on two occasions to pass language through the rule-making process to support the use of cost-effectiveness data as a factor in the making of coverage decisions. Multiple stakeholders expressed strong opposition on both occasions, with particular concern expressed that this would be the forerunner to the use of rationing under Medicare³⁷. Medicare discontinued its efforts on both occasions. This policy directly affects traditional Medicare (Parts A and B) and also affects private plan Medicare (Part C), insofar as it must provide its beneficiaries with at least the basic traditional Medicare package of benefits and must abide by all Medicare National Coverage Decisions that expand coverage³⁸. The new Medicare Part D benefit provides substantially

greater flexibility for participating private drug plans to use costs in making decisions regarding the drugs to include in their formularies.

Traditional state Medicaid programs are not allowed to use cost or cost-effectiveness data when deciding which medications to cover within their formularies³⁹. Medicaid programs must cover all FDA-approved drugs from every manufacturer that signs an agreement with the Secretary of Health and Human Services to pay rebates to the states for the drugs purchased; a preferred drug list is permitted subject to certain requirements. The states do have the flexibility to employ cost and cost-effectiveness data when deciding whether to employ prior authorization or other utilization management procedures. The previously described DERP program provides information to a number of states for this purpose. State Medicaid programs are directly influenced by cost factors. State budgets routinely go through cycles of surplus and deficits. During periods of deficit, coverage under Medicaid and other state-funded health programs is often reduced, typically by not covering specific populations or benefits that are not required under the specific program. Currently, only the state of Washington has implemented a program that formally assesses safety, efficacy, and cost-effectiveness information to inform these decisions⁴⁰. Oregon previously attempted to use cost-effectiveness analyses to prioritize Medicaid benefits in the early 1990s, but the influence of the cost-effectiveness variable on the prioritization process was rapidly minimized due to substantial criticism from multiple health care stakeholders⁴¹.

Commercial health plans and purchasers also display a reluctance to employ formal cost-effectiveness analyses. This is despite the fact that cost is admittedly considered in some form in the evaluation of new interventions in 90% of these private sector programs⁴². For example, it is a widespread health plan industry practice to use so-called “budgetary impact analyses,” in which new technologies are evaluated in terms of their projected impact on cost “per member per month,” often without relating cost to patient outcomes⁴³.

In a survey of private U.S. health plans, only 40% indicated the use of formal cost-effectiveness analyses⁴⁴. In another survey, only 51% of private payers used cost-effectiveness or cost-benefit analyses⁴⁵. Similarly, BCBSA’s respected Technology Evaluation Center, which provides assessments for development of coverage decisions and treatment guidelines for its affiliated plans, generally excludes cost-effectiveness considerations⁴⁶. When cost-effectiveness data are used within the commercial sector, the use is typically limited to the development of coverage and pricing decisions related to pharmaceuticals.

The reasons many health care stakeholders are reluctant to use (or oppose the use of) cost-effectiveness analyses include:

- **Concerns related to the use of any cost data linked to fears that it will inappropriately limit access to services and facilitate the use of rationing in the delivery of services.**

The literature reflects concerns from patients and their advocates that the use of any cost data, including formal use of cost-effectiveness analyses, in coverage decisions will inappropriately limit access, will be used solely for cost-containing purposes, and will essentially represent a significant step towards care rationing^{47,48}. The reaction of beneficiaries to Medicare’s attempts to make regulatory changes allowing limited consideration of cost-effectiveness data is a good example of this. These fears are particularly strong in this country because of the cultural belief that, as the richest nation in the world, cost should not be a factor in decisions related to the availability of treatment⁴⁹.

This viewpoint neglects to recognize the substantial, unsustainable growth in health care expenditures occurring in this country and its negative effects. Medicare Trustees have expressed concerns over the past several years regarding the future financial instability of the Medicare system⁵⁰. Furthermore, health care premium growth continues to outpace the economy and workers earnings by a significant amount, making health care benefits increasingly unaffordable to both employers and their employees⁵¹.

