

**Statement for the Record
of the
Hearing of the
House Ways and Means Committee
Subcommittee on Health
on
“Strategies to Increase Research and Information on Comparative
Clinical Effectiveness”**

**Testimony of the American College of Physicians
June 12, 2007**

I am David C. Dale, MD, FACP, President of the American College of Physicians and professor of medicine at the University of Washington. The 123,000 internal medicine physicians and medical student members of the American College of Physicians congratulate Chairman Stark and the members of the House Ways and Means Subcommittee on Health for convening today’s hearing on “Strategies to Increase Research and Information on Comparative Clinical Effectiveness.” **The College strongly supports Congressional efforts to provide Medicare and all stakeholders within the healthcare community with improved access to information about the relative strengths and weaknesses of various clinical products, procedures and services based on the best available evidence of clinical effectiveness.**

The members of this Subcommittee are well aware of the significant problems that characterize our current healthcare system:

- the unsustainable growth in healthcare costs that affect both payers and beneficiaries¹;
- the presence of significant quality gaps particularly when compared to other industrialized nations that spend much less on healthcare²;
- the presence of significant variation in healthcare costs throughout this country without any evidence that increased costs result in improved care³.

As stewards of the Medicare Trust Fund and the largest payer of healthcare services in the country, it is Congress’ responsibility to address these problems and help ensure that our taxpayer funds are being used effectively to provide high quality care and achieve the best possible patient outcomes. The increased production and availability to payers,

¹ Kaiser Family Foundation. Trends and indicators in the changing healthcare market place. 2006. Accessed at <http://www.kff.org/insurance/7031/index.cfm> on May 9, 2007.

² Anderson G, Hussey PS. Comparing Health System Performance in OECD Countries: Cross-National Comparisons Can Determine Whether Additional Health Care Spending Results in Better Outcomes. *Health Affairs*. May/June 2001;20(3):219-32.

³ Fisher, E., Wennberg, D., et al., The Implications of Regional Variations in Medicare Spending: Part 2, Health Outcomes and Satisfaction with Care, *Annals of Internal Medicine* 2003; 138:288-98.

providers and beneficiaries of methodologically sound information from a trusted source on the effectiveness of alternative treatments would be a good step towards improving the value obtained from healthcare dollars spent.

The Public Need for Comparative Clinical Effectiveness Research

From the perspective of the practicing physician, the increased availability of sound comparative effectiveness data has direct clinical usefulness. Each day in the privacy of the examination room, patients are treated for conditions that have multiple treatment options. Here we are talking about treating a common condition like intermittent heartburn, to the more serious chronic conditions of high blood pressure or diabetes, to the more immediate life and death issues of to having to choose the best approach to treat diagnosed breast or prostate cancer. The availability of valid, comparative effectiveness data supplemented by the physician's clinical experience and professional knowledge, helps ensure that an effective treatment choice is made—one that meets the unique needs and preferences of the patient.

The College has a long history of supporting evidenced based practice, and since 1981 has been developing evidenced-based clinical treatment guidelines through its Clinical Efficacy Assessment Program. In fact, I was part of the original panel of experts of this program and am currently Editor-in-Chief of "ACP Medicine," a continually updated, evidence-based reference of internal medicine published by the College. My own patient care experiences, as well as the College's experience in producing evidence-based analyses, supports the need for an objective, evidence-based and refereed source of information from a "trusted entity" to compare the effectiveness of alternative healthcare services.

The United States currently does not have a systemic means of producing comparative information on the relative effectiveness of drugs, durable equipment, therapies and procedures. The limited amount of comparative effectiveness data that is produced is done piece-meal, with little or no prioritization relative to the benefits it would provide to individual patients and the general population, little coordination or harmonization of clinical efficacy efforts, and uneven methodological standards for evaluating clinical efficacy and reporting the results to clinicians and patients. Often, evaluations are made on a "single therapy" basis without comparing such therapies to alternative treatments. The Federal Drug Administration assesses the safety and effectiveness of drugs, and to a less extent medical equipment, but the research it considers generally compares performance to no treatment (placebo) conditions, rather than to alternative products already in the market place. The National Institutes of Health (NIH) is this country's largest sponsor of clinical trials that compare alternative treatments, but funds for these studies represent only a small amount of their budget. The Agency for Healthcare Research and Quality (AHRQ) through Section 1031 of the Medicare Modernization Act (MMA) was authorized by Congress in 2003 to conduct and support research with a focus on outcomes, comparative clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services. I will discuss more about this effort later in my testimony.

Private sector entities including pharmaceutical companies, pharmaceutical benefit managers, health plans and large provider groups also produce some comparative effectiveness data, but the details of these studies are often not transparent, access to this data is limited due to its proprietary nature, and there is evidence questioning the objectivity of some of these findings.⁴

This hodge-podge of comparative effectiveness efforts is in marked contrast to the activities conducted in a number of other countries, including Canada, Great Britain, Germany and Australia. Perhaps most recognized of these efforts is the National Institute for Health and Clinical Excellence (NICE) program in Great Britain⁵, which serves as a model of a coordinated, prioritized comparative effectiveness program designed to promote trust in its findings through transparency in its proceedings and strong stakeholder involvement at all levels of the process.