These concerns also do not recognize that rationing is already occurring in this country in the form of the over 47 million people who are uninsured for their health care needs—most of whom are unable to afford the health care premiums⁵². The lack of insurance has led to a documented decrease in access to needed health care and, relatedly, substantially poorer medical outcomes⁵³.

It is clear that health care resources are limited, even in this rich country, and that cost factors already play a role and will continue to play a role in health care expenditure decisions. Making valid and reliable cost-effectiveness data from a trusted source available to all stakeholders would provide a needed tool for the general population and traditional health care purchasers (e.g., government programs and employers) to help ensure improved value in their purchases. It would also ultimately result in a better and more socially equitable means of controlling overall costs than our current approach of limiting access to care for some of our most vulnerable, needy citizens or using cost information in the decision-making process in a nontransparent manner that doesn't consider effectiveness.

A review of recent research literature indicates that there is a renewed interest from almost all stakeholders in increasing the availability of cost-effectiveness information. Survey data reflect that with appropriate safeguards, the majority of individuals in the general public believe that increased availability of cost-effectiveness data is a reasonable approach to the escalating rise in health care costs and copayments⁵⁴. This interest in cost and cost-effectiveness data will presumably increase as the employee share of health care costs increases and with the more frequent presence of high-deductible options coupled with health saving accounts in the insurance marketplace. Survey data also indicate that most physicians agree that it is appropriate for them to consider cost-effectiveness data when making clinical decisions⁵⁵. Furthermore, both the BCBSA⁵⁶ and the American Health Insurance Plans (AHIP)⁵⁷ have recently called for efforts to increase the production of cost-effectiveness data from a trusted source. Finally, the National Business Group on Health is reporting available cost-effectiveness data to members within their recommendation guidelines for covered services⁵⁸.

- **Concerns regarding the general soundness of cost-effectiveness analysis methodology and trust in the cost-effectiveness data currently being produced.**

The research literature has frequently demonstrated that traditional cost-effectiveness analyses leave substantial discretion to the researcher and differences in design decisions can lead to significantly different results. For example, a recent MedPAC-commissioned review of studies on the cost-effectiveness of colorectal screening compared with no screening yielded C/E ratios ranging from \$1,400 to more than \$42,000 per life year gained⁵⁹. The same reviewers found C/E ratios for implantable cardioverter defibrillators compared with pharmaceutical treatment ranged from \$18,000 to \$569,000 per life year gained⁶⁰. It is difficult to have much trust in a methodology that reports such varying results in addressing the cost-effectiveness of the same treatment service.

The study design decisions left to the discretion of the researchers conducting cost-effectiveness analyses include:

- The perspective of the analysis (e.g., society, insurers, or purchasers).
- The sources of the data (e.g., direct clinical trials, an integration of studies reported in the literature, or claims data).
- The discount rate used to adjust for future costs and benefits.
- The costs to include in the analysis.
- The time horizon to be considered in the analysis.
- The selection of interventions to compare.
- The form of outcome measurement used (e.g., QALYs, number of life years gained, or gains in functional capabilities).
- The means of considering the uncertainty of clinical events and costs.

In 1993, in recognition of this wide latitude in discretion and the resulting variability in findings, the Public Health Service convened a group of 13 nongovernmental scientists and scholars with expertise in cost-effectiveness and charged them with making recommendations to improve the quality and comparability of reported cost-effectiveness analyses. This respected Panel on Cost-Effectiveness and Health published a report that viewed cost-effectiveness analyses as an “aid to decision making, not a complete procedure for making resource allocation decisions”; called for increased transparency in study reporting; and recommended a “reference case,” reflecting a standard set of methodological practices that an analyst should follow in conducting cost-effectiveness studies⁶¹. These recommendations have had a positive effect on the research literature in this area. Although variations in these factors continue to occur, a review of more recently published cost-effectiveness analyses reflect improved comparability among the studies⁶². MedPAC has recently concluded that this continued variability would have to be further addressed before Medicare could routinely use cost-effectiveness analyses⁶³.

The sense of distrust is further stimulated by the observation that industry-funded cost-effectiveness analyses may be biased—they are more likely to report positive findings than non-industry-sponsored research⁶⁴. For example, Neumann has reported that “virtually all surveys of health decision makers” reveal concerns about the presence of bias in those analyses attributable to industry financing⁶⁵. This concern is highlighted by the growing number of these analyses being funded by pharmaceutical companies. In reaction to this concern, the *New England Journal of Medicine* instituted a policy limiting consideration of industry-sponsored cost-effectiveness analyses for publication to those that were only funded through a grant to a nonprofit organization; that provided assurances of author independence; and that included information on all assumptions made and data used for the sake of transparency⁶⁶. Other journals have taken similar although somewhat more limited steps.

- **Concerns that the use of cost-effectiveness analyses in the coverage decision-making process, particularly by Medicare, may inhibit technical innovation in health care.**

Representatives from the medical product industries have expressed concern that the use of cost-effectiveness analyses within coverage decision processes of purchasers will create an additional barrier within the marketplace and slow down or possibly inhibit innovation⁶⁷. This concern is particularly directed towards Medicare because of its substantial purchasing power. Denial of coverage by this program based on cost-effectiveness data would have a significant financial effect on a company and may reduce efforts toward technical advances. Neumann⁶⁸ counters this concern with the observation that innovation is dependent on multiple factors, including incentives offered by payers, society's overall willingness to spend money on health care, the available supply of capital funds to support investment, and the rigidity with which cost-effectiveness thresholds are applied. He contends that the use of cost-effectiveness data does not necessarily have to inhibit innovation but may actually stimulate the focused development of more cost-effective technological advances.

- **Concerns that use of cost-effectiveness analyses in the coverage decision-making process, particularly within the commercial sector, may lead to a significant increase in costly litigation initiated by beneficiaries.**

It has been posited that health plans have been reluctant to use cost-effectiveness analyses in coverage decisions due to concerns that it may lead to a significant increase in costly litigation initiated by beneficiaries^{69,70}. This concern is fueled by the recognition that:

- Most current health plan contracts, while emphasizing the use of clinical effectiveness evidence within the coverage decision process, make little or no reference to the use of cost-effectiveness as part of this process.
- Beneficiaries tend to have negative reactions whenever coverage is denied and have a tendency to sue.

A review of the literature indicates that little litigation has directly raised or challenged the use of cost-effectiveness analyses and that legal precedents exist for health plans successfully fending challenges to other, similar resource-containment initiatives⁷¹.

A Case for the Use of Cost-Effectiveness Analyses by the Proposed Entity for Comparative Effectiveness Information

MedPAC has recently highlighted the potential for the use of cost-effectiveness analyses to complement current clinical effectiveness considerations within Medicare's coverage and pricing processes for the purpose of obtaining increased value for its medical expenditures⁷². The Commission further outlined potential cost-effectiveness activities under Medicare, including the collection of cost-effectiveness information as part of the coverage decision process, the sponsoring of cost-effectiveness studies, the providing of results of cost-effectiveness to beneficiaries and sponsors to help assess the relative value of different treatments for the same condition, and the use of this information to prioritize various agency initiatives (e.g., services to encourage through pay-for-performance, populations in which to focus disease management interventions, and conditions for which to institute health care screening).

The College also believes that cost-effectiveness information is a necessary complement to comparative clinical effectiveness information for all health care stakeholders. This information will assist patients and their personal physicians in making treatment decisions that better reflect the needs and preferences of the patient, provide an additional factor to help health care payers and plans ensure increased value from their expenditures, and serve as a stimulus for medical innovation and technological advances to consider the relative value of any planned new equipment or procedure.