The College recommends that the Congress take efforts, including allocation of secure and sustained funding, to develop or support a trusted entity that systematically develops evidence on the relative effectiveness of various alternative healthcare services.

While the College currently has no formal position on the structure of this entity (i.e. public, private or public-private), it believes that this entity should have the following characteristics:

- it should be an unbiased independent entity protected from both governmental and private sector influence to encourage trust in its findings.
- its proceedings should be transparent.
- it should involve stakeholders, including payers, providers and beneficiaries, at all levels of the evidence development process.
- it should have a prioritization process, informed by input from the stakeholder groups, that ensures that the comparative effective evidence developed will have the greatest impact in improving the quality and efficiency of care provided.
- it should support the development of all levels of evidence including formal review and synthesis of evidence already available in the clinical literature and the initiation of new research in priority areas where such evidence does not already exist.
- it should have established processes that ensures that the comparative effectiveness findings developed are accessible in a comprehensive form to all stake holders and reported in a manner that is useful for clinicians and patients.

⁴ Medical Payment Advisory Committee. Presentation by Nancy Ray on Comparative Effectiveness. April 12, 2007 Public Meeting. Access at http://www.medpac.gov/public_meetings/transcripts/0407_allcombined_transcript.pdf on May 9, 2007

⁵ Pearson D, and Rawlins, M. Quality, innovation and value of money. JAMA, Nov. 2005;294(20):2618-2622

The entity that currently best matches this list of characteristics is the AHRQ. Through its Effective Health Initiative, this agency has established itself as a trusted source of comparative effectiveness data. Since its recent implementation, it has produced seven comparative effectiveness research reviews, it is in the process of developing at least six others and has initiated at least 14 new research projects. It has also made a substantial effort to ensure that their findings are accessible to consumers, providers and policy makers in a meaningful form. The College commends the efforts of the AHRQ and has recently urged Congress to increase its level of funding in a joint letter signed by the American Medical Association and over 80 other medical organizations⁶.

If AHRQ is to continue to be the “trusted entity” to conduct effectiveness research, then it needs to be assured of sufficient and sustained funding to support its activities and be protected from the normal political influences that arise through the annual appropriations process. If Congress chooses to create a new entity rather than facilitate increased funding of the AHRQ to advance the development of cost effectiveness evidence, it should use lessons learned from AHRQ in developing this new entity and assure that the new entity is funded in a way that will protect it from political influences that may arise through appropriations.

Use of Comparative Effectiveness in Benefit Design Decisions

The College is also aware of suggestions concerning the potential use of this data by Medicare⁷ (and other payers) to redesign their healthcare benefits by basing reimbursement and/or patient cost-sharing on the comparative evidence developed by the proposed entity. For example, those procedures that prove generally more effective could receive higher reimbursement and/or require a lower beneficiary co-payment. **The College, although recognizing potential savings obtainable through this approach, recommends that Congress walk down the path of using comparative effectiveness data in the Medicare benefit design slowly and cautiously.** It will take time for clinicians and patients to develop trust and have confidence in the evidenced produced from any new comparative effectiveness evidence producing entity. In addition, procedures will need to be developed to ensure that the unique needs of each patient can be recognized, and that clinical decisions are based upon what is best for this patient, rather than the economic incentives promoted by the benefit design.

The appropriateness of including “cost effectiveness” as an explicit element in comparative effectiveness research is complex and controversial. Cost means different things to different people: aggregate costs to a payers of services (Medicare), the economy (societal costs), the individual (in the form of out of pocket expenses, health care premiums, or individual tax payments to support public programs), or clinicians

⁶ Joint letter on SGR legislative options sent to key Congressional Committee staff delivered on May 17, 2007.

⁷ Medical Payment Advisory Committee. Presentation by Gail Wilensky and Marilyn Moon on Comparative Effectiveness. April 12, 2007 Public Meeting. Access at http://www.medpac.gov/public_meetings/transcripts/0407_allcombined_transcript.pdf on May 9, 2007

(whose professional value system often puts primacy of the individual patient's needs and preferences over societal costs) are very different from each other and will result in different value judgments. How the relative costs of a treatment and procedure should be weighted against the evidence of clinical effectiveness will involve value judgments that need to be made in an open, transparent, and methodologically sound basis that takes into account the different values that each stakeholder brings to the table. **For these reasons, the College suggests that federally-funded comparative effectiveness research should, at least in its early stages, focus on relative clinical efficacy rather than cost-effectiveness.** At the same time, however, **we support further discussion of how cost-effectiveness comparisons might be introduced into the evaluation process at a later stage and used, at least in part, to influence benefit design by Medicare and other programs.**