An even more important consideration is that cost information is currently being used to make decisions regarding health care coverage and/or rate setting/tiering/utilization management decisions in many settings—perhaps not always in a transparent, explicit manner. The more these decisions can be informed by **both** cost and clinical effectiveness factors (i.e., contribution to improved health outcomes) combined in a transparent manner, which is possible using cost-effectiveness analysis methodology, the higher the likelihood of obtaining true value within the health care system.

As outlined above, many of the concerns currently inhibiting the production and use of cost-effectiveness information can be adequately addressed or are not supported by factual information and should not continue to inhibit the availability of this information. Furthermore, a number of these concerns can be equally applied to the clinical effectiveness research arena, but they do not have the effect of inhibiting the production of information in that area.

The College believes that all relevant stakeholders should assist in being good stewards of our health care resources so that they can be used to facilitate the availability of effective care to all. The appropriate use of cost-effectiveness information provides an important tool towards this goal. Thus, based on this belief,

Position 5: The College recommends that the proposed comparative effectiveness entity be charged with systematically developing both comparative clinical and cost-effectiveness evidence for competing clinical management strategies.

The College recognizes the general sensitivity toward the use of cost-effectiveness information among stakeholders and the limited understanding of this approach among the general public. It further recognizes specific concerns regarding the methodological soundness of the approach and its potential for misuse to inappropriately restrict access to necessary health care. Thus, the College makes the following additional recommendations:

Position 6: The College recommends that as part of the implementation of the proposed comparative effectiveness entity, a panel of stakeholders and additional scientific experts, including specifically experts in the area of cost-effectiveness analyses, be formed and charged with:

- **Updating and expanding upon the recommendations of the 1993 Panel on Cost-Effectiveness and Health⁷³ and developing related procedures to ensure that the proposed entity produces high-quality cost-effectiveness information.**

- **Developing a framework and related procedures to reconcile apparently disparate estimates of cost effectiveness regarding specific clinical management comparisons.**
- **Developing recommendations, including suggested model procedures, for potential use by stakeholders who plan to consider this cost-effectiveness information in clinical, coverage, purchasing, and pricing decisions. These recommendations should:**
 - **Recognize that cost-effectiveness analysis is only a tool to be used in coverage and pricing decisions. It cannot be the sole basis for making resource allocation decisions.**
 - **Help to ensure that the use of cost-effectiveness information as part of the decision-making process within the doctor-patient relationship takes into account the unique needs and values of each patient (is patient-centered) and the clinical opinion of the treating physician, while also recognizing the limited nature of health care resources available to society in general (the Medical Commons⁷⁴).**
- **Developing recommendations to establish a mechanism to educate the general public and promote discussion on the use of comparative clinical and cost-effectiveness information to both meet the needs of the individual and help ensure the equitable distribution of finite health care resources throughout society.**

The College, furthermore, in particular recognition of the substantial, unsustainable growth in health care expenditures occurring in this country that is reflected at all payer levels, makes the following recommendation:

Position 7a: The College recommends that all health care payers, including Medicare, other government programs, private sector entities, and the individual health care consumer, employ both comparative clinical and cost-effectiveness information as factors to be explicitly considered in their evaluation of a clinical intervention.

Position 7b: The College recommends that cost should never be used as the sole criterion for evaluating a clinical intervention. Cost should only be considered along with the explicit, transparent consideration of the comparative effectiveness of the intervention.

Conclusion

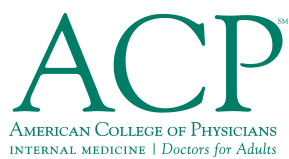
This policy paper highlights the need for a Comparative Effectiveness entity in this country to provide trusted information that can be used for the public good to promote increased patient-centered care, help address current problems stemming from the significant variability in clinical practices and quality throughout the nation, and achieve an overall higher value for health care expenditures at the level of both the health care system and the individual. This policy paper further expounds on the importance of including the development and communication of cost-effectiveness information as an integral, important mandate for this entity—despite current multiple forms of resistance. The College looks forward to taking an active role working with all other health care stakeholders in the development of this new entity.

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