Comparative Clinical Effectiveness Research and Shared Decision-Making

The greatest initial value of developed comparative effectiveness data at this time is to help answer the question of what works best for whom and the use of this information in providing effective patient-centered treatment. Comparative effectiveness research from a trusted entity will enable physicians and patients to engage in informed and shared decision-making on the most desired and effective treatment alternatives for that individual patient. Such shared decision-making is a key element of **the Patient-Centered Medical Home (PCMH).** This care model--supported by the 330,000 primary care physicians represented by the American Academy of Family Physicians, the American Academy of Pediatrics, the American Osteopathic Association and the American College of Physicians and a coalition of large employers and consumer organizations--would ensure that treatment decisions informed by comparative effective evidence will be delivered in a coordinated, integrated manner. The model also emphasizes the importance of actively making treatment decisions a shared process between the patient and their personal physician. Research using an active shared decision making process, using available comparative effectiveness evidence, indicates 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 made.⁸

Finally, the College urges the Subcommittee to report legislation to create Medicare payment incentives for physicians to acquire and use health information technology (HIT) in their practices as a means of facilitating the collection and reporting of clinical data on effectiveness and facilitating evidence-based clinical decision support and shared decision-making at the point of care. The availability of clinical decision support technology at the site of care will make evidence-based comparative

⁸ O'Connor, A. et al. Modifying unwarranted variations in health care: Shared decision making using patient decision aids. Health Affairs Web Exclusive, October 7, 2004. Accessed at <http://content.healthaffairs.org/cgi/reprint/hlthaff.var.63v1?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=O%27Connor&andorexactfulltext=and&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT> on May 7, 2007.

research readily available to physicians and their patients to support shared clinical decision-making between the physician and the patient. The College specifically supports H.R. 1952, the National Health Information Incentives Act of 2007, introduced by Representatives Charles Gonzalez (D-TX) and Phil Gingrey, MD (R-GA) to provide financial incentives to physicians through Medicare to adopt and purchase HIT.

Summary and Conclusion

In summary, **the College strongly supports Congressional efforts to provide Medicare and all stakeholders within the healthcare community with improved access to information about the relative strengths and weaknesses of various clinical products, procedures and services.** Towards this goal, the College recommends that the Congress take efforts, including the allocation of secure and sustained funding, to create or support a trusted entity that systematically develops evidence on the relative effectiveness of various alternative healthcare services. That entity should have the following characteristics:

- it should be an unbiased independent entity protected from both governmental and private sector influence to encourage trust in its findings.
 - its proceedings should be transparent.
 - it should involve stakeholders, including payers, providers and beneficiaries, at all levels of the evidence development process.
 - it should have a prioritization process, informed by input from the stakeholder groups, that ensures that the comparative effective evidence developed will have the greatest impact in improving the quality and efficiency of care provided.
 - it should support the development of all levels of evidence including formal review and synthesis of evidence already available in the clinical literature and the initiation of new research in priority areas where such evidence does not already exist.
 - it should have established processes that ensures that the comparative effectiveness findings developed are accessible in a comprehensive form to all stakeholders.
- **The Congress should give consideration to continuing to support the work of the Agency for HealthCare Research and Quality as the “trusted entity” for comparative effectiveness research, with secure and sustained funding that is not subject to the political pressures often associated with the annual appropriations process.**
- **The College believes that the greatest value of developed comparative effectiveness data at this time is to help clinicians and patients answer the question of what works best for each patient and for clinicians to partner with patients in an informed and shared decision-making process when considering alternative treatment options, a key element of the Patient-Centered Medical Home.**

- The College recognizes the potential savings obtainable through comparative effectiveness research, but recommends that Congress walk down the path of using comparative effectiveness data in the Medicare benefit design deliberately so that more experience is gained first in the impact of such research and its credibility with clinicians and patients. As confidence and trust in the process increases, steps could then be taken by Congress to create a method for incorporating such comparative effectiveness research into benefit design issues.
- Congress should recognize that inclusion of “cost effectiveness” as an element of the comparative evaluation process will introduce complex and controversial issues of how individual patients, purchasers, clinicians, and society assign a relative value to clinical effectiveness and cost. Such value judgments need to be made in an open, transparent, and methodologically sound basis that takes into account the different value systems that each stakeholder brings to the table. For these reasons, the College suggests that federally-funded comparative effectiveness research should, at least in its early stages, focus on relative clinical efficacy rather than cost-effectiveness. At the same time, however, we support further discussion of how cost-effectiveness comparisons might be introduced into the evaluation process at a later stage and used, at least in part, to influence benefit design by Medicare and other programs.
- The College asks Congress to recognize the value that a more systemized approach to developing comparative effectiveness evidence can be leveraged through:
 - The establishment of mechanisms to facilitate the implementation of health information technology (HIT) throughout the system
 - The implementation of the Patient-Centered Medical Home (PCMH) care model.